

SAFETY & TECHNOLOGY ORGANIZER

MAY 2017

ENCLOSED

Safety Topic: Child labor regulations Please contact Mike Dodd, GAWDA DOT, Security, OSHA & EPA Consultant for more information.

Traffic Bulletin: Cylinder Decal Change on Large Cylinders Please contact Mike Dodd for more information.

Medical Gas Bulletin:

- 1. FAQ's about Oxygen
- 2. Medical Gas Roundtable: May 26: Subpart E Control of Components Training
 - Specialty Gas Making Your Own Working Calibration Gas Standards
 - Food Gas Roundtable –

CGMP Training – Part 117 Subpart C – Hazard Analysis and Risk Prevention Controls (HARPC) – The latest information about food gas regulations is reviewed –

The sample Food Gas SOPs are available for downloading during the seminar.

3. Micro Audit Suggestions

Please contact GAWDA Medical Gas Consultant, Tom Badstubner for more information.

GAWDA is pleased to distribute this information to: Distributor and Supplier Key Contacts and all Compliance Manual Owners. Please carefully review this mailing and be sure the information is passed to the appropriate person within your organization. Timely Safety data is a benefit of Membership in GAWDA.







Child labor regulations

Summer time is upon us again and our members are hiring summer help so this bulletin is a reminder that we have to follow certain rules for underage workers.

The Fair Labor Standards Act child labor provisions (29 CFR 570-580) are designed to protect minors by restricting the types of jobs and the number of hours they may work.

Prohibited jobs

Seventeen hazardous non-farm jobs, as determined by the Secretary of Labor, are out of bounds for teens below the age of 18. Generally, they may not work at jobs that involve:

- 1. Manufacturing or storing explosives
- 2. Driving a motor vehicle and being an outside helper on a motor vehicle
- 3. Coal mining
- 4. Logging and sawmilling
- 5. Power-driven wood-working machines*
- 6. Exposure to radioactive substances and to ionizing radiation
- 7. Power-driven hoisting equipment (Forklifts)
- 8. Power-driven metal-forming, punching, and shearing machines*
- 9. Mining, other than coal mining
- 10. Meat packing or processing (including power-driven meat slicing machines)
- 11. Power-driven bakery machines
- 12. Power-driven paper-products machines*
- 13. Manufacturing brick, tile, and related products
- 14. Power-driven circular saws, band saws, and guillotine shears*
- 15. Wrecking, demolition, and ship-breaking operations
- 16. Roofing operations*
- 17. Excavation operations*

* Limited exemptions are provided for apprentices and student-learners under specified standards.

Hour limitations

- Youths 18 or older may perform any job, whether hazardous or not, for unlimited hours, in accordance with minimum wage and overtime requirements.
- Youths age 16 and 17 may perform any non-hazardous job, for unlimited hours.
- Youths age 14 and 15 may work outside school hours in various nonmanufacturing, non-mining, nonhazardous jobs up to:
 - 3 hours on a school day
 - 18 hours in a school week
 - 8 hours on a non-school day
 - 40 hours in a non-school week
- Work must be performed between the hours of 7 a.m. and 7 p.m. (extended to 9 p.m. from June 1 through Labor Day).
- Youths enrolled in an approved Work Experience and Career Exploration Program may work up to 23 hours in a school week and 3 hours on a school day (including during school hours).

Requirements

Department of Labor regulations require employers to keep records of their employees under age 19 including their date of birth, starting and quitting times, daily and weekly hours worked, and their occupation. Employers may protect themselves from unintentional violation of the child labor provisions by keeping on file an employment or age certificate for each youth employed to show that the youth is the minimum age for the job. It is a violation of the Act to fire, or in any other manner discriminate against, an employee for filing a complaint or for participating in a legal proceeding under the Act.

Penalties

Employers are subject to a civil money penalty of up to \$10,000 for each employee employed in violation of the child labor provisions. When a penalty is assessed, employers have the right, within 15 days of receipt, to file an exception to the determination that will be referred to an administrative law judge for a hearing. Either party may appeal the judge's decision to the Secretary of Labor. If an exception is not filed in a timely manner, the penalty becomes final.

An employer who is convicted of a second offense is subject to a fine of not more than \$10,000, imprisonment for up to six months, or both. The Secretary of Labor may also bring suit to obtain injunctions to restrain persons from violating the Act.

SAFETY TOPIC

Relation to state laws

GAWDA

Many states have child labor laws. When both this Act and a state law apply, the law setting the higher standards must be observed.

Feel free to contact me if you have any questions.

Michael Dodd

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May 2017

Cylinder Decal Change on Large Cylinders

There has been another change for our cylinder decals. This change only affects our cylinders that have a water capacity larger than 60 liters. Typically, these will be our larger LPG cylinders, the large acetylene cylinders, and cryogenic liquid containers. This is not all of them but it gives you some typical examples. Here are the words from the regulations:

172.301 General marking requirements for non-bulk packagings.

(a) **Proper shipping name and identification number.** (1) Except as otherwise provided by this subchapter, each person who offers a hazardous material for transportation in a non-bulk packaging must mark the package with the proper shipping name and identification number (preceded by "UN", "NA" or "ID," as appropriate) for the material as shown in the §172.101 Hazardous Materials Table. The identification number marking preceded by "UN", "NA", or "ID" as appropriate must be marked in characters at least 12 mm (0.47 inches) high. Packages with a maximum capacity of 30 liters (8 gallons) or less, 30 kg (66 pounds) maximum net mass, or cylinders with a water capacity of 60 liters (16 gallons) or less must be marked with characters at least 6 mm (0.24 inches) high. Packages with a maximum capacity of 5 liters (1.32 gallons) or 5 kg (11 pounds) or less must be marked in a size appropriate for the size of the package.

So here are some options to consider:

- Maintain separate decals with the two different sizes of UN numbers for the large cylinders and then everything else
- Make all the decals with the larger UN numbers
- Use stickers with the larger UN numbers to place on or next to the older decals with the smaller UN numbers until you get new decals made

Please note, your current inventories of the older decals with the smaller UN numbers are still good to use now and in the future for most of your cylinders. You just need to decide what you are going to do for your larger cylinders.



Please see the following page for examples of cylinder sizes and their water capacity in liters.

Feel free to contact me on any of these items if you have questions.

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Traffic Rulletin

Common Industrial Cylinder Dimensions

Standard High Pressure Cylinders AGE

APPROXIMATELY	<u> </u>		0	A		Î		
Size	20	40	60	80	125	150	200	300
Volume (cf)	20	40	60	80	125	150	200	300
Tare Weight (lbs)	11	24	29	47	58	61	117	139
Height (inches)	14	17	23	32	43	47	51	55
Diameter (inches)	5	7	7	7	7	7	9	9
Water Capacity (liters)	3.5	7.8	10.3	15.4	21.6	23.4	43.2	49

All values are approximate Tare weight includes valve but excludes cap. Standard cap is 5 inches in length and 2 pounds in weight

Propane* Cylinders



Size	and the second of the second	- 33	60	60 100		
Volume (lbs)	20	33	60	100		
Tare Weight (lbs)	26	36	48	77		
Height (inches)	19	27	44	49		
Diameter (inches)	12	12	12	15		
Water Capacity (liters)	21.6	36.3	64.8	108.4		

Acetylene Cylinders

All values are approximate Tare weight includes valve but excludes cap. Standard cap is 5 inches in length and 2 pounds in weight *Measurements represent steel cylinders. Aluminum cylinders also available.

Propylene Cylinders



Size				
Volume (lbs)	6	25.5	60	100
Tare Weight (lbs)	8	25.9	48	75
Height (inches)	22	33	44	48
Diameter (inches)	6	9	12	15
Water Capacity (lbs)	8	26	48	75

All values are approximate

Tare weight includes valve but excludes cap. Standard cap is 5 inches in length and 2 pounds in weight



All values are approximate Tare weight includes valve but excludes cap.

Standard cap is 5 inches in length and 2 pounds in weight



05/01/2017

Frequently Asked Questions

Q - What Is The Latest FDA Thinking About Emergency Use Of Oxygen?

A - According to the FDA, any oxygen inhaled by a human or animal is considered a drug as per section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), and is required to be dispensed by prescription. *However*, the agency allows medical oxygen to be dispensed without a prescription to properly trained individuals for oxygen deficiency and resuscitation, as long as the following conditions are met:

- A high-pressure cylinder filled with medical oxygen and used for oxygen deficiency and resuscitation must have the following statement present on the drug label: "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only."
- 2) The equipment intended for such use must deliver a minimum flow rate of 6 liters of oxygen per minute for a minimum of 15 minutes, and include a content gauge and an appropriate mask or administration device, and
- 3) Proper training is documentation that an individual has received training within the past twenty-four months or other appropriate interval, in the use of emergency oxygen including providing oxygen to both breathing and non-breathing patients, and safe use and handing of emergency oxygen equipment. Training may be obtained from any nationally recognized professional organization, such as the National Safety Council, the American Heart Association, the American Red Cross, etc.
- 4) Under no circumstances can emergency oxygen be used to fill high-pressure cylinders or be used in a mixture or blend.

Once all of these conditions are met, an individual may have access to medical oxygen without a prescription.

Keep in mind that this is the Federal FDA position and that some state Boards of Pharmacy may have different rules.

Q - Can I sell medical oxygen to a fire department or Emergency Medical Service (EMS) without a prescription?

A - Yes. According to the 2003 Draft Medical Gas Guidance here is the definition of an Emergency Medical Service:

EMSs include fire departments, ambulance companies, and rescue squads that are usually government-affiliated emergency services. EMSs transfill medical oxygen for their own use (no other gases are filled on site other than compressed breathing air) and administer medical oxygen to patients and/or victims in emergency situations.

And later in the Draft Guidance, the FDA provides the prescription exception for selling medical oxygen to EMS's:

If a medical gas company sells medical oxygen to emergency medical services for emergency use, the label would contain the statement:

"For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only."



FDA would not prohibit the sale of medical oxygen with this labeling to emergency medical services (see Glossary for definition of an EMS) without a prescription

Q - Can I sell medical oxygen to a doctor, hospital or clinic without a prescription?

A - Yes, if the doctor, hospital or clinic has a valid medical license, you may sell medical oxygen to them. Keep in mind that the licensing of medical businesses is regulated by the states and the licensing and commercial requirements vary from state to state. You may be required to list the customers' license number on the invoice.

Q - Can I sell medical oxygen to a school, airport or company without a prescription?

A - Yes, in certain limited circumstances. The agency allows medical oxygen to be dispensed without a prescription to properly trained individuals for oxygen deficiency and resuscitation, if the conditions in the first question are met.

Q - Can I sell medical oxygen to scuba shops for routine diving use?

A - No, scuba diving is not a medical application. However, medical oxygen can be sold for emergency care or treatment at the scene of a diving emergency if the conditions in the first question are met.

F. Can I sell medical oxygen for aircraft pilot use?

No, Aviator Breathing Oxygen is not a medical application. However, medical oxygen can be sold to EMS's for patient use in LifeFlights.

G. Can I sell medical oxygen for maritime use?

Yes, in certain circumstances.

- For United States flag vessels, the medical oxygen must be supplied via a valid prescription or to a licensed medical doctor.
- For foreign flag vessels, the ship must produce a certificate of proficiency of medical care aboard the ship.

May Medical Gas Roundtable - Subpart E – Control of Components Training

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, May 26, we will cover **Subpart E – Control of Components Training**. This training covers the qualification of your raw materials (including bulk products) used in making medical gases.



In addition, we will be conducting the following additional training on May 26:

- Specialty Gas Making Your Own Working Calibration Gas Standards
- Food Gas Roundtable
 - CGMP Training Part 117 Subpart C Hazard Analysis and Risk Prevention Controls (HARPC) – General Program
 - The latest information about food gas regulations is reviewed –
 - The sample Food Gas SOPs are available for downloading during the seminar.

If you would like to receive invitations to the training webinars, just send an email to jodie@asteriskllc.com.

Micro-audit

This section of the Medical Gas Bulletin lists small steps you can take each month to improve your medical gas management system. These steps are not designed to be a full audit, but rather small steps to sample your compliance.

For this month, simply do these items:

- 1. **Dead Ring Test –** Verify that the dead ring test is actually being performed on highpressure steel oxygen cylinders. Of course, the dead ring test should not be performed on aluminum cylinders. This simple item has appeared in recent FDA audits.
- Certificate of Analysis (CoA) Be sure that the CoAs you receive for your bulk medical product and for your Servomex span/zero gas cylinders have the following mandatory items:
 - Name and address of the calibration standard supplier
 - □ Name of the product
 - Lot number or unique identification number specific for each cylinder
 - □ Analytical methodology used to assay the calibration standard
 - Actual analytical results (for example, 99.9 percent nitrogen)
 - □ The responsible person's signature and the date signed

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