GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

JUNE 2018

ENCLOSED

Safety Topic: **LPG Filling and Storage**

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

Traffic Bulletin: **Medical Certificates, New Important Change**

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. Recent Recent FDA Observations (excerpts from actual FDA inspections at medical gas companies): Calibration
2. FDA Compliance ToDo List; FDA Drug Listing Review
3. Frequently Asked Questions: Q – How often must I send the Servomex to the factory for recalibration?
4. Dates & Topics for Medical & Food Gas Roundtable; CGMP & Specialty Gas Training.
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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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:

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Traffic Bulletin

June 2018

Medical Certificates, New Important Change

MOTOR CARRIERS:

- Motor carriers using interstate CDL/CLP drivers whose driving record currently includes their most recent medical certification status must use the driving record (MVR) as proof of physical qualification and keep that driving record in the driver's qualification file. The MVR must be updated every time the driver's medical certification status changes, i.e., after every new DOT medical exam. This requirement has been in place since January 30, 2012, for any interstate CDL driver whose MVR includes medical certification status.
- If a CDL/CLP driver obtains a new medical certificate then the motor carrier can retain a copy of that certificate for up to 15 days, giving the state time (up to 10 days) to add the new information to the driver's record. By the end of those 15 days, the carrier must have a new MVR showing the updated medical information.
- Motor carriers must verify that their CDL/CLP drivers self-certified under the appropriate operational category for their jobs. For example, a driver who self-certified as an intrastate driver is not authorized to operate in interstate commerce.

Medical examiners and state licensing agencies are required to keep a copy of each driver's medical card for three years. Employers also have to continue maintaining medical cards for any drivers not subject to the rule, including non-CDL drivers.
The requirements only applies to interstate CDL/CLP holders and their motor carrier employers, but states are expected to adopt similar rules for most in-state CDL/CLP drivers.

Changes due in June 2018 (This section has been delayed. I will let you know when they put it into place.)
For interstate CDL and CLP drivers, the steps in recordkeeping will be revised for all driver medical examinations on or after **June 22, 2018**.
The medical examiner is instructed to submit the medical exam results directly to the FMCSA via the National Registry of Certified Medical Examiners web portal by midnight (local time) of the next calendar day after the completed exam. In turn, FMCSA will transmit the results to CDLIS within a day or two of the exams.
As of the result of these new processes for exams performed as of June 22, 2018:

- The CDL and CLP drivers will not be issued a medical examiner's certificate by the examiner. As a result, he/she will no longer have to carry the certificate, even temporarily, since enforcement will have access at roadside.

Traffic Bulletin

- The motor carrier will not use a medical examiner's certificate as temporary proof of the medical certification. The motor carrier must request an MVR within a couple of days of the exam and is not given 15 days as previously allowed since the information should accessible to the state as soon as FMCSA enters it into CDLIS.
- The motor carrier no longer needs to verify the examiner appears on the National Registry of Certified Medical Examiners website since the examiner must be certified in order to submit the results of the exam via the secured web portal. This does not apply to non-CDL drivers.

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin
06/01/2018

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.

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.

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 tom@asteriskllc.com if you need any assistance with this.

Medical, Food/Beverage and Specialty Gases Bulletin

Frequently Asked Questions

Q – How often must I send the Servomex to the factory for recalibration?

A – The Servomex oxygen analyzers are robust instruments. The instrument should be sent for repair when it is no longer stable or will not calibrate. The annual maintenance frequency mentioned in the operating manual is generally not needed to maintain the instrument's reliability.

Servomex prepared a letter to explain the position. Contact jodie@asteriskllc.com if you would like a copy of this explanatory letter.

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 29, 2018, 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.

Medical, Food/Beverage and Specialty Gases Bulletin

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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