GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

DECEMBER 2018

ENCLOSED

Safety Topic: **GAWDA Safety Posters available**

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

Traffic Bulletin: **DOT Records Retention (What to Keep and How Long)**

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. Recent FDA Observations: **Batch Production and Control Records**
2. FAQ's: **Drug Establishment Registration; CGA SB-26**
3. SEMINARS: **December Medical Gas Roundtable (11/30/2018) – (12/28/2018) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products.** **WEBINARS:** **Specialty Gas - Gas Chromatography Fundamentals; Food Gas Roundtable – 21 CFR Part 117 - Subpart G - Supply-Chain Program.**
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.

GASES AND WELDING DISTRIBUTORS ASSOCIATION
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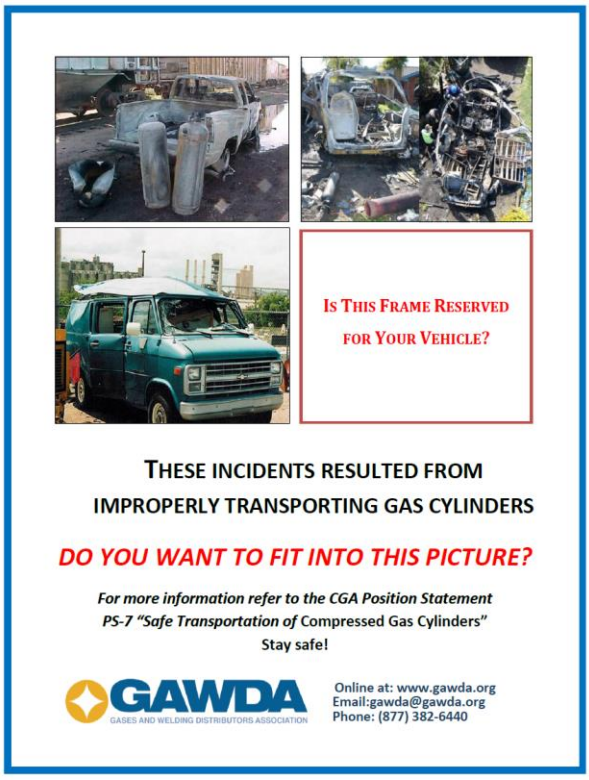
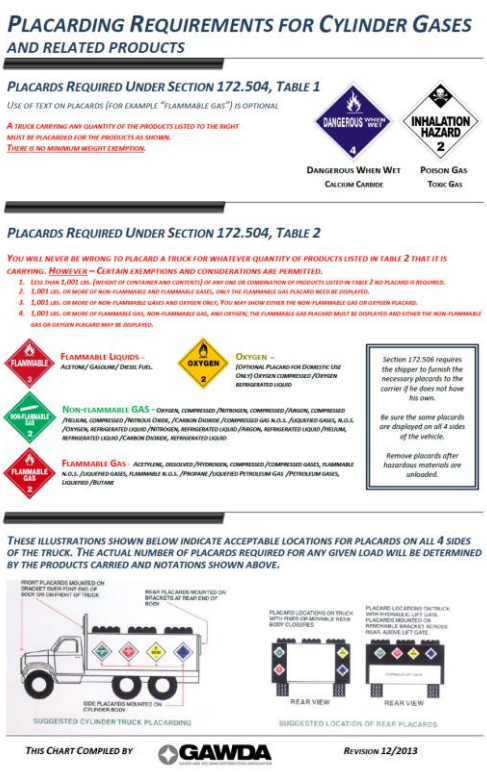
GAWDA Safety Posters available

The GAWDA safety committee has updated the safety posters we are very used to seeing in our locations. These posters are extremely helpful in explaining our position on properly transporting cylinders in vehicles and the requirements for placards when transporting certain quantities of hazardous materials.

You will find these very suitable for framing or attaching to bulletin boards.

The posters are available for GAWDA members to purchase online at $15 each. Click here to log in to your account and “Shop GAWDA Products”





SAFETY TOPIC

December 2018

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 _____

Michael Dodd

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Traffic Bulletin

December 2018

DOT Records Retention
What to Keep and How Long

You are required to maintain certain records on your drivers and vehicles for specified periods of time. Look for the drug and alcohol program recordkeeping requirements in next month's Traffic Bulletin.

Accident Records (390.15)

Motor carriers shall maintain for a period of three years after an accident occurs, an accident register (a list of accidents) containing at least the following information:

- Date of accident,
- City or town in which or most near where the accident occurred and the State in which the accident occurred,
- Driver name,
- Number of injuries,
- Number of fatalities, and
- Whether hazardous materials, other than fuel spilled from the fuel tanks of motor vehicles involved in the accident, were released.
- Copies of all accident reports required by State or other governmental entities or insurers.

If you need any sample forms for the **Accident Register** and **Accident Report, then please contact me.**

Driver Qualification File (391.51)

You must retain the driver qualification file for 3 years after you no longer employee the person as a driver. There are several items required in the DQ file.

Hours of Service (395.1 & 395.8)

You are required to keep driver hours of service records for 6 months. This is kept via driver logs unless you meet the exceptions in 395.1 where you are allowed to keep other records of driver hours which must contain at least; the start time, the stop time and the total hours worked for each day, and the total time for the preceding 7 days in accordance with 395.8(j)(2) for drivers used for the first time or intermittently.

Insurance (387)

You are required to show proof of financial responsibility. Our members need a current copy of the DOT MCS-90 form, which is supplied by your insurance company. If you ship hazard zone A poisons or have cargo tanks exceeding 3500 gals. of water

capacity, then you will need to show $5,000,000 in coverage. Everyone else will need $1,000,000 in coverage.

Post-trip Vehicles Inspections (396.11)

The driver is required to perform a post-trip inspection on their vehicle at the end of each day. If you driver fills out a report because something was found defective, then report must note any defects found and the certification of the repairs if any defects were noted. The following day, the next driver must review the report and certify the repairs were made. These must be kept for 3 months.

Periodic Inspection (396.21)

Each vehicle must be inspected at least once per year and a copy of the inspection must be kept for 14 months. A copy of the report or a decal containing minimal information (see 396.17(c)(2)) must be on the vehicle.

Roadside Inspection (396.9)

You must keep for one year any roadside inspections that were done on your vehicles. You have 15 days to fix any noted defects, sign the report and return it to the authorities. I suggest you keep the reports for 2 years because the Safety Management System shows roadside inspections for 2 years.

Vehicle Maintenance Files (396.3)

You are required to keep maintenance records for one year on any vehicle you have controlled for one month or longer. These records must be maintained where the vehicle is housed or they may be kept by the servicing location. The file must contain the vehicle information (company number, make, serial number, year, and tire size) and the inspection, repair and maintenance records. You must keep these records for 6 months after the vehicle is sold, traded or scrapped.

Hazardous Materials

If you handle hazardous materials, then you must keep a copy of the following items:

1. Federal Hazardous Materials Registration (107.608) (3 years)
2. State Hazardous Materials Registration (if your State has a program)
3. If you cross state lines, then you must do the annual Unified Carrier Registration and I suggest you keep these for 3 years.
4. Training records for all affected hazardous materials employees. The training must be done at least every 3 years. (172.704)
    a. Hazmat training
    b. Security In-depth training (Only if you are required to have a written security plan.)
    c. Security Awareness training
5. Shipping papers (Hazardous Materials Manifest) must be kept for 2 years.

Traffic Bulletin

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

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin
12/01/2018

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.

Batch Production and Control Records

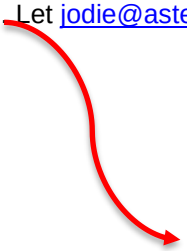
Form 483 Observation-03-03 - The batch production and control records are deficient in that they do not include specimen of labeling. Specifically, your firm does not include all label specimens in the batch record, specifically the medical gas label specimen or copy is not included in the production record. Your firm only includes the sticker specimen label which has the lot number and container size.

How to prevent this from showing up in your inspection?
We have a basic disagreement with the agency about what is appropriate for medical gases. Corrective Action – None required since our procedures follow long-standing FDA accepted industry practice. Please note that the observation noted above is contrary to a medical gas industry position identified in CGA PS-42 and communicated to FDA in 2012 and 2013 after the U.S. Congress passed and President Obama signed FDASIA which requires FDA to make necessary changes to the Federal drug regulations for medical gases. A copy of the CGA Position Statement on Appropriate and Effective Regulations for Medical Gases within 21 CFR Parts 201, 205, and 210/211 (CGA PS-42- 2014) has been provided to the districts from FDA Headquarters.

Compliance ToDo List – Review your Drug Listings

The FDA drug registration and listing regulations (21 CFR 207) require drug manufacturers to review their online drug labels in June and December each year. Look for obsolete labels, “unapproved medical gas” statements, or errors in the submission.

To verify your Drug Listing log on to: http://dailymed.nlm.nih.gov/dailymed/search.cfm. Enter your NDC Code (Labeler Code). Let jodie@asteriskllc.com know if you would like to know your labeler code.



Medical, Food/Beverage and Specialty Gases Bulletin

Frequently Asked Questions – Drug Establishment Registration

Q – How can I be sure that all my medical gas manufacturing locations are properly registered with the FDA?

A – The only way you can be completely certain that your registration is current is by logging onto the FDA registration search website: http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm. Enter a portion of your firm's name and press the "Submit Query" button. Your search results will be displayed along with the Expiration Date of your registration.

Frequently Asked Questions – CGA SB-26

Q – Is CGA SB-26 still in effect since the FDA adopted the new container and closure rules?

A – The relevant portion of the new FDA regulations specify:

> *Portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (e.g., those that have been silver- brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the containers' use) except by the manufacturer.*

CGA SB-26 was developed in 2000 following several tragic incidents where cryogenic container outlet connections had been switched to connect the wrong gas to a customer's distribution system. Using different words, the FDA has adopted the principles behind CGA SB-26.

We strongly encourage you to get your own copy of CGA SB-26 and follow its guidance. This publication is available for free to GAWDA members who participate in the CGA safety program (www.cganet.com). If you are not a part of the CGA safety program, this would be a good time to join. Otherwise, the publication's cost is only $5.00.

Hold the Date! – Spring GAWDA Professional Compliance Seminar

At Chart Industries, Ball Ground GA

March 19-20, 2019

Medical, Food/Beverage and Specialty Gases Bulletin

December Medical Gas Roundtable (12/28/2018) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products.

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In December, we will be discussing the various records required by the FDA. In addition, we will have an easy to use handout about how to document your Annual Records Review.

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

- ***Specialty Gas*** - Gas Chromatography Fundamentals
- **Food Gas Roundtable** – 21 CFR Part 117 - Subpart G - Supply-Chain Program

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. **Complaints -** Verify that your complaint file has any instances of customers asking for credit because they thought the cylinder was not full. (Even if the complaint was found to be without merit).
2. **QCU Review -** Verify that your QCU reviews all complaints.
3. **Other Lots? –** Be sure your complaint investigations consider whether any other cylinders from the same or different lots should be investigated. Document your decision to not investigate other cylinders/batches on the complaint record.

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