Public Safety in the Healthcare Facility

APPENDIX E

Ground Resistance and Leakage Current Limits

This appendix summarizes the most common electrical safety test limits for patient-care-related appliances (NFPA terminology) and medical electrical (ME) equipment (IEC terminology). The tables includes all applicable tests from NFPA 99 (2005).

The tables also include comparable tests from AAMI ES60601-1:2005 and IEC 62353:2007. Both of these standards include additional tests that could be adopted by a healthcare facility, especially for initial acceptance testing of devices manufactured to AAMI ES60601-1:2005.

These tables should be used only as quick references. Each standard has additional details for each test that must be kept in mind when designing the electrical safety program. These details may be found elsewhere in the *Electrical Safety Manual* and in the original standards.

As is apparent in these tables, test conditions and limits differ across standards. Following each table there is a recommendation that takes into account the various standards and the practical considerations of electrical safety programs in healthcare facilities.

Ground Conductor Resistance (NFPA 99) Protective Earth Impedance (AAMI 60601-1) Protective Earth Resistance (IEC 62353)		
Reference	**Limit**	**Application**
NFPA 99 (2005) 8.4.1.3.2	0.5 Ω	Patient-care-related equipment used in the patient care vicinity.
AAMI ES60601-1:2005 8.6.4	0.3 Ω	ME equipment.
IEC 62353:2007 5.3.2.2	0.3 Ω	ME equipment.

RECOMMENDATION

A practical limit for identifying ground conductor problems is 0.5 Ω.

Chassis Leakage Current (NFPA 99) Touch Current (AAMI 60601-1) Equipment Leakage Current (IEC 62353)			
Reference	**Limit**	**Application**	**Conditions**
NFPA 99 (2005) 8.4.1.3.5	300 µA	New patient-care-related equipment.	Normal polarity, power switch on and off ground closed and open.
	500 µA	Existing and special patient-care-related equipment.	
AAMI ES60601-1:2005 8.7.3	100 µA	ME equipment.	Normal Condition.
	500 µA		Single Fault Condition.
IEC 62353:2007 5.3.3.2.3	500 µA	Class I ME equipment.	Direct method. Normal and reverse polarity, ground closed and open.
	100 µA	Class II (double-insulated) ME equipment.	

RECOMMENDATION

A practical limit for identifying chassis leakage current problems is 500 µA. The conditions of NFPA 99 are recommended (reverse polarity testing is not needed in healthcare facilities with an appropriate receptacle testing program).

ECRI-Recommended Leakage Current Limits*

Type of equipment	Patient-applied parts or leads: Leakage to ground	Patient-applied parts or leads: Current with line voltage applied to lead	Chassis
Patient-care-related devices			
Equipment without patient connections	NA	NA	300 µA**
Patient-contact equipment			
With isolated*** patient connections	50 µA each lead (ground open); 10 µA each lead (ground intact)	50 µA, each lead (ground intact)	300 µA**
With nonisolated patient connections	100 µA with all leads together	NA	300 µA**
Nonpatient devices and devices used outside the patient care vicinity			
Equipment that may be used within the patient vicinity (not intended to contact patient)	NA	NA	500 µA
All other equipment used outside the patient care vicinity, including clinical laboratory devices	NA	NA	3,500 µA

* For line-powered, cord-connected equipment for routine healthcare facility testing under single-fault conditions.

** 500 µA for healthcare facilities following IEC 60601-1 rather than NFPA 99.

*** Type CF for healthcare facilities following IEC 60601-1 rather than NFPA 99 (see the discussion comparing these two standards on page 59).

The Isolated Power Systems Debate

by Matthew F. Baretich, PE, PhD

Does your new facility need isolated power? Here's how to decide

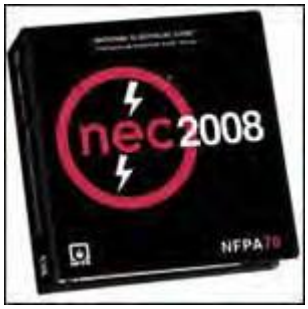
Isolated power systems were originally developed to reduce the risk of fire and explosion during surgical procedures using flammable anesthetics. Because the power conductors in these systems were electrically isolated from ground, the likelihood of electrical arcing to ground (representing a potential ignition source) was reduced. Conductive flooring, explosion-proof receptacles and plugs, enhanced grounding, and isolated power were installed in operating rooms to make the use of flammable anesthetics less hazardous. However, flammable anesthetics are no longer used in health care facilities in the United States.

In the 1970s, extensive efforts were made to mitigate the perceived microshock hazard. This was in response to research findings that microampere-level currents applied directly to the heart could induce fibrillation. Health care facilities worked to reduce leakage currents to the lowest levels possible anywhere a direct cardiac connection might occur. For a time, isolated power systems were regarded as beneficial in this effort. As a result, isolated power continued to be installed in operating rooms and, increasingly, in intensive care units. However, isolated power systems have little effect on leakage currents.[1] Therefore, national standards have moved away from specifying isolated power as a method for reducing the microshock hazard.

Isolated power remains in the National Electrical Code (NEC) as one means for reducing the hazard of electrical shock in "wet locations." It is important to note that the term "wet location" has a very specific meaning in the NEC when applied to health care facilities. Questions have been raised as to whether or not modern operating rooms fall within this specific definition.

Regardless of the uncertain definition, it is not clear that significant hazards exist in modern clinical practice that can be mitigated by isolated power systems. The potential benefits must be balanced against the costs of installation and maintenance and the possibility that isolated power systems may have adverse effects as well.

Background Information



The primary source for guidance on isolated power systems in health care facilities is the National Electrical Code (NFPA 70).[2] This standard has been adopted by, and has the force of law, in all states. Information based on NFPA 70 is also found in the Standard for Health Care Facilities (NFPA 99).[3] The latest edition of the *Health Care Facilities Handbook*, which contains the text of NFPA 99 plus additional explanatory material, is well worth having in every clinical engineering department library.

The fundamental characteristic of an isolated power system is that electrical power supplied by the system is "isolated" from ground (ie, not referenced to ground). In an isolated power system, two conductors (referred to as line 1 and line 2) supply power to equipment and receptacles. These conductors are analogous to the "hot" and "neutral" conductors that supply power in a conventional (ground-referenced) power system. Both systems also include a third conductor providing a connection to ground.

In a conventional power system that is properly installed and maintained, the voltage from neutral to ground is near zero, whereas the voltage from hot to ground is approximately 120 V AC. Connecting a low impedance pathway from hot to ground will allow heavy current to flow. If this current passes through a person, serious electrical shock can occur.

In an ideal isolated power system—one with perfect isolation—the voltage from either line 1 or line 2 is undefined. Connecting a low impedance pathway from either line to ground would not produce any current flow.

In a real isolated power system (one that can actually be manufactured), the voltage from either line 1 or line 2 typically measures around 60 V AC on a high impedance voltmeter. This is because real systems typically have roughly balanced faults on each line. Connecting a low impedance pathway from either line to ground will produce some current flow, typically in the range of a few milliamperes. Better isolation allows less current; degraded isolation allows more current.

Below are some basic definitions from NFPA 99 (numbers in square brackets indicate the paragraph of NFPA 99, 2005 edition, from which the material is taken):

- Isolated Power System (IPS). A system comprising an isolating transformer or its equivalent, a line isolation monitor, and its ungrounded circuit conductors [3.3.85].
- Line Isolation Monitor (LIM). A test instrument designed to continually check the balanced and unbalanced impedance from

each line of an isolated circuit to ground and equipped with a built-in test circuit to exercise the alarm without adding to the leakage current hazard [3.3.99]. The line isolation monitor shall be designed such that … a red signal lamp and audible warning signal shall be energized when the total hazard current reaches a threshold value of 5.0 mA under normal line voltage conditions [4.3.2.6.3.2]. An ammeter connected to indicate the total hazard current of the system shall be mounted in a plainly visible place on the line isolation monitor with the "alarm on" zone at approximately the center of the scale [4.3.2.6.3.4].

- Hazard Current. For a given set of connections in an isolated power system, the total current that would flow through a low impedance if it were connected between either isolated conductor and ground [3.3.66].

It is important to note that the hazard current, the reading displayed on the LIM, is a predictive value. For example, a reading of 2.0 mA does not mean that two milliamperes of current are flowing from either line to ground; it means that the system isolation has degraded to the point that two milliamperes could flow from line to ground through a low impedance pathway. For this reason, a LIM alarm does not indicate that an immediate hazard exists; it indicates that a potential hazard has developed.

Patient Care Areas

NFPA 99 requires the hospital's "governing body" to designate patient care areas within the facility [13.2.4]. For this purpose, a patient care area is defined as "any portion of a health care facility wherein patients are intended to be examined or treated" [3.3.138]. In addition, each patient care area is to be classified as either a general care area or a critical care area.

General care areas are "patient bedrooms, examining rooms, treatment rooms, clinics, and similar areas in which it is intended that the patient shall come into contact with ordinary appliances such as a nurse call system, electric beds, examining lamps, telephones, and entertainment devices" [3.3.138.2].

Critical care areas are "those special care units, intensive care units, coronary care units, angiography laboratories, cardiac catheterization laboratories, delivery rooms, operating rooms, postanesthesia recovery rooms, emergency departments, and similar areas in which patients are intended to be subjected to invasive procedures and connected to line-operated patient-care-related electrical appliances" [3.3.138.1].

The potential benefits of isolated power systems must be balanced against the costs of installation and maintenance and the possibility that they may have adverse effects as well.

A patient care area (general or critical) may also be classified as a wet location, which is defined as "an area in a patient care area where a procedure is performed that is normally subject to wet conditions while patients are present including standing fluids on the floor or drenching of the work area, either of which is intimate to the patient or staff" [3.3.185]. Annex A (not an official part of the standard) notes that "routine housekeeping procedures and incidental spillage of liquids do not define a wet location" [A.3.3.185].

Finally, a patient care area may also be classified as an anesthetizing location [13.2.5], which is defined as "any area of a facility that has been designated to be used for the administration of nonflammable inhalation anesthetic agents in the course of examination or treatment, including the use of such agents for relative analgesia" [NFPA 99 (2007) 3.3.9]. Note that NFPA 99 no longer addresses flammable anesthetizing locations, except in an annex to the standard.

Some typical classifications that might be adopted by the governing body in consultation with clinical staff and clinical engineering personnel:

- Nursing station: nonpatient care area.
- Patient room on a medical-surgical unit: general care area.
- Hydrotherapy treatment area: general care area, wet location.
- Patient room on an intensive care unit: critical care area.
- Operating room: critical care area, anesthetizing location.

Where Is Isolated Power Required?

If an area of the health care facility is classified as a wet location, then ground fault circuit interrupter (GFCI) circuits or an IPS must be installed [4.3.2.2.8.1]. The GFCI option is allowed only when the interruption of power can be tolerated [4.3.2.2.8.5]. Thus, the GFCI option may be appropriate in a hydrotherapy treatment area. But, because interruption of power cannot be tolerated in an operating room, classification of operating rooms as wet locations means that isolated power is the only option.

Isolated power systems were regarded as beneficial in reducing leakage currents and were installed in operating rooms.

Therefore, the decision of whether or not to classify an area of the health care facility as a wet location is critical in terms of the type of electrical system that must be installed. The most controversial issue has been whether or not operating rooms are wet locations, as defined by NFPA 99. A growing consensus holds that they are not.

Department of Defense guidelines for medical facilities state that "operating rooms, delivery rooms, cystoscope rooms, oral surgery, cardiac catheterization rooms, and other such rooms are not wet areas."[4] In the past, the Veterans Administration mandated classification of operating rooms and cardiac catheterization laboratories as wet locations requiring isolated power;[5] however, that directive has expired and a task force has recommended removal of the mandate.

ECRI Institute's most recent position is that "the use of isolated power systems in the OR is unnecessary and of no significant benefit to patient safety."[6] An extensive survey of health care facilities conducted recently for Mazzetti & Associates found that "the general trend appeared to be away from the use of IPSs in ORs."[7]

Evidence-based Engineering

What is the evidence regarding the hazards targeted by IPS? In recent years, many operating rooms have been constructed without isolated power. However, no evidence has appeared suggesting that these operating rooms have caused harm to patients or staff.

Vernon and Nash collected data from Kaiser Permanente facilities regarding problems that might be related to electrical systems in operating rooms, about half of which had IPSs. They found that such problems were rare but concluded, "The Kaiser evidence-based results show that not only do IPSs not provide the promised benefits, but also that the side effects may themselves be harmful."[7]

How to Decide

The first step is to decide if a specific patient care area such as an operating room is a wet location under the NFPA 99 definition. Include clinical representatives and clinical engineering personnel in the decision. Also, determine if any authority having jurisdiction relevant to your facility has requirements in this regard. For example, the state of North Carolina requires isolated power in operating rooms and intensive care units. This decision should be submitted for confirmation by the governing body and documented for future reference.

If you decide that the area is a wet location, install GFCI circuits (if interruption of power is tolerable) or an IPS (if interruption of power is not tolerable). If an IPS is required, budget for the fact that "in addition to the initial acquisition cost, isolated power systems present an ongoing testing and maintenance burden."[6]

If you decide that the area is not a wet location, you may install a conventional—or ground referenced—power system.

The more you know about applicable codes and available evidence, the better you will be able to participate in effective decision-making about IPSs. You will likely encounter a wide range of strongly held opinions, not all of which are based on accurate information. Know your codes and regulations, and help your facility make good decisions.

Matthew F. Baretich, PE, PhD, is president of Baretich Engineering, Fort Collins, Colo, (www.baretich.com) and is a member of 24x7's *editorial advisory board. He provides clinical engineering, health care facilities engineering, and safety management consulting, and incident investigation and forensic engineering services. For more information, contact 24x7Editor@ascendmedia.com.*

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LOCTITE®

Material Safety Data Sheet

Henkel Technologies

Revision Date: 04/12/2006 **Issue date:** 04/12/2006

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: 242® Threadlocker
Product type: Anaerobic Sealant
Company address:
Henkel Corporation
1001 Trout Brook Crossing
Rocky Hill, Connecticut 06067

Item No. : 24231
Region: United States
Contact Information:
Telephone: 860.571.5100
Emergency telephone: 860.571.5100
Internet: www.loctite.com

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components	%	ACGIH TLV	OSHA PEL	OTHER
Polyglycol dimethacrylate 25852-47-5	60-100	None	None	None
Polyglycol oleate 9004-96-0	10-30	None	None	None
Saccharin 81-07-2	1-5	None	None	None
Silica, amorphous, fumed, crystalline-free 112945-52-5	1-5	6 mg/m³ TWA	10 mg/m³ TWA	3 mg/m³ TWA respirable dust
Cumene hydroperoxide 80-15-9	1-5	None	None	1 ppm (6 mg/m³) Skin (WEEL), 1ppm, skin TWA, (WEEL)
Propylene glycol 57-55-6	1-5	None	None	10 mg/m³ TWA, (WEEL)

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

HMIS:

Physical state: Liquid
Color: Blue
Odor: Mild

HEALTH: 2*
FLAMMABILITY: 1
PHYSICAL HAZARD: 1
Personal Protection: See Section 8

WARNING: CAUSES EYE IRRITATION.
MAY CAUSE SKIN IRRITATION.
MAY CAUSE ALLERGIC SKIN REACTION.
MAY CAUSE RESPIRATORY TRACT IRRITATION.

Relevant routes of exposure: Skin, Inhalation, Eyes

Potential Health Effects

Inhalation: May cause respiratory tract irritation.
Skin contact: May cause allergic skin reaction. May cause skin irritation.
Eye contact: Contact with eyes will cause irritation.
Ingestion: Not expected to be harmful by ingestion.

Existing conditions aggravated by exposure:	Eye, skin, and respiratory disorders.

See Section 11 for additional toxicological information.

4. FIRST AID MEASURES

Inhalation:	Remove to fresh air. If symptoms develop and persist, get medical attention.
Skin contact:	Wash with soap and water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention if symptoms occur.
Eye contact:	Flush with copious amounts of water, preferably, lukewarm water for at least 15 minutes, holding eyelids open all the time. Get medical attention.
Ingestion:	Do not induce vomiting. Keep individual calm. Obtain medical attention.

5. FIRE-FIGHTING MEASURES

Flash point:	Greater than 93ºC (200ºF) Tagliabue closed cup
Autoignition temperature:	Not available
Flammable/Explosive limits-lower %:	2.6 % (propylene glycol)
Flammable/Explosive limits-upper %:	12.5 % (propylene glycol)
Extinguishing media:	Foam, dry chemical or carbon dioxide.
Special fire fighting procedures:	None
Unusual fire or explosion hazards:	None
Hazardous combustion products:	Oxides of carbon. Oxides of sulfur. Oxides of nitrogen. Irritating organic vapors.

6. ACCIDENTAL RELEASE MEASURES

Environmental precautions:	Prevent product from entering drains or open waters.
Clean-up methods:	Soak up with inert absorbent. Store in a partly filled, closed container until disposal.

7. HANDLING AND STORAGE

Handling:	Avoid contact with eyes, skin and clothing. Avoid breathing vapor and mist. Wash thoroughly after handling.
Storage:	For safe storage, store at or below 38°C (100°F). Keep in a cool, well ventilated area away from heat, sparks and open flame. Keep container tightly closed until ready for use.
Incompatible products:	Refer to Section 10.

For information on product shelf life contact Henkel Customer Service at (800) 243-4874.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering controls:	No specific ventilation requirements noted, but forced ventilation may still be required if concentrations exceed occupational exposure limts.

Respiratory protection: Use NIOSH approved respirator if there is potential to exceed exposure limit(s).

Skin protection: Use impermeable gloves and protective clothing as necessary to prevent skin contact. Neoprene gloves. Butyl rubber gloves. Natural rubber gloves.

Eye/face protection: Safety goggles or safety glasses with side shields.

See Section 2 for exposure limits.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Color: Blue
Odor: Mild
Vapor pressure: Less than 5 mm Hg at 27ºC (80ºF)
pH: Not applicable
Boiling point/range: Greater than 149ºC (300ºF)
Melting point/range: Not available
Specific gravity: 1.1 at 23.9ºC (75ºF)
Vapor density: Not available
Evaporation rate: Not available
Solubility in water: Slight
Partition coefficient (n-octanol/water): Not available
VOC content: 4.48%; 49.3 grams/liter (EPA Method 24)

10. STABILITY AND REACTIVITY

Stability: Stable.

Hazardous polymerization: Will not occur.

Hazardous decomposition products: Oxides of carbon. Oxides of sulfur. Oxides of nitrogen. Irritating organic vapors.

Incompatability: Strong oxidizers. Free radical initiators. Strong reducing agents. Alkalis. Oxygen scavengers. Other polymerization initiators. Copper. Iron. Zinc. Aluminum. Rust.

Conditions to avoid: See "Handling and Storage" (Section 7) and "Incompatabilty" (Section 10).

11. TOXICOLOGICAL INFORMATION

Product toxicity data: Acute oral LD50 greater than 10, 000 mg/kg (rat). Acute dermal LD50 greater than 5000 mg/kg (rabbit).

Carcinogen Status

Hazardous components	NTP Carcinogen	IARC Carcinogen	OSHA Carcinogen
Polyglycol dimethacrylate 25852-47-5	No	No	No
Polyglycol oleate 9004-96-0	No	No	No
Saccharin 81-07-2	No	No	No
Silica, amorphous, fumed, crystalline-free 112945-52-5	No	No	No
Cumene hydroperoxide 80-15-9	No	No	No
Propylene glycol 57-55-6	No	No	No

Literature Referenced Target Organ & Other Health Effects

Hazardous components	Health Effects/Target Organs
Polyglycol dimethacrylate 25852-47-5	Allergen, Irritant
Polyglycol oleate 9004-96-0	Irritant
Saccharin 81-07-2	No Target Organs
Silica, amorphous, fumed, crystalline-free 112945-52-5	Nuisance dust
Cumene hydroperoxide 80-15-9	Allergen, Central nervous system, Corrosive, Irritant, Mutagen
Propylene glycol 57-55-6	Irritant

12. ECOLOGICAL INFORMATION

Ecological information: Not available

13. DISPOSAL CONSIDERATIONS

Information provided is for unused product only.

Recommended method of disposal: Dispose of according to Federal, State and local governmental regulations.

EPA hazardous waste number: Not a RCRA hazardous waste.

14. TRANSPORT INFORMATION

U.S. Department of Transportation Ground (49 CFR):

Proper shipping name: Unrestricted
Hazard class or division: None
Identification number: None
Packing group: None

International Air Transportation (ICAO/IATA):

Proper shipping name: Unrestricted
Hazard class or division: None
Identification number: None
Packing group: None

WaterTransportation (IMO/IMDG):

Proper shipping name: Unrestricted
Hazard class or division: None
Identification number: None
Packing group: None
Marine pollutant: None

15. REGULATORY INFORMATION

United States Regulatory Information

TSCA 8 (b) Inventory Status:	All components are listed or are exempt from listing on the Toxic Substances Control Act Inventory.
TSCA 12 (b) Export Notification:	4-Methoxyphenol (150-76-5).
CERCLA/SARA Section 302 EHS:	None above reporting de minimus.
CERCLA/SARA Section 311/312:	Immediate Health Hazard, Delayed Health Hazard
CERCLA/SARA 313:	This product contains the following toxic chemicals subject to the reporting requirements of section 313 of the Emergency Planning and Community Right-To-Know Act of 1986 (40 CFR 372). Cumene hydroperoxide (CAS# 80-15-9) .
California Proposition 65:	This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

Canada Regulatory Information

CEPA DSL/NDSL Status:	All components are listed on or are exempt from listing on the Domestic Substances List.
WHMIS hazard class:	D.2.B

16. OTHER INFORMATION

This material safety data sheet contains changes from the previous version in sections: 15

Prepared by: Kyra Kozak Woods, Product Safety and Regulatory Affairs Specialist

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Power and Precision

Laser Safety in the Surgical Suite

It's a nightmare scenario of every administrator or facilities manager—an injury to a member of the hospital's surgical staff during laser surgery. In a typical case, a patient might be undergoing a surgical procedure in which the surgeon is using a laser instrument. The hospital has a well-established laser safety program, and everyone on the surgical team is wearing eye protection. However, a laser beam from the surgical field bounces off a stainless-steel metal instrument and strikes the eyes of a surgical tech who's standing a few feet away from the surgical field. When she cries out in pain, the procedure is suspended as the tech is led from the operating room, complaining that her vision is blurred and her right eye hurts. On examination by an ophthalmologist, it becomes clear that, although the tech was wearing eye protection, it wasn't the correct optical density for the wavelength of the laser that was used, and she has sustained a burn on her retina.

While this incident is fictional, it could happen in almost any hospital or surgical center today.

Applicable Standards

The use of lasers by hospitals and surgical centers is covered by several Joint Commission standards, including the following:

- Standard EC.01.01.01, Element of Performance (EP) 3, requires a hospital to have a written plan for managing the safety of everyone who enters the hospital's facilities.
- Standard EC.02.02.01, EP 7, requires a hospital to minimize risks associated with selecting and using hazardous energy sources.
  Note: *Hazardous energy sources include, but are not limited to, those generated while using ionizing or non-ionizing radiation equipment and lasers.*
- Standard EC.02.02.01, EP 9, requires a hospital to minimize risks associated with disposing of hazardous gases and vapors.
  Note: *Hazardous gases and vapors include, but are not limited to vapors generated while using lasers.*
- Standard HR.01.04.01, EP 2, requires a hospital to orient staff members to key safety content before they provide care, treatment, and services. Completion of this orientation must be documented.

In addition, OSHA Regulation 1926.102(b)(2) requires hospitals to provide protective eyewear for staff.

The Surgical Tool of Choice

Albert Einstein laid the foundation for the invention of the laser in 1917; 43 years later came the first working laser, in 1960. Today, lasers are not just the technology behind bar-code scanners and optical storage devices such as CDs and DVDs but the technology for a host of powerful medical tools. Among the scores of uses for lasers in health care are applications as diverse as dentistry, eye surgery, facial resurfacing, removal of facial port wine stains, and pulverization of kidney stones. Lasers are also used in treating esophageal tumors and in a type of coronary surgery called transmyocardial revascularization, where a laser drills holes into the heart to allow blood flow to the ischemic heart muscle.

"Surgeons like lasers because they offer convenience, accuracy, and precision," says Gus Anibarro, education director, Laser Institute of America. "They use lasers to get up close and

Protect health care workers' eyes from lasers.

target a small area of tissue without having to disrupt anything around it. A large amount of energy can travel through a fiber optic to the surgical target but without having to perform more invasive surgery." Lasers are used for vascular welding and intravascular sealing, to treat endometriosis, and to remove warts from genitalia. "All this is done simply by selecting the appropriate wavelength and adjusting the parameters of the laser beam according to the surgeon's needs," says Anibarro.

Laser Hazards

"While lasers are really powerful medical tools," says Anibarro, "the downside is the harm they can do, not just to patients but to members of the medical staff." The Joint Commission recognizes the hazards of lasers and mentions them specifically in Standard EC.02.02.01, EP 7 and EP 9. (See "Applicable Standards," page 8.) Among the laser hazards cited by Anibarro are the following: burns, fire, and smoke.

Burns to Eyes and Skin

To prevent burns to their skin, operating room (OR) staff members should wear long-sleeve gowns made of flame-resistant fabric. Although any burns to the skin are usually minor, burns to the eyes can damage the retina, the cornea, or the lens—and even cause total blindness. That can happen when a laser beam bounces off a shiny surface such as an instrument or a stainless-steel tray or cart. (For information on choosing personal protective eyewear with the correct optical density, see "Choosing the Right Personal Protective Eyewear," above.)

Fire in the Surgical Suite

Three components are needed to start a fire: fuel, oxygen, and heat. The first step in avoiding a fire in the surgical suite is to minimize or remove one side of the "fire triangle." For example, all alcohol- and petroleum-based products should be removed, and the use of inhalation gases such as oxygen, nitrous oxide, and anesthetic gases should be controlled to reduce combustion. The buildup of O_2 and N_2O beneath surgical drapes should be minimized. The laser assistant should place the laser in standby mode when it is not in active use and activate it only when the tip is under the surgeon's direct control. Only the person delivering the laser energy should be allowed to operate the foot pedal, and before removing the laser from the surgical site, the laser assistant should put it in standby mode. The hospital should also have a plan for dealing with a fire in the surgical suite.

Smoke Plume

Surgical procedures that use a laser unit can produce a smoke byproduct that may contain toxic gases and vapors. At high concentrations, that smoke causes ocular and upper respiratory tract irritation among health care personnel. Other hazards of the smoke plume include eye, nose, and throat irritation; nausea; fatigue; nasal congestion; vomiting; and flu-like symptoms. The Occupational Safety and Health Administration (OSHA) estimates that 500,000 workers a year are exposed to laser and electro-surgery smoke.[1] Smoke evacuators can help remove surgical smoke from most ORs. Surgical smoke management is addressed in Joint Commission Standard EC.02.02.02, EP 9.

Laser Safety Measures

Lasers are customarily labeled according to their hazard class, which indicates how dangerous the laser is. Class 1 lasers (use, for example, in CD players) and Class 2 lasers (for example,

Continued on page 11

Choosing the Right Personal Protective Eyewear

The American National Standards Institute standard ANSI Z136.3 (2005) for the Safe Use of Lasers in Health Care Facilities recommends that, to protect against eye injury, hospitals and surgical center personnel should use laser protective eyewear such as goggles or glasses with side shields during laser operations. "Laser eye protection will attenuate laser light to safe levels," says Gus Anibarro, the Institute's education director. "To conform to the ANSI Z136.3 (2005) guidelines, a specific type of protective eyewear is used with each laser." Anibarro recommends that hospitals keep the following factors in mind when selecting laser eyewear: laser wavelength and optical density (OD), visual transmittance, impact resistance, and the user's comfort level.

"The style and color of some eyewear can look the same," says Anibarro, "so to avoid putting on the wrong pair of eyewear, the worker or the laser safety officer should check both the wavelength and OD imprinted on all laser eyewear in use, especially where more than one laser is located in the same room. The wavelength marked on the eyewear should match the wavelength of the laser being used. In addition, the optical density should be appropriate for the power of the laser being used. If either of these parameters is incorrect, the individual will not be protected from the laser beam. "Users shouldn't move eyewear from one laser room to another; the eyewear should remain with the laser." says Anibarro. "Nor should users carry eyewear in the pocket of their lab coat between use." He also suggests inspecting the eyewear periodically, because small cracks or loose-fitting filters could permit hazardous levels of laser light to pass through directly to the eye.

Designing and Maintaining Buildings to Minimize the Effects of Fire (continued)

Continued from page 5

coverings, or other objects. "The primary purpose of this EP is to prevent organizations from hanging decorations, such as holiday or other celebration decorations, on their fire-rated doors," says Mills. "Informational signs, such as nameplates, are allowed in most cases."

Maintaining Fire Ratings Around Ductwork

When ductwork—including that which supports heating and cooling systems—penetrates a 2-hour-rated fire wall, an organization must have fire dampers, per EP 8. These dampers help maintain the fire rating of the surrounding wall during a fire. "Dampers look something like metal venetian blinds," explains Mills. "Dampers are normally held open with a fusible link—two pieces of metal soldered together. During a fire, the solder melts, releasing the spring and causing the dampers to automatically shut, preventing the passage of fire." Once the dampers close, they must have a fire rating of 1½ hours.

Although EP 8 of Standard LS.02.01.10 requires organizations to have fire-rated dampers, testing of these dampers is covered in the EC chapter. In hospital occupancies, organizations must test fire dampers every 6 years. In nonhospital occupancies, organizations must test every 4 years. (See EC.02.03.05, EP 18.)

Using Fire-Stop Material

According to EP 9, penetrations in fire-rated walls involving pipes, conduits, cables, wires, and so forth must be protected with a fire-rated material that has been approved by a designated testing agency, such as UL. Approved fire-stop material has been tested by the testing agency—per the manufacturer's directions—and has been shown to be capable of adequately preventing the spread of fire.

"When fire-stop material is heated, it expands," says Mills. "During a fire, the material expands to a point that it seals the opening, conduit, or other penetration, preventing the passage of fire and smoke. Testing ensures that the material will expand sufficiently to seal the penetration."

One important point organizations should be aware of is that: *polyurethane expanding insulation foam is* not *considered to be fire-stop material unless it has been approved as an appropriate fire-stop material by a testing agency such as UL.* "Some polyurethane products on the market are designed for use in insulating around windows," says Mills. "This material burns hot, emits a toxic vapor, and consequently is not acceptable as a fire stop." Mills points out, however, that there are "other polyurethane products designed for use as fire stop and approved by a testing agency such as UL. These would be acceptable when protecting penetrations. If your organization chooses to use an approved polyurethane product, you should retain the spec sheet on the product to verify to a Joint Commission surveyor that it is an approved fire-stop material."

Other Requirements

EP 10—the final EP for LS.02.01.10—requires organizations to meet any other applicable *Life Safety Code* requirements related to fire protection features. Meeting these requirements, in addition to those outlined in LS.02.01.10, can help ensure that your organization preserves and maintains the safety of patients, staff, volunteers, and visitors in your organization.

Power and Precision (continued)

Continued from page 9

supermarket scanners) are normally safe because the eye is protected by the aversion response. Class 3R lasers (for example, laser pointers) are potentially hazardous if directly viewed for a long period of time. Class 3B lasers (used, for example, in low-level laser therapy) may be hazardous due to direct or specular reflections, and Class 4 lasers (for industrial, scientific, military, and medical lasers) can cause eye and/or skin damage from direct and specular or diffuse reflections. Hospital staff members who work with Class 3 and 4 lasers should protect their eyes with safety goggles that are designed to absorb laser light of a specific wavelength.

Several organizations, including the Laser Institute of America and OSHA (although not the Joint Commission), recommend that medical facilities using Class 3 or 4 lasers designate a laser safety officer to make sure that laser safety policies and procedures are formulated and implemented. In some hospitals and ambulatory surgery centers, a nurse or a radiation safety officer also serves as the laser safety officer.

"Lasers can be an important and effective part of today's health care," says Anibarro. And he recommends that "any health care facility that's doing laser procedures needs a laser safety program to protect patients and staff alike."

This article was developed through the cooperative efforts of OSHA and The Joint Commission/Joint Commission Resources Alliance.

Reference

1. The Joint Commission: Reducing the danger of surgical smoke exposure to health care workers. *Environment of Care News* 10:4–5, 10, Sep. 2007.

How to use a Portable Fire Extinguisher

Brought to you by

FEMA | the life safety group

www.femalifesafety.org

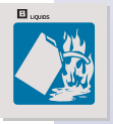
BEFORE USING A FIRE EXTINGUISHER, BE SURE

- the fire department has been called
- you have announced the fire to alert others
- occupants have begun evacuating or are leaving the structure
- the fire is small and not spreading
- you know how to operate the fire extinguisher, and
- the fire won't block your unobstructed escape route

Provided by the National Fire Protection Association (NFPA).

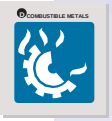
TYPES OF FIRES

Class A fires are fires in ordinary combustibles such as wood, paper, cloth, trash, and plastics.



Class B fires are fires in flammable liquids such as gasoline, petroleum oil, and paint. Also included are flammable gases such as propane and butane. Class B fires do not include fires involving cooking oils and grease.

Class C fires are fires involving energized electrical equipment such as motors, transformers, and appliances. Remove the power and the Class C fire becomes one of the other classes of fire.



Class D fires are fires in combustible metals such as potassium, sodium, aluminum and magnesium.

Class K fires are fires in cooking oils and greases such as animal fats and vegetable fats.

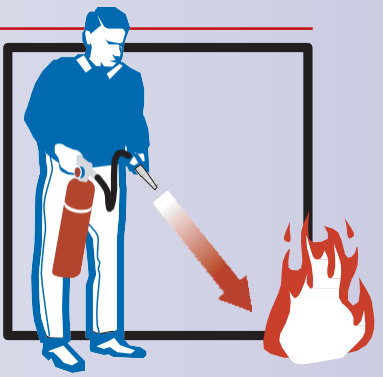
When it's time to use a Fire Extinguisher, just remember **PASS!**

PULL

Pull the pin.

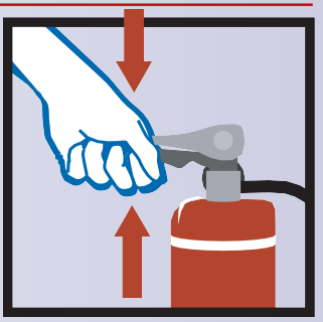
AIM

Aim the nozzle or hose at the base of the fire from the recommended safe distance.



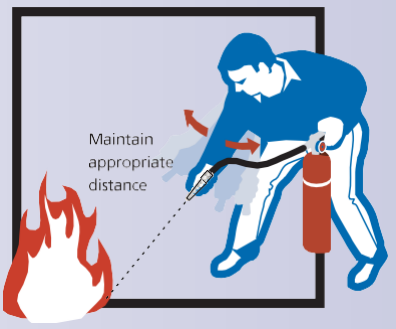
SQUEEZE

Squeeze the operating lever to discharge the fire extinguishing agent.



SWEEP

Starting at the recommended distance, **Sweep** the nozzle or hose from side to side until the fire is out. Move forward or around the fire area as the fire diminishes. Watch the area in case of re-ignition.



TYPES OF EXTINGUISHERS

Dry Chemical fire extinguishers extinguish the fire primarily by interrupting the chemical reaction in the fire. *Today's most widely used type of fire extinguisher is the multipurpose dry chemical that is effective on Class A, B and C fires. This agent also works by creating a barrier between the oxygen element and the fuel element on Class A fires. Ordinary dry chemical is for Class B & C fires only. It is important to use the correct extinguisher for the type of fuel! Using the incorrect agent can allow the fire to re-ignite after apparently being extinguished successfully.*

Water and Foam fire extinguishers extinguish the fire by taking away the heat from the fire. Foam agents also separate the oxygen from the fuel and heat. *Water extinguishers are for Class A fires only, they should not be used on Class B or C fires. The discharge stream could spread the flammable liquid in a Class B fire or could create a shock hazard on a Class C fire. Foam extinguishers can be used on Class A & B fires only. They are not for use on Class C fires due to the shock hazard.*

Carbon Dioxide fire extinguishers extinguish the fire by separating the oxygen element from the fuel and heat, and also by removing the heat with a very cold discharge. *Carbon dioxide can be used on Class B & C fires. They are usually ineffective on Class A fires.*

Wet Chemical is a new agent that extinguishes the fire by removing the heat from the fire and prevents re-ignition by creating a barrier between the oxygen and fuel elements. *Wet chemical or Class K extinguishers were developed for modern, high efficiency deep fat fryers in commercial cooking operations. Some may also be used on Class A fires in commercial kitchens.*

Halogenated or Clean Agent extinguishers are either based on halocarbon agents or on the older and no longer made halon 1211 agent, which can no longer be used for training. *Halocarbon agents replaced halon 1211 within the last 8 years and are much more environmentally acceptable. Commercialized halocarbon agents extinguish the fire by removing heat from the combustion zone. Halon 1211 extinguishers, however, were chemically active and interfered with the chemical reactions occurring in the combustion zone. Halocarbon and halon 1211 extinguishers are effective on Class A, B, and C type fires, although very small sizes do not achieve the lowest UL Class A rating, 1-A.*

Dry Powder extinguishers are similar to dry chemical except that they extinguish the fire by separating the fuel from the oxygen element of the fire. *However, dry powder extinguishers are for Class D or combustible metal fires, only. They are ineffective on all other classes of fires.*

Water Mist extinguishers are a recent development that extinguishes the fire by taking away the heat from the fire. They are an alternative to the clean agent extinguishers where contamination is a concern. *Water mist extinguishers are primarily for Class A fires, although they are safe for use on Class C fires as well.*

fireextinguisher.com

Joint Ventures

— JCAHO and You —

The Performance Improvement Cycle

by Matt Baretich

The concept of "performance improvement" is at the heart of all JCAHO standards. Although it often seems buried under many layers of mandates to "do this" and "document that," the driving force is "do better."

We can probably agree that JCAHO standards are, at best, only imperfect attempts to implement the concept. However, it's still a valid concept and one worth keeping in mind as we think about the JCAHO programs we're responsible for.

We should ask ourselves two questions: First, "Are we doing OK?" And second, "Are we getting better?" If we can look at ourselves in the mirror and answer "Yes" to both questions then we can sleep peacefully at night. If not, we might have some "opportunities for improvement" to pursue.

When the answer to the first question is "No," or anything short of a confident "Yes," then we need to initiate some sort of corrective active as quickly as possible. The first order of business is to have all the basics in place. That's the foundation we build on.

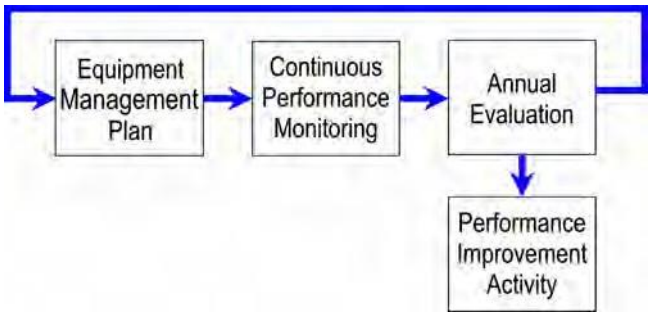
My experience is that EC programs are generally in pretty good shape. The basics are in place and we can usually say that our programs are at least OK – and in many respects they're much better than OK. But that alone doesn't mean we can rest comfortably.

The second law of thermodynamics says that all physical systems move toward entropy unless energy is added. Organizational systems behave this way too. In any organization, the systems we put in place will deteriorate unless we put energy into them. "OK" can become "not-OK" before we know it.

And, let's face it, we may be good but we're not perfect. We can always do better. And, since our fundamental mission is to support high-quality patient care, we *should* always strive to do better. The challenge is to do better within the financial and organizational constraints that confront us. Meeting that challenge is the interesting part of our jobs.

So what does JCAHO have to say about all of this? First, we are required to write seven management plans. These are "executive summaries" of the programs we have in place to meet JCAHO Environment of Care standards regarding safety, security, hazardous materials and waste, emergency management, fire prevention (life safety), medical equipment, and utility systems.

Second, we are required to continuously monitor the performance of our EC programs as defined in our management plans. Continuous monitoring typically includes monthly calculation of performance statistics that are reported quarterly to the safety committee (or whatever group is charged with oversight of EC-related programs).



Third, we are required to annually evaluate the "objectives, scope, performance, and effectiveness" of each of our EC management plans. Management plans, continuous monitoring, and annual evaluation represent the "Are we doing OK?" part of the process. It gives us a working definition of what's OK and tells us when we're not.

Finally, we use the results of the annual evaluation to modify our management plans and the methods we will use to monitor them. The annual evaluation will also help us identify one or more performance improvement activities to implement (and monitor) during the new year. This is the "Are we getting better?" part of the process. If we keep moving steadily through the performance improvement cycle the answer will be, "Absolutely!"

Matthew F. Baretich, P.E., Ph.D., is President of Baretich Engineering, Inc., a consulting firm based in Fort Collins, Colorado. His areas of practice include safety management, facilities management, and medical equipment management. Joint Ventures articles can be downloaded from www.baretich.com.

NFPA 99 Standard for Health Care Facilities

Major Changes in the 2012 Edition

By Matt Baretich

Most of the NFPA codes and standards focus on the design and installation of equipment and systems. Although NFPA 99 is based on documents such as NFPA 70 National Electrical Code, it also addresses *operational* issues such as the testing and maintenance of systems. For example, NFPA 99 has been a primary source for electrical safety test procedures.

When referring to any NFPA standard, it's important to specify the edition because requirements are regularly updated. Although NFPA 99 is normally revised on a three year cycle, the most recent previous edition is dated 2005. After that edition was published, NFPA decided to completely review and rewrite the standard for a variety of reasons.

One of the reasons for a makeover was that, since its first edition in 1985, NFPA 99 has been sort of a mash-up of various earlier documents. A thorough review of scope and consistency was in order.

Another reason was to reposition NFPA 99 from "standard" to "code." In NFPA jargon, standards are akin to guidelines that organizations may choose to follow. On the other hand, codes mandate minimum requirements suitable for adoption and enforcement by legal authorities. The two best known NFPA codes are NFPA 70 National Electrical Code and NFPA 101 Life Safety Code, both of which have the force of law in many jurisdictions.

A proposed 2010 edition of NFPA 99 was rejected by NFPA in June 2009 and returned to committee for further review. The primary concern was that the many changes in content and format needed to be better integrated. Also, some of the proposed changes were highly controversial. Following the review, a 2012 edition was created and then accepted at the NFPA Annual Meeting last June. Various authorities having jurisdictions (including CMS and the Joint Commission) will likely adopt the new edition over time.

A fundamental change in the 2012 edition (which is now available at www.nfpa.org) is a move from basing requirements on the type of occupancy to basing them on patient risk. In the 2005 edition there were separate chapters for hospitals, nursing homes, and other occupancy types. Requirements for electrical and medical gas systems and equipment were based on the type of occupancy in which they were installed.

However, in recent years there has been a proliferation of different types of patient care facilities, many with substantial overlap in terms of patient acuity. In an alternative approach, the 2012 edition of NFPA 99 defines four levels of patient risk, ranging from Category 1 (life support) to Category 4 (no patient impact). For example, a medical gas system that provides life support must meet Category 1 requirements for reliability in operation.

The 2012 edition also offers the organization greater latitude in defining test procedures and schedules for medical equipment. This brings NFPA 99 into agreement with current practice and the standards of accrediting agencies such as the Joint Commission.

A potentially far-reaching change in the 2012 edition requires electrical safety testing of medical devices for chassis leakage current (now referred to by the international terminology of touch current) and ground conductor resistance *only* "before being put into service for the first time and after any repair or modification that might have compromised electrical safety." This is in recognition of the evidence that routine scheduled electrical safety testing is unnecessary and should no longer be required.

In many hospitals a substantial portion of scheduled inspection and maintenance efforts consist of electrical safety testing. In the absence of a requirement for such testing it will be hard to justify the continued allocation of scarce resources for this purpose.

Some people I have talked to expect to continue routine electrical safety testing, at least temporarily, on the theory that it's important for medical equipment to be regularly located and looked at, even if electrical safety testing itself is of little value. However, in the long run, we will need to move toward "evidence based maintenance" or "reliability centered maintenance" in which we focus our resources on activities that produce benefits worth their cost.

The 2012 edition also includes detailed language requiring equipment manufacturers to include useful operator and maintenance manuals. It's not clear if or when authorities having jurisdiction (AHJs) will enforce these requirements, but moving NFPA 99 from standard to code may make this more likely.

The most controversial change in the 2012 edition is in regard to isolated power systems, particularly for operating rooms. As specified in NFPA 70 National Electrical Code, an isolated power system (and the associated line isolation monitor or LIM) are generally required in any operating room that is designated as a "wet location" as defined in the code. It's important to keep in mind that, in this context, a "wet location" is not a place that simply gets wet from time to time; it's a location in which patients and clinicians are normally subject to conditions that require the use of special electrical distribution systems to protect them from electrical shock.

Based on the best evidence, the consensus in the engineering community is that isolated power systems do not provide significant safety benefits for OR staff and patients, particularly when the cost of these systems is considered.

In the 2005 edition of NFPA 99, the decision to designate an area as a wet location was made by the hospital's governing board. Ideally, this decision was based on policies developed by the engineering staff.

However, in the 2012 edition, an operating room is presumed to be a wet location unless a specified risk assessment process determines that it is not. In other words, despite the evidence and engineering consensus, the default is installation of isolated power. I'm not alone in thinking that's a step in the wrong direction.

Matt Baretich is president of Baretich Engineering in Fort Collins, Colorado (www.baretich.com). An earlier version of this article appeared in the CABMET newsletter (www.cabmet.org).

The Sleeping Giant

Many of us are surrounded by compressed gas cylinders. Here is a reminder of just what respect they command.

GET TO KNOW ME

I can contain very high pressure.
I wear a label to identify the gas I am holding.
My color does not tell you what gas I contain.
I am only one piece of a two-part system. Without a correct regulator or manifold I cannot function safely.

KNOW HOW TO USE ME

Know how to safely install and remove me from your system.
Make sure I am properly secured when in use and when stored.
Open my valve slowly when I am to be used.
Close my valve when you are done.
Know the dangers of my contents, read the MSDS, and follow proper procedures when using me.

WHEN THINGS GO WRONG

If my valve or regulator snaps off, all my power is unleashed through an opening no larger than a pencil.

- I will jet away faster than any dragster.
- I will smash through brick walls.
- I will spin, ricochet, crash and splash through anything in my path.

TO BE MY MASTER REMEMBER

Secure me,
Cap me, and
Always follow recommended safety procedures.

Compressed Gas Association

Safetygram #10

Handling, Storage, and Use of Compressed Gas Cylinders

General

As a member of the chemical industry, Air Products is committed to the tenets of Responsible Care® to help guide our performance with respect to environmental, health, and safety performance and the distribution and use of our products. As our customer, you need to share in the responsibility for safe handling, storage, and use of our products.

Follow these seven general safety recommendations:

1. Know and understand the properties, uses, and safety precautions before using any gas or gas mixture. Consult the Air Products Material Safety Data Sheet (MSDS) and Safetygrams for safety information on the gases and equipment you will be using.

2. Determine the appropriate equipment required to use the product and know how to safely operate the equipment.

3. Be aware of potential hazards and develop plans to cover possible emergencies. Use emergency drills to practice implementing these plans. Inform local hospitals, fire departments, and other emergency response organizations of the gases in use so that they, too, will be prepared in the event of an emergency.

4. Provide personal protective equipment (PPE) and the required training for its use. Require personnel to wear the proper PPE for each task. Locate other safety equipment such as fire extinguishers, eye wash stations, and showers at appropriate locations. Thoroughly inform everyone about the hazards of the gases they are using and how to respond to an emergency.

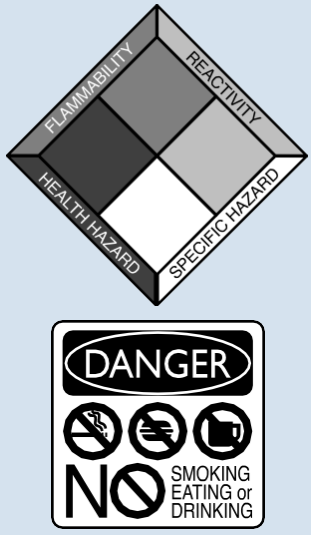
5. Follow all national, state, and local regulations pertaining to the storage, use, and disposal of compressed gases and cryogenic liquids. This document highlights the recommendations set forth in ISO Standard 11625, "Gas Cylinders—Safe Handling." In the United States, this document is published by the Compressed Gas Association as Pamphlet P-1, "Safe Handling of Compressed Gases in Containers," and has been incorporated into the regulations, making the contents of the document legal requirements in the United States, not recommendations. Other regional organizations such as the Asian Industrial Gases Association (AIGA), the European Industrial Gases Association (EIGA), and the National Fire Protection Association (NFPA) also provide guidance for the storage and use of compressed gas cylinders.

6. If you are unfamiliar with the hazards associated with a particular gas, contact your supplier for additional information.

7. Use appropriate equipment when handling portable cylinder banks. They have a high center of gravity, and extreme care must be taken during their movement. Portable banks may fall over when being moved if they are stopped suddenly by an object or crack in the floor.

Figure 1

Examples of signage used in storage areas



Responsible Care®
Good Chemistry at Work

Handling

Compressed gas cylinders should be handled only by those familiar with the hazards and who are trained in the proper handling techniques. Cylinders containing compressed gases are heavy and awkward to move. Improper handling of compressed gas cylinders can result in sprains, strains, falls, bruises, or broken bones. Other hazards such as fire, explosion, chemical burns, poisoning, and cold burns could occur if gases accidentally escape from the cylinder due to mishandling. Take the following precautions to prevent injuries caused by the improper handling of compressed gas cylinders.

NEVER

- Drag or slide cylinders, even for short distances.
- Drop cylinders or permit them to strike each other violently.
- Subject cylinders to mechanical shocks that may cause damage to their valves.
- Use cylinders as rollers for moving material or other equipment.
- Tamper with pressure-relief devices.
- Permit oil, grease, or other readily combustible substances to come in contact with cylinders, valves, or other equipment in oxidizer service.
- Remove any product labels or shipping hazard labels.
- Refill compressed gas cylinders. This is to be done only by qualified producers of compressed gases.
- Lift a cylinder by its cap using a sling or a magnet.
- Attempt to catch a falling cylinder.

ALWAYS

- Move cylinders using a suitable hand truck or cart.
- Leave the valve protection cap and valve seal outlet in place until the cylinder has been secured in place and is ready to be used.
- Secure cylinders when in storage, transit, or use.
- When returning cylinders to the supplier, properly close the cylinder valve, replace and secure any valve outlet seals, and properly install the cylinder cap.

Figure 2

Typical cylinder hand trucks

- Use a cylinder cage or cradle to lift a cylinder.
- Use the proper PPE for cylinder handling. Wear safety glasses with sideshields, leather gloves, safety shoes, and other appropriate equipment.
- Use extreme care and restrict the movement of portable banks to localize movement on clean, smooth, level stationary surfaces.
- Use two people for localized manual movement of a portable bank. Stay out of the bank's travel path. Also, be aware of escape routes should the bank get out of control or start falling. If a smooth, level surface is not available over which to move the portable bank, use a forklift, crane, or other appropriate moving equipment.

Storage

Take the following precautions to prevent injuries caused by asphyxiation, fire, explosion, high pressure, and improper handling of compressed gas cylinders.

NEVER

- Allow storage temperature to exceed 125°F (52°C).
- Permit smoking or open flames in oxidizer or flammable gas storage areas.
- Expose cylinders to corrosive materials such as ice melting compounds.

ALWAYS

- Store cylinders in accordance with ISO Standard 11625 or CGA Pamphlet P-1.
- Store cylinders upright with valve outlet seals and valve protection caps in place. See Air Products' Safetygram-14, "Don't Turn a Cylinder Into a Rocket."
- Secure cylinders when in storage, transit, or use.
- Store cylinders in areas designated for that purpose.
- Segregate full and empty cylinders.
- Store cylinders in a dry, cool, well-ventilated, secure area protected from the weather and away from combustible materials.
- Ensure that there is adequate separation from combustibles as specified by national regulations.
- Monitor the atmosphere in areas where gases may vent and collect.
- Use a first-in, first-out (FIFO) inventory system to prevent full containers from being stored for long periods of time.
- Store only the amount of compressed gas required for the specific application.
- Store cylinders away from heavily traveled areas and emergency exits.
- Provide adequate access for cylinder handling.
- Visually inspect stored cylinders on a routine basis, or at least weekly, for any indication of leakage or problems.
- Restrict access to cylinder storage areas.
- Protect cylinders from wet or damp ground.

Proper Use of Compressed Gases

Take the following precautions to prevent injuries caused by the improper use of compressed gases.

NEVER

- Attempt to mix gases in a cylinder.
- Insert an object (e.g., wrench, screwdriver, etc.) into valve cap openings to remove a stuck cylinder cap. Doing so may damage or open the valve, causing a leak to occur. Use an adjustable strap-wrench to remove over-tight or rusted caps.
- Allow any part of a cylinder to be exposed to temperatures exceeding 125°F (52ºC).
- Permit cylinders to become part of an electrical circuit.
- Use oxygen as a substitute for compressed air.
- Strike an arc on a cylinder.
- Return product into a cylinder.
- Introduce another product into a cylinder.
- Use cylinder color as a primary means to identify the contents of a cylinder.
- Heat a cylinder to increase its pressure or withdrawal rate unless using an approved method. See Air Products' Safetygram-30, "Handling of Liquefied Compressed Gases."
- Discharge the contents from any gas cylinder directly toward any person.
- Refill any nonrefillable cylinder after use of the original contents.
- Force cylinder valve connections that do not fit.
- Reduce the residual pressure of a cylinder below the operating pressure of the system or 7 psig (0.5 bar), whichever is higher.
- Change service of equipment from the particular gas or group of gases for which they were intended.

ALWAYS

- Know and understand the gases and associated equipment you will be using. Refer to the supplier's MSDS to determine the proper PPE and any other special requirements for the gas being used.

Figure 3

The correct way to safely check a system

- Secure cylinders when in storage, transit, or use.
- Use a pressure-reducing regulator or separate control valve to safely discharge gas from a cylinder.
- Use regulators approved for the specific gas.
- Leak-test lines and equipment with an inert gas before using.
- Use regulators and pressure-relief devices when connecting cylinders to piping circuits with lower pressure service ratings.
- Use check valves to prevent reverse flow into the cylinder.
- Loosen the valve outlet seal slowly when preparing to connect a cylinder.
- Open cylinder valves slowly and carefully after the cylinder has been connected to the process.
- Stand clear of the regulator and valve outlet while opening the valve.
- Prevent sparks and flames from contacting cylinders.
- Discontinue use and contact the supplier if a cylinder valve is difficult to operate. Wrenches should not be used on valves equipped with handwheels. If the valve is faulty, tag the cylinder, identifying the problem, and notify the supplier.
- Close the cylinder valve and release all pressure from the downstream equipment connected to the cylinder anytime an extended non-use period is anticipated.
- Use oxygen-compatible threading compounds, such as Teflon® tape on systems for use in oxygen or oxidizer service.
- Remember, the cylinder label or decal is the only positive way to identify the contents of a cylinder.

More information on gas handling is provided in Air Products' Safetygram-12, "Regulator Selection, Installation, and Operation."

AIR PRODUCTS

Emergency Response System

- Call: +1-800-523-9374
  (Continental U.S. and Puerto Rico)
- Call: +1-610-481-7711 (other locations)
- 24 hours a day, 7 days a week
- For assistance involving Air Products and Chemicals, Inc. products

Product Safety Information

- For MSDS
  www.airproducts.com/msds/search.asp
- For Safetygrams
  www.airproducts.com/Responsibility/EHS/ProductSafety/ProductSafetyInformation/Safetygrams.htm
- For Product Safety Information
  www.airproducts.com/Responsibility/EHS/ProductSafety/ProductSafetyInformation/

Technical Information Center

- Call: +1-800-752-1597 (U.S.)
- Call: +1-610-481-8565 (other locations)
- Fax: +1-610-481-8690
- E-mail: gasinfo@apci.com
- Monday–Friday, 8:00 a.m.–5:00 p.m. EST

Information Sources

- Compressed Gas Association (CGA)
  www.cganet.com
- European Industrial Gases Association (EIGA)
  www.eiga.org
- Japanese Industrial Gases Association (JIGA)
  www.jiga.gr.jp/english
- American Chemistry Council
  www.americanchemistry.com

Table 1: Typical Medical Gas Cylinders Volume and Weight of Available Contents at 70F

Cylinder Style & Dimensions	Nominal Volume Cu In/Liter	Contents	Air	Carbon Dioxide	Cyclo-Propane	Helium	Nitrogen	Nitrous Oxide	Oxygen
		Cylinder Color	**yellow**	**gray**	**orange**	**brown**	**black**	**blue**	**green**
B 3 1/2 od x 13" 8.89 x 33cm	87/ 1.43	psig Liters Lbs.-Oz. Kilograms		838 370 1-8 .68	75 375 1- 7 1/4 .66				1900 200 - -
D 4 1/4" od x 17" 10.8 x 43 cm	176/ 2.88	psig Liters Lbs.-Oz. Kilograms	1900 375 - -	838 940 3-13 1.73	75 870 3- 5 1/2 1.51	1600 300 - -	1900 370 - -	745 940 3-13 1.73	1900 400 - -
E 4 1/4" od x 26" 10.8 x 66 cm	293/ 4.80	psig Liters Lbs.-Oz. Kilograms	1900 625 - -	838 1590 6-7 2.92		1600 500 - -	1900 610 - -	745 1590 6-7 2.92	1900 660 - -
M 7" od x 43" 17.8 x 109 cm	1337/ 21.9	psig Liters Lbs.-Oz. Kilograms	1900 2850 - -	838 7570 30-10 13.9		1600 2260 - -	2200 3200 - -	745 7570 30-10 13.9	2200 3450 122 cu ft -
G 8 1/2" od x 51" 21.6 x 130 cm	2370/ 38.8	psig Liters Lbs.-Oz. Kilograms	1900 5050 - -	838 12,300 50-0 22.7		1600 4000 - -		745 13,800 56-0 25.4	
H or K 9 1/4" od x 51" 23.5 x 130 cm	2660/ 43.6	psig Liters Lbs.-Oz. Kilograms	2200 6550 - -			2200 6000 - -	2200 6400 - -	745 15,800 64 29.1	2200 6900 244 cu ft -

Credit: Based on a table created by Ismael Cordero, Clinical Engineer. Used with permission.

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/05)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Page ____ of ____

Mfr Report #
UF/Importer Report #
FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**	2. **Age at Time of Event:**	3. **Sex**	4. **Weight**
In confidence	or ____ **Date of Birth:**	☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)*
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*	4. **Date of This Report** *(mm/dd/yyyy)*

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*

#1

#2

2. **Dose, Frequency & Route Used**	3. **Therapy Dates** *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. **Diagnosis for Use** *(Indication)*	5. **Event Abated After Use Stopped or Dose Reduced?**
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**	7. **Exp. Date**	8. **Event Reappeared After Reintroduction?**
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC# or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

3. **Manufacturer Name, City and State**

4. **Model #**	**Lot #**	5. **Operator of Device**
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	**Other #**	☐ Other: ____

6. **If Implanted, Give Date** *(mm/dd/yyyy)*	7. **If Explanted, Give Date** *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

10. **Device Available for Evaluation?** *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

E. INITIAL REPORTER

1. **Name and Address**	**Phone #**

2. **Health Professional?** ☐ Yes ☐ No		☐ ☐ ☐

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

MEDWATCH

FORM FDA 3500A (10/05) *(continued)* **Page ____ of ____**

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One**
☐ User Facility ☐ Importer

2. **UF/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*

7. **Type of Report**
☐ Initial
☐ Follow-up # ____

8. **Date of This Report** *(mm/dd/yyyy)*

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code ____ – ____ – ____
Device Code ____ – ____ – ____

11. **Report Sent to FDA?**
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. **Location Where Event Occurred**
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. **Report Sent to Manufacturer?**
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other: ____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # ____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. **If Follow-up, What Type?**
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?**
☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*
Method ____ – ____ – ____ – ____
Results ____ – ____ – ____ – ____
Conclusions ____ – ____ – ____ – ____

7. **If Remedial Action Initiated, Check Type**
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. **Usage of Device**
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**