



JUNE 2021

ENCLOSED

Safety Topics

LPG Filling, Transportation and Storage

Please contact [Marilyn Dempsey](#), GAWDA DHS, EPA, & OSHA Consultant for more information.

Traffic Bulletin

Driver Eligibility Requirements

Please contact [Mike Dodd](#), GAWDA DOT Consultant for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FDA Compliance ToDo List
2. Recent FDA Observations
3. FAQs
4. June Medical Gas Roundtable (6/25/2021); GAWDA Professional Compliance Training (10/25-29/2021)
5. Micro-Audit Suggestions

Please contact [Tom Badstubner](#), GAWDA FDA Food, Medical & Specialty Gases Consultant for more information.

**** Visit GAWDA's COVID-19 Resource Center at www.gawda.org/covid-19/ ****

Here you will find information on Live GAWDA Consultant Roundtables, Covid -19 Safety Alerts, and Members-Only links.

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 _____

June 2021**LPG Filling, Transportation and Storage**

As summer approaches and the use of BBQ grills increases, we need to be mindful of the dangers Propane can introduce when not properly filled, transported and stored. This article is an overview of propane filling, transportation and storage and in-depth training should be conducted for all three topics.

The greatest hazard of propane during the summer months is IF liquid propane is vented into the atmosphere, it will vaporize into gas and expand to 270 times the volume. Propane gas is colorless, heavier than air and will pool in low places; if a source of ignition comes into contact with the propane gas (e.g. spark, cigarette butt, static electricity) it would ignite.

The most common cause for propane cylinder venting is from overfilled cylinders. The tank farm and fill assembly should be inspected daily or before use. Propane cylinders should be visually inspected prior to filling. If using a manual scale the fill weight must be properly calculated; the fill assembly should be included in the final gross weight (cylinder tare weight+fill assembly+ net product weight = final weight).

Propane cylinders should be transported secured, in open vehicles, NEVER in automobile trucks. GAWDA has safety posters for consumer transporting compressed cylinders available on the website/ shop GAWDA products/ safety poster.

Cylinders should be stored in dry areas, away from sources of ignition/heat and combustibles. Not as in this picture.



Cylinders must be stored with the safety relief device in contact with the gas vapor space, never in the liquid phase area...and NEVER upside down! CGA has published S-8 "Guideline for the Safe Handling of Liquefied Petroleum Gas Cylinders."

Cylinder on the left = PRD in liquid phase space.
Cylinder on right = PRD in vapor phase space.



Training

OSHA requires employees to be trained in the jobs they perform. This is a good time to review your operating procedures (SOP) with your fillers to see if the procedures should be updated or the filler needs refresher training. If your company does not have pre-fill, fill and storage procedures, this is a good time to create them.

DOT requires employees filling cylinders to be trained, tested and certified every 3 years. This falls under the "Function Specific" training requirements in 172.704.

Training may be found:

- Propane and Education Research Council
- Propane training services, inc.
- CETP
- Your bulk propane supplier

If you have any questions on Propane safety or any other OSHA, EPA, DHS issue, please contact me.

Marilyn Dempsey
GAWDA DHS/EPA/OSHA Consultant
Safety Dragons Workplace Consultants, LLC
www.SafetyDragons.com
Marilyn@SafetyDragons.com
M:940-999-8466



Traffic Bulletin

Traffic Bulletin

June 2021

Driver Eligibility Requirements

Following up on last month's Traffic Bulletin "Qualifying a New Driver", here are some suggestions to consider for driver eligibility requirements. These suggestions have some minimum requirements and some items that would possibly disqualify a driver from being considered for a driver position.

These are only suggestions, and you are free to modify these to meet your local hiring environment and driver availabilities.

Eligible drivers must:

- Have at least two years driving experience or have completed a course of instruction from a driver training school that operates equipment similar to the company.
- The appropriate license for the type of vehicle to be operated and the applicable endorsements.
- A current medical examiner's certification (medical card or MVR showing current medical examination certification)
- The ability to read and write in English.
- Have an acceptable driving record.

Acceptable Driving Record Means:

- No major violations in the last three years
- Maximum of three minor moving violations in the last 3 years
- Maximum of one at-fault accident in the last 3 years

Major violation is a citation that involves:

- Any drug or alcohol violation in connection with the operation of a motor vehicle
- Homicide, manslaughter or use of a motor vehicle for felonious purposes.
- Hit and run
- Reckless driving
- A speeding violation 15 MPH or more above the posted limit
- Speed contests, drag racing, or attempting to elude an officer of the law
- Driving while license is suspended or revoked
- Use of a cell phone while driving
- Failure to use a seatbelt (This is one of my personal opinion items.)



Traffic Bulletin

Minor violations:

- Any moving traffic citation (speeding less than 15 MPH above the posted limit, failure to stop or yield, improper lane change, etc.) other than a major violation.

The following are **not** moving citations:

- Motor vehicle equipment, load or size requirements
- Improper display or failure to display license plates
- Failure to sign or display registration card

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

Michael Dodd
GAWDA DOT Consultant
P.O. Box 93, Poplar Bluff, MO 63902
(573) 718-2887
Email: MLDSafety@hotmail.com



Medical, Food/Beverage and Specialty Gases Bulletin

06/01/2021

FDA Compliance ToDo List

FDA Drug Listing Review – 21 CFR 207.30(a) specifies that drug manufacturers review their Drug Listings in June and December and make revisions, if needed. For example, verify that:

- The purity and cylinder sizes are correct
- The label is up-to-date. Be sure your GHS compliant label is posted to the FDA website.
- The locations distributing the drug are correctly identified.
- The “unapproved medical gas” marketing category has been removed and replaced with “New Drug Application”.

See item 2, below, under the “Micro-Audit” for website information. Contact jodie@asteriskllc.com if you need any assistance with this.

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.

Calibrations

Form 483 Observation-03-04 - Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance. Specifically, you did not follow your SOP "Measuring Devices" which requires you to perform calibration activities on at least an annual basis. You have not performed calibration activities on the scale used during Liquid Oxygen USP filling operations since ____.

How to prevent this from showing up in your inspection?

Assure your scales, HP gauges, vacuum gauges and thermometers are calibrated on time.



Medical, Food/Beverage and Specialty Gases Bulletin

Frequently Asked Questions

Q – Do I need to apply the 360 degree wrap around label on the small (41 liter) liquid oxygen “liberators” that we fill for use by the patient?

A – No. The 360 degree wrap around labels are not required for liberators. They are required for the larger cryogenic vessels (LS230, GP45, etc.).

June Medical Gas Roundtable – CGMP – Subpart E – Control of Components

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On June 25, 2021, 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.

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

- **Specialty Gas** - Robust and Efficient Gas Sampling Techniques
- **Food Gas Roundtable** – Part 117 Subpart C - Recall Plan & Preventive control management components and Monitoring – 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.

GAWDA Professional Compliance Training – HOLD THE DATES

This year, the Fall Professional Compliance Training will be held via Teleconference
October 25 to 29, 2021



Medical, Food/Beverage and Specialty Gases Bulletin

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. **Annual Records Review** – Verify that you have looked at your records to determine if changes are needed in your medical gas program. This review can be easily completed and documented. Contact Tom if you need a form to document your annual records review.
2. **Electronic Registration and Listing** – Be sure your electronic registration and listing is correct. Print out the web pages with your information below to document your compliance:
Facility Registration - <http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>
Drug Listing - <http://dailymed.nlm.nih.gov/dailymed/search.cfm>

Tom Badstubner
GAWDA Medical Gas Consultant
Telephone: 508-883-0927
Email: tom@asteriskllc.com

