

SAFETY & TECHNOLOGY ORGANIZER

FEBRUARY 2013

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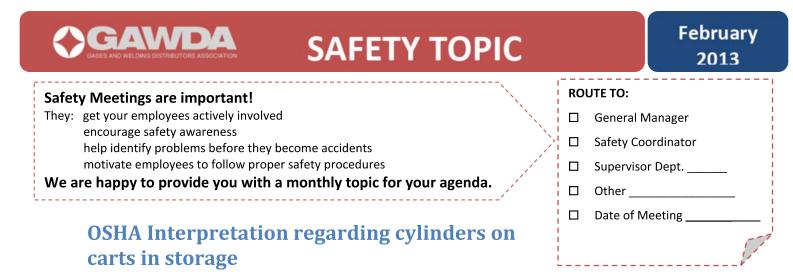
Safety Topic: *"OSHA Interpretation Regarding Cylinders on Carts in Storage"* Please contact GAWDA's OSHA and EPA Consultant, Mike Dodd for more information.

Traffic Bulletin: *"Shipping Papers – Part II"* Please contact GAWDA's DOT and Security Consultant, Mike Dodd for more information.

Medical Gas Bulletin: FAQs, Medical Gas Roundtables, and Micro-audit 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





Here is something that will help many of our members and our customers. OSHA issued a letter of interpretation on 5-10-2006 that outlines their viewpoint and how they will handle cylinders stored on cylinder carts.

Here are a few selected high points from the letter:

"With respect to OSHA's general industry standards related to oxygen and gas cylinder storage, 1910.253(b)(2)-1926.253(b)(4), cylinders in general industry workplaces are not considered to be in storage when they are either "in use" or "connected for use". However, with respect to the provisions for oxygen and gas cylinder storage in the construction industry, e.g., 1926.350(a)(10), a cylinder would be considered to be in use only when gas is being drawn or it is reasonably anticipated that gas will be drawn from the cylinder within 24 hours. Absent these conditions, compliance with the storage requirements is required.

The difference in interpretations of the respective provisions is in part attributable to the language of the respective standards. The language of 1910.253 indicates that cylinders are in "storage" if they are not in use or connected for use. See 1910.253(b)(2)(iv) and 1910.253(b)(3). There is no comparable language in the construction standard. Under the language of 1926.350, cylinders could be subject to the storage requirements even though the cylinders are connected for use. In interpreting the term "storage" in 1926.350, therefore, OHSA has focused on balancing the standard's purposes and the dynamics of a construction environment.

In general industry workplaces, oxygen and acetylene cylinders that are in use or are connected for use will not be considered to be in "storage" for purposes of the 1910.253 storage requirements. OSHA also will not cite a general industry employer if a single oxygen cylinder and a single acetylene cylinder are maintained with their cylinder valves closed and valve protection caps affixed. Closing the valves and affixing the valve protection caps can provide an equivalent level of protection to that achieved when the two cylinders are connected to a properly functioning regulator. This conclusion also finds support in the most recent versions of the consensus standard on which the 1910.253 standard is based. Pursuant to OSHA's *de minimis* policy, a citation is not justified in such situations.

SAFETY TOPIC

Although OSHA is not changing its interpretations of the construction and general industry provisions, the agency has taken steps to harmonize the manner in which it administers the respective standards so that employers doing construction work who follow prescribed practices also will not be cited for maintaining oxygen and acetylene cylinders for periods exceeding 24-hours. Moreover, both general industry employers (as detailed above) and construction employers who close cylinder valves and place cylinder protection caps on the cylinders will not be subject to citation for violating the respective cylinder storage provisions regardless of the period of time between uses."

This will be a handy document to have when OSHA visits either your facility or your customer. Please note that you must have cylinder valve protection in place while the cylinders are on the carts and not in use. OSHA uses the word "caps", but I would assume that protective collars would meet the same intent. The use of the split caps would also meet the intent and could be left on the cylinder while in use or storage and the regulators are still attached. Remember, that the cylinder valves must be closed while not in use.

You can read the full interpretation letter at this website: <u>http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATION</u> <u>S&p_id=25371</u>

Feel free to contact me if you have any questions.

GAWD

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February 2013

Shipping Papers, Part II

Last month, I talked about some changes and some typical mistakes found on shipping papers. This month I will talk about some additional items on shipping papers.

Basic Description

As discussed last month, the basic description consists of the identification number, full proper shipping name, hazard class number (and subsidiary hazard class numbers as applicable), and the packing group, if assigned. There can be no distributor information, such as codes, stock numbers, etc., inserted in the above order. You may place any other descriptive information after the basic description. I find product descriptions being abbreviated such as CO2 or C-25. No abbreviations are allowed in the proper shipping name unless specified in the Hazardous Materials Table (e.g.,"n.o.s.").

The quantity of the hazardous materials may be listed by the number of cylinders (hazard class 2 only), the volume in cubic feet, or the weight in pounds. The metric system is an option. A common mistake is to show cubic feet or pounds next to liquid product descriptions and then show only the number of containers shipped. If you use cubic feet or pounds, then you have to show the actual cubic feet or the total pounds of the package and product shipped. The easiest quantity description would have been cylinders. Abbreviations may be used to express units of measurement and types of packages.

RQ

Sometimes I find the letters "RQ" preprinted on the shipping paper with a particular product. This is all right to do provided at least one of the packages contains the reportable quantity or more. If the package being shipped doesn't contain the reportable quantity of the product and your shipping paper shows "RQ", then you would be in violation.

DOT Special Permits

Each shipping paper issued in connection with a shipment made under a special permit must bear the notation "DOT–SP" followed by the special permit number assigned and located so that the notation is clearly associated with the description to which the special permit applies.

Shipper's Certification

I find wrong or misspelled words in the shipper's certification. The words must be exactly as shown in the regulations. For highway transportation this statement must be:

"This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation." (The words "herein-named" may be substituted for the words "above-named".)



Shipper's Certification (continued)

There are several exceptions and there are alternate certifications to use depending on the mode of transportation. Please read 172.204 for all the details. Remember, distributors do not have to certify shipments on their own vehicles. Many distributors do certify their own vehicles to avoid conflicts with roadside inspectors that are unaware of this exception.

Shipping Names

Nitrous oxide no longer has the word "compressed" in the shipping name.

Do you still show rare gas descriptions on your shipping paper? These descriptions have been gone for over 4 years. All the rare gas descriptions reverted back to the compressed gas, n.o.s. descriptions.

Do you ship any mixtures with oxygen greater than 23.5%? Remember to use the description "UN 3156, Compressed Gas, oxidizing, n.o.s., (oxygen, *the other gas*), 2.2 (5.1)" that describes the hazardous properties of the mixture more accurately.

If you ship LPGs, be sure your shipping paper description matches the description on the cylinder decal. There are several correct descriptions so long as they both match.

Are your shipping papers readable? I find some pretty poor copies being run off of copying machines.

Engine Drive Welders

A common question is, "How do I properly describe our engine drive welders on our shipping papers?"

The quick answer is you don't put it on your shipping paper because you are not required to so long as you have the battery securely installed and in an upright position. A fuel tank containing a flammable liquid fuel must be drained and securely closed, except that up to 500 ml (17 ounces) of residual fuel may remain in the tank, engine components, or fuel lines provided they are securely closed to prevent leakage of fuel during transportation. If you have a welder where the battery is not properly secured or you have left too much fuel in the tank, then the regulations are not being followed and you would be open for citations.

The long answer is that the best shipping name description in the hazardous materials table is "Battery, wet, filled with acid or alkali with vehicle or mechanical equipment containing an internal combustion engine, see **Vehicle**, etc. or **Engines**, **Internal combustion**, etc." When you go to the "UN3166, Engines, internal combustion, flammable liquid powered, 9" you will see an exception listed as 173.220, which is, (c) *Wet battery powered or installed*. Wet batteries must be securely installed and fastened in an upright position. Batteries must be protected against short circuits and leakage or removed and packaged separately under 173.159. Battery powered vehicles, machinery or equipment including battery powered wheelchairs and mobility aids are excepted from the



Engine Drive Welders (continued)

requirements of this subchapter when transported by rail, highway or vessel. (This means the hazardous materials regulations do not apply to our welders as long batteries as are securely fastened upright, the fuel is less than 17 ounces in the closed tank, and you don't ship them by air.)

I have an example of a good shipping paper. If you need one, just ask.

If there are any questions or concerns with your shipping paper and you would like to have me review it, then send me a copy and I will be happy to look it over for you.

Feel free to contact me if you have questions.

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02/01/2013

Frequently Asked Questions

Q – Why are some companies allowed to electronically register for FDA Drug Establishment for 2013 and other need to wait until October 1?

A – The FDA has changed the registration period for Drug Establishments. We used to be able to register anytime during the year. And now the registration period has changed to the fourth quarter. But there are some exceptions. To clarify this we asked the FDA directly and received the following response:

The legislation states for firms to submit an annual registration between October 1st to December 31st of each year. If your firm have already registered for 2012, your firm will be current through 2013. You do not need to re-register until the 4th quarter of 2013.

The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012, and effective on October 1, 2012, amends the Act by requiring additional information to be submitted for the annual registration of domestic or foreign drug facilities. Furthermore, as of October 1, 2012, the annual registration period for domestic and foreign drug manufacturers has been changed to October 1st to December 31st of each year. If a company registers anytime between October 1st and December 31st each year, the company is in compliance with the registration requirements of the Food Drug and Cosmetic Act. Information regarding the Food and Drug Administration Safety and Innovation Act can be found at the following internet link:

http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf

For more detailed instructions on the drug registration and listing process, visit our Electronic Drug Registration and Listing System website at:

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrati onandListing/default.htm

If your firm's "Ourrent Registration Year" block on the Drug Establishments Ourrent *Registration Site*

(DECRS) <u>http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm</u> is filled in with "2012," that is the current registration year. 2012 will remain as the current registration year until 4th Qtr of 2013 when the firm is required to renew for 2013 (between Oct 1 and Dec 31, 2013).

So... why are some firms showing a 2013 registration date already? If you have any changes to your registration (acquisition, divestiture, name change, contact person change, email change, phone number change, etc.) we can revise the registration. Then your registration will show a 2013 date. Just let us know if you want to make any changes to your registration.



February Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, February 3, we will cover **Subparts C** - **Buildings and Facilities**. A sample facility maintenance and cleaning record will be available for downloading during the training.

In addition we will be conducting the following additional training on February 3:

Specialty Gas - Analytical Math (Precision, Accuracy, Linearity, Chromatography Performance) - *Includes and Excel spreadsheet to help make the calculations easier.* **ISO 17025 -** Measurement Uncertainty – *Includes an Excel spreadsheet to calculate your own measurement uncertainty.*

Food Gas Roundtable – 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 juliet@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. Cryogenic Hoses** Be sure that your cryogenic fill hoses are capped when not in use. (Homecare vans and large cryogenic containers)
- **2. Quarantine** Be sure you are quarantining cylinders that have been filled but not yet "released" by the Quality Control Unit.
- **3.** Nitrous Oxide Be sure that your nitrous oxide is secure.

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