

SAFETY & TECHNOLOGY ORGANIZER

JUNE 2019

ENCLOSED

Safety Topic: LPG Filling and Storage

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

Traffic Bulletin: Preventing Vehicle Backing Accidents

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1 FDA Compliance To Do List: FDA Drug Listing Review

2. Recent FDA Observations: Calibrations

3. FAQ's: Do the FDA regulations require chrome plated valves for medical gas cylinders?

4. June Medical Gas Roundtable (28 June 2019): – How to Survive an FDA Audit.

**Specialty Gas – Robust and Efficient Gas Sampling Techniques ; Food Gas Roundtable- – Part 117
Subpart C - Preventive Controls**

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 _____

LPG Filling and Storage

This month's Safety Topic is to remind people of the upcoming hot months of summer and the problems of overfilling LPG cylinders. This Topic is not meant to provide all the details of proper filling and storage of LPG cylinders. See **Filling and Storage** later in this Topic.

Hot Summer Days

The extreme heat of the summer months will cause overfilled cylinders to begin venting product and this venting product can be liquid which expands 270 times the volume when going from a liquid to a gas. Provide an ignition source and you have the equation for big trouble.

Key Mistakes

A very common mistake that I find is an employee putting a cylinder on the scale and then sliding the weight on the beam or adding weight to the electronic scale to add the weight of the product to the weight indicated on the scale. This doesn't take into consideration any residual in the cylinder. If product or any foreign substance is inside the cylinder, the result is an overfilled cylinder.

You should be taking every opportunity to check the weight of the cylinder prior to filling. There are times that residual product will still be in the cylinder, but many times the cylinder is empty, and this lets you check the tare weight.

Another common mistake I find is the employee not taking into consideration the weight of the filling valve and hose assembly. This results in under filling the cylinder. Not a safety issue but certainly a weights and measures issue and a customer satisfaction issue.

Filling and Storage

There are many sources of information available on the proper procedures for filling and storage of LPG cylinders. Some of these sources are:

- NFPA 58, Liquefied Petroleum Gas Code; www.nfpa.org
- National Propane Gas Association; www.npga.org
- Your supplier

Some other storage issues to consider are:



Empties upside down on trucks and docks: The regulations require that the safety relief valve must be in contact with the gas vapor and not the liquid. Placing forklift style cylinders upside down on the truck or dock to denote they are “empties” is violating the regulations. If the safety would start to vent, you could be releasing liquid which expands about 270 times from liquid to gas.

Cylinders in racks at customers (not pin indexed): You should consider training your drivers and customers to place full or “empty” forklift cylinders into a storage rack with the safety relief valve pointed up. The index pins take care of this orientation while on the forklift, but many storage racks do not have the pins.

Too many together in one place: You should consider not storing too many flammable gas cylinders in one place or large groups. If you would ever have a problem, you will have a very big problem fast. Smaller groups and spread out between the groups will let you deal with smaller problems should you ever have a leaking / venting cylinders or a fire.

Training

OSHA requires employees to be trained in the jobs they perform.

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.

There is an excellent DVD training program, “Dispensing Propane Safely”, available from the Propane Education & Research Council, that includes a test that along with an employer certification will satisfy the DOT requirements.

Final Thoughts

One of the most important items is the correct filling limit.

Tare Weight + Product Weight + Filling Assembly = Full Cylinder Scale Weight. Check the full cylinder weight prior to removing the filled cylinder from the scale.

Another important item is proper storage. Keep the required distances in mind and think about your cylinder storage. Think about the worst scenario and ask yourself if the way you are storing your cylinders would be a problem if you had a fire situation.

Finally, are your employees properly trained on cylinder inspection, cylinder selection, filling procedures, proper marking and labeling, handling and storage, and what they should do in emergency situations?

If there are any questions regarding this Safety Topic, please contact:

Michael Dodd

GAWDA DOT, Security, OSHA & EPA Consultant

P.O. Box 93

Poplar Bluff, MO 63902

(573) 718-2887

Email: MLDSafety@hotmail.com



Traffic Bulletin

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June 2019

Preventing Vehicle Backing Accidents

Backing is the single most frequent cause of truck accidents, but all backing accidents are preventable. Many backing accidents are caused by drivers who are in a rush or lose their focus. When backing, drivers should go slowly and concentrate on what they are doing. Avoid over confidence in your backing skills.

Here are some simple guidelines on backing:

- Don't backup if you don't have to. If you can, you should pull into a spot that lets you pull out going forward when you need to leave.
- The closest place is not always the safest place. Most people try to park close to the door so they can do the least walking. The problem is that so does everyone else which increases the activity and traffic. Choose a place farther away and you will avoid potential hazards of the increased traffic which equals increased risk.
- Adjust your mirrors before driving.
- When you do have to back:
 - Check the area behind you first. Get out and look. Many companies have made this mandatory. You may have to get out more than once, especially if blind-side backing.
 - Back up slowly.
 - Remember to keep your blind areas in mind while backing.
 - Look constantly and often to the rear, both sides, and front while backing. Things change and can happen fast.
 - Back up no further than you must.
 - Whenever possible, backing should be completed from the driver's side. Blind-side backing should be the last resort.
 - Let people around you know what you are doing. Use your lights and horn as needed to communicate your intentions.

The driver has the ultimate responsibility for the vehicle when backing. You might receive help while backing, but you are still the responsible person if an accident happens.

If you use a spotter, then here are some things to consider:

- Carefully choose a spotter capable of performing the duty.



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- Discuss the spotter's responsibilities and the hand signals to be used.
- Discuss the desired final position of the vehicle.
- Inspect the backing site (ground, sides, and overhead) for any obstacle or backing hazard.
- Stress that at no time should the spotter position himself or herself or any part of his or her body behind the vehicle.
- Understand that any time the spotter is not in full view, the vehicle must be stopped, and the spotter repositioned before proceeding with the backing maneuver.
- Proceed with caution

Remember, backing accidents are preventable.

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

Michael Dodd

GAWDA DOT, Security, EPA, & OSHA Consultant

P.O. Box 93

Poplar Bluff, MO 63902

(573) 718-2887

Email: MLDSafety@hotmail.com



Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin
06/01/2019

FDA Compliance To Do 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 tom@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.

Frequently Asked Questions

Q – Do the FDA regulations require chrome plated valves for medical gas cylinders?

A – No, chrome plated valves are not required for medical gas cylinders. However, customers may come to expect chrome plated valves and they often look cleaner than non-plated brass valves.

Medical, Food/Beverage and Specialty Gases Bulletin

June Medical Gas Roundtable – CGMP - How to Survive an FDA Audit

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On June 28, 2019, we will cover strategies to survive an FDA audit. There are some simple items you can do before, during and after an FDA audit that will contribute to a better compliance outcome. In addition, we will make available a proven template for responding in writing to FDA investigations.

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 - Preventive Controls - 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 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. **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