

SAFETY & TECHNOLOGY ORGANIZER

NOVEMBER 2018

ENCLOSED

Safety Topic: CGA Subscription Program

Please contact Mike Dodd, GAWDA DOT, Security, OSHA & EPA Consultant for more information.

Traffic Bulletin: DOT Training, Documentation, and Frequency

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. Recent FDA Observations: Annual Record Review

2. FAQ's: FDA Drug Listings: Must I register my facility if I am only warehousing product and not filling the cylinders at this location?

3. SEMINARS: November Medical Gas Roundtable (11/30/2018) – Subparts H & I – Holding and Distribution, Laboratory Controls. WEBINARS: Specialty Gas Operations - - Measuring and Controlling Uncertainty in Gas Chromatographs (ISO 6143). Food Gas Roundtable – Part 117 Subpart F – Records Policy

4. Micro Audit Suggestions.

Please contact Tom Badstubner, GAWDA FDA Food, Medical and Specialty Gases Consultant, 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.



Safety Meetings are important!

They: get your employees actively involved
encourage safety awareness
help identify problems before they become accidents
motivate employees to follow proper safety procedures

We are happy to provide you with a monthly topic for your agenda.

ROUTE TO:

- General Manager
- Safety Coordinator
- Supervisor Dept. _____
- Other _____
- Date of Meeting _____

CGA Subscription Program

To get the word out on a great program, I want to use this month's Safety Topic to promote the CGA Subscription Program. In a few quick words; **this is a fantastic program for our members! I think you would be nuts not to take advantage of this offer.** Here is the reason why. The free program could potential be worth several hundreds of dollars if not into the thousands of dollars of savings depending on how many of the CGA pamphlets you need in your business.

CGA will provide free subscription access to all electronic publications, except for the *CGA Handbook of Compressed Gases* and all video items, as well as CGA member pricing for hardcopy publications, to one person per location from each GAWDA member in their Distributor and Canadian Distributor membership categories.

All this is in exchange for the GAWDA member submitting their annual OSHA 300A data to the CGA contact. Data of individual companies are held in confidence and are not shared with any person outside of CGA staff, including CGA or GAWDA members. It is only shared with your permission.

Safety Awards – Jointly sponsored by CGA and the Gases and Welding Distributors Association (GAWDA), the award program was created in 2012. The awards recognize participating GAWDA distributor member companies that have shown the greatest improvement in safety performance during the previous two years. The Distributor Safety Award is intended to promote safety awareness as an extension of both CGA and GAWDA's safety missions. There are two divisions of the award (Less than / More than 100,000 Employee Exposure Hours).

Requirements? To qualify, you must:

- Be a distributor member of GAWDA in good standing,
- Be from GAWDA's Distributor or Canadian Distributor membership category,
- Not be a former member of CGA with a membership termination date later than October 10, 2011,
- Provide the required safety data for a minimum of the calendar year prior to the subscription access request for access to the publications plus the prior four years to be eligible to win the safety improvement award.

Cost?

- This is a free benefit of GAWDA membership



What Publications Should I Get? There are approximately 300 publications available. Here is a small sampling of the “must have” publications:

- **CGA C-10**, Guidelines to Prepare Cylinders and Tubes for Gas Service and Changes in Gas Service
- **CGA C-13**, Guidelines for Periodic Visual Inspection and Requalification of Acetylene Cylinders
- **CGA C-6**, Standard for Visual Inspection of Steel Compressed Gas Cylinders
- **CGA C-6.1**, Standard for Visual Inspection of High Pressure Aluminum Alloy Compressed Gas Cylinders
- **CGA C-7**, Guide to Classification and Labeling of Compressed Gases
- **CGA G-4.1**, Cleaning Equipment for Oxygen Service
- **CGA M-10.2**, Food Safety Management Systems and Good Manufacturing Practices for Food Gas Manufacturers at Cylinder Filling and Small Bulk Locations
- **CGA M-2**, General Guide for the Manufacture of Medical Gases Classified as Drugs
- **CGA P-15**, Filling of Industrial and Medical Nonflammable Compressed Gas Cylinders
- **CGA PS-40**, CGA Position Statement on Requirements for Installers of Bulk Medical Gas Supply Systems
- **CGA PS-42**, CGA Position Statement on Appropriate and Effective Regulations for Medical Gases within 21 CFR Parts 201, 205, and 210/211
- **CGA SA-22**, Safety Alert, Potential of Carbonated Beverage Systems to Create a Life-Threatening Environment

I can suggest many more publications that would should have for your business based on your operations. If you would like more suggestions, just contact me. Please remember that there are several CGA publications incorporated into Federal law via the 49 CFR 171.7 section. For those that apply to your business you will need the versions referenced in the CFR plus you should also have the most current version to follow.

How Do I Sign Up?

- Visit: <http://www.cganet.com/customer/gawda.aspx>
- Or email: GAWDASubscription@cganet.com
- Or call: 703-788-2722

It's simple.... It's a great benefit.... Do it. Take a few minutes and get signed up for this great CGA Subscription Program.

Michael Dodd

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Traffic Bulletin

Traffic Bulletin

November 2018

DOT Training, Documentation, and Frequency

Here is a compiled list of all required DOT training, documentation and frequencies.

Hazmat Training (172.700-.704)

A **hazmat employer must train, test and certify** (sign the training documentation form) **every hazmat employee** who, in the course of employment, has any function that directly affects hazardous materials transportation safety. The hazmat employee must be trained in General Awareness, Safety, Function Specific, and Driver issues as applicable to the employee's duties.

Function Specific items for our industry would include:

- Cylinder filling of high pressure, cryogenic liquids, liquefied gases such as carbon dioxide, LPG products, and acetylene
- Cylinder requalification such as high pressure (hydrotest), low pressure gases (visual inspection), and acetylene

Driver Training (177.816)

177.816 says that the driver must receive training on the safe operation of the motor vehicle that will be transporting hazardous materials. This section goes on to describe in detail the issues the driver must be trained on. Please note: 177.816 (c) states: The driver training requirements may be satisfied by compliance with the current requirements for a Commercial Driver's License (CDL) with a tank vehicle or hazardous materials endorsement.

GAWDA has an excellent Driver Training Manual available. This would be an excellent source of driver safety meetings. It is setup into 6 short training modules with each module having its own test. Then there is a final overall test covering all the topics in the manual. Each of these modules would make an excellent driver safety meeting training session of a few minutes each. If a company did one module every 2 months, they would cover the complete manual in the year and could start back over again the following year with refresher training.

Security

- **In-depth training on the written plan**

Hazmat employees of employers that are required to have a security plan must receive in-depth security training on the security plan and its implementation. In-depth security training must include company security objectives, specific security procedures, employee responsibilities, actions to take in the event of a security breach, and the organizational security structure.

- **Security Awareness training**

Each hazmat employee must receive security awareness training. This training must include an awareness of security risks associated with hazardous materials transportation and methods designed to enhance transportation security. A component covering how to recognize and respond to possible security threats must be included.



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I have a hazmat general awareness, safety, and security awareness test and certification if you wish to use it. Just ask and I will email it to you. If you need to do only the security awareness portion with certain employees, then you just scratch through the other portion of the answer page and just do the security part of the test questions and answers.

Documentation of Training (172.704(d))

A record of current training, inclusive of the preceding three years, must be created and retained by each hazmat employer for each hazmat employee for as long as that employee is employed by the employer as a hazmat employee and for 90 days thereafter.

The record must include:

- Hazmat employee's name;
- Most recent training completion date of the hazmat employee's training;
- Description, copy, or the location of the training materials used to meet the training requirements;
- Name and address of the person providing the training; and
- Certification that the hazmat employee has been trained and tested. (This is where someone within the company **signs** the training documentation.)

Drug and Alcohol

- 382.601 covers two important points: a written policy and distributing that policy to your drivers. Drivers are not required to undergo formal training. However, the employer must provide a copy of the company written drug and alcohol policy to each driver. Written notice of the availability of these materials must be provided to union representatives. These materials must be distributed prior to the start of alcohol and drug testing. Each driver must sign a receipt that he/she has received a copy of the materials. The JJ Keller pamphlet 532-H does a great job of this.
- 382.603 covers training for driver supervisors. Each employer shall ensure that all persons designated to supervise drivers receive at least 60 minutes of training on alcohol misuse and receive at least an additional 60 minutes of training on controlled substances use. The training will be used by the supervisors to determine whether reasonable suspicion exists to require a driver to undergo testing under §382.307 (reasonable suspicion testing). The training shall include the physical, behavioral, speech, and performance indicators of probable alcohol misuse and use of controlled substances. Recurrent training for supervisory personnel is not required.
- This training is available on the GAWDA University website.



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Training Frequency

The hazmat (general awareness, safety, function specific (which includes driver training), and security awareness) must be done at least every 3 years.

The security in-depth training is required every 3 years unless you update your security plan and then you must train on the changes to the plan.

The supervisor drug and alcohol awareness training is only one time training, but I suggest that you that conduct this training every few years to keep the supervisors aware of the requirements.

If there are any questions regarding this Traffic Bulletin, then please contact:

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin
11/01/2018

Recent FDA Observations

Please see these excerpts from actual FDA inspections at medical gas companies. Consider if these observations could happen at your facility and correct the problem, if needed. For the full list of recent FDA observations and a training record, contact tom@asteriskllc.com. Please forward a scanned copy of any FDA inspections you receive. We will remove any company identification and include in the recent FDA activity report.

Annual Record Review

Form 483 Observation-03-02 - Written procedures are not followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected. Specifically, your firm does not perform an annual product review of each medical gas by reviewing the batch records, complaints, returned products, investigations and or recalls to determine the need for changes in the process or control procedures for the following medical gases: _____

How to prevent this from showing up in your inspection?

Document your Annual Records Review. Contact tom@asteriskllc.com for a sample SOP and Annual Records Review form.

Frequently Asked Questions – FDA Drug Listings

Q – Must I register my facility if I am only warehousing product and not filling the cylinders at this location?

A – This answer depends on whether the cylinders are drugs or food/beverage gases.

- **Food/Beverage Gases** – Warehousing and production locations must both be registered with the FDA if they handle food/beverage gases. The registration process is exactly the same, except that the facility type is marked as a warehouse or a manufacturing location.
- **Drug gases** – Only production locations need to be registered with the FDA. If you are simply warehousing drug gas cylinders at a location, you may need to license with your state board of pharmacy even though you are not required to be registered with the federal FDA.

November Medical Gas Roundtable (11/30/2018) – Subparts H & I – Holding and Distribution, Laboratory Controls

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In November we will be discussing warehousing and laboratory operations.

Medical, Food/Beverage and Specialty Gases Bulletin

For your information, we are also conducting the following webinars in November:

- **Specialty Gas** - Measuring and Controlling Uncertainty in Gas Chromatographs (ISO 6143)
- **Food Gas Roundtable** – Part 117 Subpart F – Records Policy

These and other webinars are available as a streaming recording at a time convenient to you. If you are unable to view the webinar live, just let us know and we will send you the link to the recording. 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. **Servomex Filter** - Verify that you have records that the filter on the Servomex has been inspected according to the frequency in your instrument manual.
2. **Segregation** – Be sure your full medical gas cylinders are segregated from your industrial gas cylinders.

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