



JUNE 2020

ENCLOSED

Safety Topic

COVID-19 Exposure Prevention Plan

Please contact Marilyn Dempsey, GAWDA DHS, EPA, & OSHA Consultant for more information.

Traffic Bulletin

LPG Filling and Storage

Please contact Mike Dodd, GAWDA DOT Consultant for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FDA Compliance To Do List
2. Recent FDA Observations
3. Frequently Asked Questions – Label Printers; Chrome Plated Valves
4. June Medical Gas Roundtable: CGMP – Instrument Qualification and Analytical Method Validation
GAWDA Professional Compliance Training: Onsite & via Teleconference - October 27-29, November 3-5
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/ ****

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 _____

Exposure Prevention Plan

Recently, a member brought to my attention a new Wisconsin state requirement for any business currently conducting business: COVID-19 Exposure Prevention Plan. I researched the plan and found that several other states also require this plan and I encourage you to review your state COVID-19 regulations. Even if this plan is not required it will be helpful when COVID-19 or another pandemic attempts to waylay our society.

[Click here](#) to view/download the [COVID-19 Exposure Prevention, Preparedness, and Response Plan](#).

Please contact me if you would like to discuss this plan or any other DHS, EPA or OSHA issue.

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Traffic Bulletin

Traffic Bulletin

June 2020

LPG Filling and Storage

This month's bulletin is to remind people of the upcoming hot months of summer and the problems of overfilling LPG cylinders. This bulletin 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



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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 LPG filling 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. It is available as a free download. <https://propane.com/resource-catalog/resources/dispensing-propane-safely-training-program-english-version/>

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.



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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 bulletin, please contact:

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Medical, Food/Beverage and Specialty Gases Bulletin

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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.

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Frequently Asked Questions

Q – My label printer made a minor punctuation change on our address for a medical gas label. The label is still compliant, but slightly different from the label that we have submitted to the FDA. Do I need to resubmit the new label to the FDA?

A – No. This is a good question and illustrates the different standards used by the FDA vs your Quality Control Unit.

- For FDA Drug Listing Purposes – This does not represent a substantive label change. Therefore, the submission of the new label is optional.
- For your QCU purposes – This is a different label and would need to be separately approved in your SOPs Master Label. It is likely that you will have your old label and your new label both approved for a while... until the old labels are removed from circulation.

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.

June Medical Gas Roundtable – CGMP – Instrument Qualification and Analytical Method Validation

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On June 26, 2020, we will cover Instrument Qualification and Analytical Method Validation for Medical Gases. We will discuss the qualification of instruments (required by the FDA) and the validation of alternate analytical methods.

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.

Medical, Food/Beverage and Specialty Gases Bulletin

GAWDA Professional Compliance Training – HOLD THE DATES

This year, the Fall Professional Compliance Training will be held onsite AND via Teleconference
October 27 to 29, 2020 - Onsite at Weldcoa in Aurora, IL
November 3 to 5, 2020 – Teleconference hosted by Weldcoa

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>

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