GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

DECEMBER 2017

ENCLOSED

Safety Topic: Filling Liquefied Products

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

Traffic Bulletin: Qualifying a new driver

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQ: Drug Establishment Registration & CGA SB-26
2. December Medical Gas Roundtable (12/29/2017) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products.
3. Webinars:
   ***1*. Gas Chromatography Fundamentals**
   ***2*. Food Gas Roundtable - 21 CFR Part 117 - Subpart G - Supply-Chain Program**
4. Micro Audit

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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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 _____

Filling Liquefied Products

Many of our members fill carbon dioxide cylinders and some fill nitrous oxide. Here are some suggestions to consider when filling these and other liquefied (liquid in the cylinder at room temperature) products. This is not a complete checklist. Please refer to the several CGA publications on the product and the filling of cylinders. As a reminder, if you have not already signed up, please check out the "CGA & GAWDA Subscription Program" at this website: http://www.cganet.com/customer/gawda.aspx This is a great service that is available for free to all GAWDA distributors.

Please note: Highly suggested CGA publications to read are G-6.3, "Carbon Dioxide Cylinder Filling and Handling Procedures" and P-15, "Filling of Industrial and Medical Nonflammable Compressed Gas Cylinders".

Here are just a few selected items from the above publications, but please read the publications for all the details involved in the inspection and filling process.

Carbon Dioxide and Nitrous Oxide Filling

- **Check the ownership, DOT or ICC specification number, pressure rating, retest date, and label for gas service.**
- **Check for serious damage such as cracks and harmful dents, gouges, arc burns, fire burns, excessive corrosion, etc., and the need for repainting.**
- **Check for oil, grease, and other contaminates on the valve, neck ring, and cylinder exterior.**
- **Check the valve outlet and outlet connection for cleanliness. Check for thread damage. (Remember that racing nitrous uses a CGA 660 valve.)**
- **Check the pressure release device for damage and proper pressure rating.**
- **Warning: No fusible metal backed safeties. (The presence of fusible metal backed safeties has extreme fatality potential with liquefied products.)**
- **Any pure CO_2 cylinders or cylinders with mixtures greater than 30% CO_2 must have the "star" peened out of the last retest date. (49 CFR 180.209 (b)(3)) I suggest limiting the mixture to 25% just to make sure you never go past the 30% limit. It is not worth the potential DOT penalty.**
- **Check for the presence of contaminants in the cylinder. (No odor test for health reasons.)**
- **Vent and evacuate as required to ensure the absence of contaminants.**
- **Dead ring test (hammer test)**

  - Required for Nitrous Oxide to go 10 years on retest.
    - Please note that racing nitrous mixtures are not allowed to go 10 years between retest because of the addition of the sulfur dioxide.
  - Not required but highly recommended for steel CO2 cylinders.
- All cylinders should be tare weighted. The CGA publication G-6.3 says that if no tare weight is present, then do not fill it. Send it out to a manufacturer or authorized retester to have the proper tare weight stamped on it.
- All cylinders should be checked on the scale to verify the cylinder tare weight prior to hooking up the fill lead. If the weight is 1.5% more or less than the stamped tare weight, tag the cylinder and set it aside for further inspection.
  - Any cylinder over the tare weight should be checked for residual product or foreign material inside the cylinder. (A common item is water or beverage syrup inside CO2 cylinders.)
  - Any cylinder under the tare weight could indicate loss of metal due to corrosion and should be internally inspected.
- Cylinders without a residual pressure valve should be inverted and discharged prior to filling to ensure that all water, syrups, and other foreign materials are removed. Any evidence of water or other fluids requires removing the cylinder from service, removal of the valve, and internal inspection by an authorized cylinder retester. Water will cause internal corrosion in steel cylinders by the formation of carbonic acid.
- Fill by weight and do not exceed the maximum filling density for the product and size (water capacity) of the cylinder. For example, 68% of water capacity for CO2 is the maximum permitted filling density.
- Check to make sure that you have a proper decal with none of the words missing and the colored diamond is complete and not faded. For products that chill the cylinder during the filling process, you will need to affix the decals prior to filling.
- Secure the cylinder cap if it has provisions for a cap.

If the cylinder is marked with a DOT E (exemption) or DOT SP (special permit), then the provisions of the permit must be followed. Also, you must train your employees involved with the permit every 3 years on the provisions of the permit and document the training per 172.704.

As always, if there are questions or items that I can help you with, please don't hesitate to contact me.

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Traffic Bulletin

December 2017

Qualifying a new driver

What are the things that I need to do to hire a driver? How fast can I put a new driver on the road? What items do I need to have in my hands before letting a driver go out on the road? What should I look for on the motor violation records when deciding to hire a driver? What minimums should I have for hiring a driver? These are some of the questions that I get when someone is trying to put on a new driver. The following guidance assumes that you want a driver for loads requiring placards.

Must have items before letting a person drive

1. **DOT employment application**
2. **CDL with hazmat endorsement (if you have a tank(s) bolted to the vehicle with more than 119 gals of capacity, then you need a cargo tank endorsement)**
3. **Current medical card certification (either a medical card or an MVR showing current medical certification)**
4. **Medical examiner certification where you have checked the National Registry of Medical Examiners to check that the driver used a certified examiner.)**
5. **A negative pre-employment drug test**
6. **Road test form and certificate (391.31(g)), or CDL license or certificate accepted in lieu of road test (391.33),**
    a. **A CDL is acceptable.**
    b. **Doubles / triples or cargo tankers must have a road test certification for the specific vehicle within the previous 3 years.**

Items that you must have within 30 days

1. **Motor vehicle record from states (391.23),**
    a. **Must be obtained within 30 days of employment**
    b. **Must be for the prior 3 years**
    c. **Please note that the regulations require this within 30 days, but I suggest that you have this and review it prior to letting the driver drive your vehicles.**

2. **Previous employer information (391.23),**
    a. **Must be obtained within 30 days of employment**
    b. **Must be for the prior 3 years**
    c. **The information must be verification of employment, any DOT accidents (or any other accidents that the previous employer may want to provide), and the drug and alcohol test results/violations.**

Items needed later down the road

1. **Annual review of driving record (391.25),**
    a. **Must be done at least annually**
    b. **Must keep a copy of the state inquiry results in the file.**
    c. **The motor carrier must consider the driver's accident record and any evidence that the driver has violated laws governing the operation of motor vehicles, and must give great weight to violations, such as speeding, reckless driving, and operating while under the influence of alcohol or drugs, that indicate that the driver has exhibited a disregard for the safety of the public**
2. **List of violations (391.27) (part of the above annual review),**
    a. **The driver shall provide a list of driving violations for the previous 12 months. The driver shall sign this list.**
    b. **If the driver has already provided this information as required by 383.31, then they don't have to repeat the information. 383.31 requires that drivers notify their carrier within 30 days of any vehicle violations, other than parking tickets, of which they have been convicted. The notification must be in writing and contain the 7 items listed in 383.31.**
3. **Medical examination kept current.**
4. **Medical Examiner's Certification kept current**

Suggested items for the DQ file

1. **Not required, but highly suggested is to have a copy of their current driver's license in the file.**

Common Question

"What do I do about an existing employee that I want to make a driver?" The easiest and best thing to do is to treat the employee as a brand-new hire. Make sure you have used a DOT driver application form. If not, then have them fill out a new DOT employee application. You still must do the previous employer background checks for the previous 3 years, but you do get to count the time the

employee was working for you in that 3-year time period. Be sure to do the pre-employment drug screen.

Driver Eligibility Requirements

Next month, I will have some suggestions to consider for driver eligibility requirements. The suggestions will have some minimum requirements and some items that would possibly disqualify a driver from being considered for a driver position.

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

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Medical, Food/Beverage and Specialty Gases Bulletin

12/01/2017

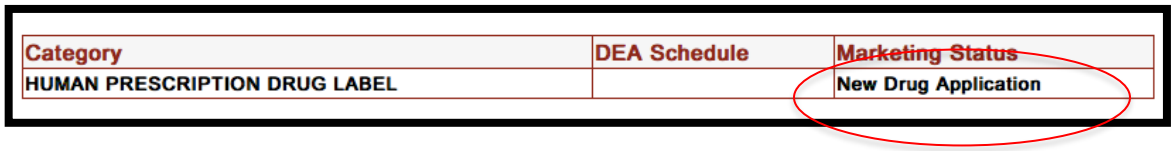
Frequently Asked Questions – Drug Establishment Registration

Q – How can I remove the “unapproved medical gas” statement from my FDA Drug Listing?

Category	DEA Schedule	Marketing Status
HUMAN PRESCRIPTION DRUG LABEL		unapproved medical gas

NOTE: THIS DRUG HAS NOT BEEN FOUND BY FDA TO BE SAFE AND EFFECTIVE, AND THIS LABELING HAS NOT BEEN APPROVED BY FDA. For further information about unapproved drugs, click here.

A – The key to removing the “unapproved medical gas” statement from your FDA Drug Listing is to notify the agency (through the Drug Listing submission) that your medical gas was originally manufactured by an FDA “certified” firm. You submit your supplier’s NDA (New Drug Application) number and/or the NADA (New Animal Drug Application) number as a part of your Drug Listing. You also submit their supply location as one of your “confidential locations”. When this is validated by the FDA, the agency will remove the “unapproved medical gas” statement from your FDA Drug Listing and it will look like this:



Category	DEA Schedule	Marketing Status
HUMAN PRESCRIPTION DRUG LABEL		New Drug Application

If you work with a registrar to submit your registrations and listings, they should know how to do this. If you need a copy of all the NDA/NADA numbers for your reference, just let me know (tom@asteriskllc.com).

If you want to verify your Drug Listing log on to: http://dailymed.nlm.nih.gov/dailymed/search.cfm. Enter your NDC Code (Labeler Code). Let tom@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.

December Medical Gas Roundtable (12/29/2017) – 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.

Medical, Food/Beverage and Specialty Gases Bulletin

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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