

SAFETY & TECHNOLOGY ORGANIZER

OCTOBER 2018

ENCLOSED

Safety Topic: Carbon Monoxide

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

Traffic Bulletin: Annual Driver Review 391.25

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Medical, Food/Beverage and Specialty Gases Bulletin

- 1. Recent FDA Observations: Equipment Cleaning and Maintenance**
- 2. FAQ's: What do I need to do in order to be a "Qualified Facility" under the Food Safety Modernization Act?**
- 3. SEMINARS: GAWDA Professional Compliance Seminar (10/16/18): DOT Audit Survival, FDA PCQI & Drug CGMP Training. October Medical Gas Roundtable (10/26/2018) – High Pressure Prefill Inspection and Filling High Pressure Cylinders WEBINARS: Specialty Gas Operations - High Pressure Prefill Inspection and Filling High Pressure Cylinders. Food Gas Roundtable – Part 117 Subpart D & E - Modified Requirements and Qualified Facility Exemption**
- 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 _____

Carbon Monoxide

I have a few safety topics that warrant repeating on an annual basis. One is the proper filling and storage of LPG products and another is carbon monoxide asphyxiation. With the heating season coming upon us, now is the time to remind people about carbon monoxide.

Do you know the leading cause of poisoning in the America? It is odorless. It is colorless. It is tasteless. It is deadly. It is carbon monoxide. Mild poisoning can cause such symptoms as nausea, dizziness or headaches while severe poisoning can result in brain or heart damage or even death.

Carbon monoxide (CO) is a gas produced during the incomplete combustion of carbon containing substances (paper, wood, and petroleum products). Forklifts powered by gasoline, natural gas, or propane may emit dangerous levels of CO. Because CO has no warning properties, employees can be exposed to high levels without realizing that there is a problem. This also applies to other gasoline, natural gas, or propane fueled vehicles, power tools, or other equipment used indoors, such as floor buffers, pressure washers, ice cleaners used to resurface ice rinks, or unvented space heaters.

The most effective way to keep CO concentrations below the 35 parts per million of air (ppm) eight-hour time-weighted average permissible and the ceiling of 200 ppm (as measured over a 15 minute period) (individual State regulations may be more stringent) is to utilize one or more of the following controls:

Suggestions for Employers:

- Where possible, substitute equipment that doesn't produce CO or Nitrogen Oxides (NOx) (e.g. electric forklifts).
- Ensure proper maintenance of forklifts to reduce emissions.
- Maintain appliances and equipment in good order, adjusting flames, burners and drafts to reduce the formation of carbon monoxide.
- Do not allow forklifts to idle while waiting to resume operations.
- Ensure proper ventilation of work areas. This is especially a potential problem during periods of cold weather when shop and warehouse doors and windows are shut tight and ventilation is restricted.
- Use CO sensors or alarms; conduct periodic sampling of the work area for CO and NOx.
- Provide training to employees on the symptoms, sources, and prevention of CO and NOx poisoning.



Suggestions for Workers:

- Report to your employer any condition which might make carbon monoxide form or accumulate.
- Be alert to ventilation problems, especially in enclosed areas where gases of burning fuels may be released.
- Report complaints early. Don't overexert yourself if you suspect carbon monoxide poisoning. Physical activity increases the body's need for oxygen and thus increases the danger of poisoning.
- If you get sick, don't forget to tell your doctor about the possibility of exposure to carbon monoxide.
- Think carefully about your smoking habits. Tobacco, when burned, releases carbon monoxide which reduces the oxygen-carrying ability of the blood, even before any industrial exposure is added.

Two more areas to consider for fuel burning forklifts are:

1. Catalytic Converter

Recent technology has produced the catalytic converter. Once installed on the exhaust system of a fork lift, the converter works by chemically changing the carbon monoxide to relatively harmless carbon dioxide. This device is particularly valuable in situations where large numbers of fork lifts are operated in a limited space, or they can't be removed from service frequently. Catalytic converters can reduce carbon monoxide levels dramatically. Be aware that catalytic converters are not inexpensive, and the catalyst must be replaced periodically to maintain its effectiveness. Also, to work properly, they require high exhaust gas temperatures, so they are not as effective when engines are run cold or for brief periods of time.

2. Carbon Monoxide Controller

This computer operated device detects the level of carbon monoxide in the exhaust pipe and automatically causes the proper air to fuel ration adjustments to be made in the engine. This device not only reduces carbon monoxide emissions, but has the added benefit of better fuel economy.

These control measures should also keep NO_x exposures below the permissible exposure limit. It is important to recognize that although adjustment of carburetor balance on fueled engines can reduce CO emissions to safe levels, over-adjustment can actually increase NO_x emissions to hazardous levels. It is very important to establish and maintain correct carburetor balance of fueled equipment used indoors.

What about the home?

The Consumer Product Safety Commission (CPSC) recommends installing at least one carbon monoxide detector per household, near the sleeping area. I highly recommend the **Nighthawk** CO Detector which is available almost everywhere. If you have any type of propane or natural gas burning equipment in your home, or a fire place, please consider the purchase of a CO detector. It is a gift of life that you would be giving your family. Don't forget relatives or friends. Many of them may not have heard about CO detectors and how effective they are at saving lives.



In the workplace:

Remember, any fuel burning apparatus will emit carbon monoxide. People think about forklifts and vehicles but tend to forget about the heating system or the hot water heater. I know of many instances where we have installed the Nighthawk CO Detector and found a cracked heat exchanger in a heater or a plugged vent pipe or chimney.

If you suspect carbon monoxide, get out of the area and into the open fresh air. Remove anyone overcome by the gas immediately and give the person artificial respiration. Call for a doctor and continue the artificial respiration until the doctor arrives or the person recovers. Prompt action can make the difference between life and death.

Feel free to contact me if you have any questions.

Michael Dodd

GAWDA DOT, Security, OSHA, and EPA Consultant
MLD Safety Associates, LLC
P.O. Box 93
Poplar Bluff, MO 63902
(573) 718-2887
Email: MLDSafety@hotmail.com



Traffic Bulletin

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October 2018

Annual Driver Review 391.25

At least every 12 months, the motor carrier must review the driving record of each driver, including compliance with the Federal Motor Carrier Safety Regulations and the Hazardous Materials Regulations. **This means doing the review on or before the same date next year.** If you go past the date, then DOT during their audit will try to find if you used the driver during the lapse. If they find this, then you will receive a penalty for “allowing and permitting an unqualified driver” to operate a commercial motor vehicle.

This review is a 3-part process. First, you should have the driver certify the previous 12 months of driving violations. Then you would check their records for any violations, one of which should be the appropriate state motor vehicle record (MVR). Finally, you then certify as the carrier whether the driver is qualified or not to continue driving.

You can use third-party companies to do the MVR checks. You can pull the MVR yourself or you can have the driver obtain their own MVR, which is the easiest way many times.

In reviewing each driver's record for the preceding year, attention should be given to any accidents and indications of violations of motor vehicle laws and regulations. Of particular importance are violations indicating a disregard for the safety of the public, such as speeding or operating a vehicle while under the influence of alcohol or drugs.

The reviewer's evaluation of the record should determine whether the driver remains qualified or is disqualified to drive a motor vehicle under the provisions of §391.15 for such infractions as operating a vehicle while under the influence of alcohol or drugs, leaving the scene of an accident involving personal injury or death, etc.

A written record, including the date and the name of the person who reviewed the driving record, must be placed in the driver's qualification file. **This review must be maintained in the driver qualification file for three years after the carrier certification date.** If you need a form to do this documentation, just send me an email and I'll be glad to send you one.

I recommend stapling any paperwork such as the state motor vehicle record and any other reviews that you may have done to the back of the certification form for ease of recordkeeping.



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DOT Interpretations:

Question 1: To what extent must a motor carrier review a driver's overall driving record to comply with the requirements of §391.25?

Guidance: The motor carrier must consider as much information about the driver's experience as is reasonably available. This would include all known violations, whether or not they are part of an official record maintained by a State, as well as any other information that would indicate the driver has shown a lack of due regard for the safety of the public. Violations of traffic and criminal laws, as well as the driver's involvement in motor vehicle accidents, are such indications and must be considered. A violation of size and weight laws should also be considered.

Question 2: Is a driver service or leasing company that is not a motor carrier permitted to perform annual reviews of driving records (§391.25) on the drivers it furnishes to motor carriers?

Guidance: The driver service or leasing company may perform annual reviews if designated by a motor carrier to do so.

Question 3: May motor carriers use third parties to ask State agencies for copies of driving records to be examined during the carrier's annual review of each driver's record?

Guidance: Yes. Although an examination of the official driving record maintained by the State is not required during the annual review, motor carriers that choose to do so may use third-party agents, such as driver information services or companies, to obtain the information. However, the motor carrier is responsible for ensuring the information is accurate.

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



Medical, Food/Beverage and Specialty Gases Bulletin

10/01/2018

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.

Equipment Cleaning and Maintenance

Form 483 Observation-03-05 - Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance. Specifically, written procedures for cleaning are deficient because they do not describe the methods, materials or tools needed for cleaning equipment such as; manifold, leads (pigtailes), or manifold valve assemblies. Written procedures are lacking describing the maintenance of equipment such as the leads (pigtailes) replacement, frequency or manifold valve assembly O-ring inspections.

How to prevent this from showing up in your inspection?

Assure your equipment is clean. However, we have a basic disagreement with the agency about what is appropriate for medical gases. A designated medical gas firm has fundamentally different processes and procedures when compared to a traditional pharmaceutical firm. For example, our products are not reacted or “manufactured” in the traditional sense. We are closer to “repackers”, in that the raw material is actually the same as the finished medical gas in terms of composition, purity, etc. We pump the product out of a closed, pressurized large tank through dedicated high-pressure, closed piping and into closed, high-pressure or cryogenic containers. Indeed, Congress and the FDA recognizes the fundamental differences between traditional pharma and medical gas firms and is in the process of considering revisions or replacements to the regulations as it applies to medical gases.

Equipment cleaning and maintenance is a key area of difference between traditional pharma and medical gases. Specifically, we conduct a 100% prefill inspection on the equipment, containers, raw material and finished product. The manifold and pigtailes are inspected during each use. Pigtailes and o-rings are replaced when they are visibly damaged, or a leak develops. The maintenance is not according to a preset schedule. This practice has been confirmed with the pigtail manufacturers.

Medical gases are manufactured and filled utilizing pressurized closed systems and equipment that should not be cleaned between batches and lots. Significant cleaning is performed when initially assembled and prior to commissioning. Unnecessary cleaning introduces contaminants (the cleaning solution) which must be completely removed prior to using the system.... Adding additional unnecessary hazards.

Medical, Food/Beverage and Specialty Gases Bulletin

Frequently Asked Question

Q – What do I need to do in order to be a “Qualified Facility” under the Food Safety Modernization Act?

A – If your annual sales are below a threshold, you can claim “Qualified Facility” status. This exempts you from the more burdensome requirements of the regulations (HARPC and Supply-chain Program). You may find it easier to actually do the HARPC and Supply-chain program using the sample SOPs we provide. But, if you decide to claim Qualified facility status, there are certain steps you must take (attestation, less formal risk analysis, etc.). Join us at the Food Safety Roundtable on 10/26/18 for more details, forms, guidance, etc.

GAWDA Professional Compliance Seminar – Audit Survival



Hold The Date (October 16-18, 2018)... GAWDA Professional Compliance Seminar at Weldcoa, Aurora, IL. [Click here for more information.](#)

This seminar focuses on:

- DOT Audit Survival
- FDA PCQI and Drug CGMP Training

October Medical Gas Roundtable (10/26/2018) – CGMP - High Pressure Prefill Inspection and Filling High Pressure Cylinders

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In October we will be discussing basic procedures to conduct a prefill inspection and how to fill medical high-pressure cylinders.

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

- **Specialty Gas Operations** - High Pressure Prefill Inspection and Filling High Pressure Cylinders.
- **Food Gas Roundtable** – Part 117 Subpart D & E - Modified Requirements and Qualified Facility Exemption

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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. **Filling Procedures** – Copy the fill procedure from the SOPs and watch a cylinder filling operator actually perform the procedure. This is the same technique the FDA uses to see if we are following our fill procedures.
2. **Documented Training** – Complete a training record for the cylinder filling operator that was observed. Attach a copy of the completed SOP to the training record.

Tom Badstubner
GAWDA Medical Gas Consultant
Telephone: 508-883-0927
Fax: 508-883-3558
Email: tom@asteriskllc.com