GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

OCTOBER 2015

ENCLOSED

Safety Topic: Carbon Monoxide

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

Traffic Bulletin: Special Permits

Please contact Mike Dodd for more information.

Medical Gas Bulletin:

1. **Food Safety Modernization Act - Final Rule**
2. **GAWDA Professional Compliance Seminar: DOT & FDA certified training**
3. **Medical Gas Roundtable – CGMP - High Pressure Prefill Inspection and Filling High Pressure Cylinders**
4. **Webinars: Complaints, Non-conformances, corrective & preventative action; Specialty Gas: Measuring & controlling analytical uncertainty; Food Gas Roundtable: free resources, procedures & training for your food gas compliance.**
5. **Micro Audit Suggestions**

Please contact GAWDA Medical Gas Consultant, Tom Badstubner 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 _____

October 2015 Safety Topic

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 NOx 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 NOx 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

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Traffic Bulletin

October 2015 **Special Permits**

There are basically two kinds of DOT special permits (SP). There are permits for manufacturing packages that are different from approved specifications. There are also permits that let you do things differently than what is found in the published regulations.

On file at each location

If you have a package that has a SP on it, you must have a current copy of the permit on file at the location that ships or requalifies the package. You must follow the requirements outlined in the SP. Some SPs require a copy to be kept on the motor vehicle and if it does this will stated in the SP.

Transporting a Special Permit package

It is possible that if you receive a cylinder that is being operated under a special permit that you can reoffer it for transportation without a grantee letter in your company's name. Example – if Honeywell fills a cylinder under a special permit and you order it from Honeywell you can then take it to your customer by using the Honeywell grantee letter and special permit. The key is that you did not fill the cylinder or modify the package when you shipped or transported it.

If you have to offer a special permit container to a common or contract carrier then you must provide them with a current copy of the special permit at or before the time of shipment. There are a few exceptions to this requirement but almost all of the time this requirement will apply.

You must enter the special permit number onto the hazardous material shipping paper in association with the proper shipping name. There are a very few exceptions to this rule but 99% or more of the special permits require this.

Training

All employees that handle the SP package must be trained on the requirements of the SP and the training is required every 3 years. You will need to document this training per 172.704 (d) and here is a brief summary of what you need to document:

(d)(1) The hazmat employee's name;

(d)(2) the most recent training completion date of the hazmat employee's training;
(d)(3) a description, copy, or the location of the training materials used to meet the requirements;
(d)(4) the name and address of the person providing the training; and
(d)(5) certification that the hazmat employee has been trained and tested.

Do I need to be a "party to" the Special Permit?

If you read item 1. Grantee on the SP and see the words "See individual authorization letter", then you need to have your company authorized by DOT to be a party to the SP in order to fill or use the SP.

How do I become a "party to" a Special Permit?

There is a PHMSA website with an online procedure but unfortunately it is very difficult to use and most times doesn't work properly. What has worked very well is to use the templates provided on the website and make your own Word document application, then to email it as an attachment to specialpermits@dot.gov , and they will email you back your approval letter. Here is the link to the new party to application: http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_A191D2DF3F3735BD287B45553A6D9AB0F45C0000/filename/pt_app.pdf

Your SP is the authorization letter stapled to the top of the SP that you will print off. You keep the two items together as your permit.

Please note that just because you apply doesn't mean that you are automatically granted. Your current DOT safety score and performance can keep you from getting party to special permits.

Special Permit Renewals

When it comes time to renew your SP, you use the template that PHMSA has provided and do the same email process as above. Here is the template: http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_DEAD8B1FF0F5570C72D1DD8D8799386748640000/filename/renewal_app.pdf

It is extremely important that the renewal takes place at least 60 days or more before the SP expires. If you renew more than 60 days before expiration and DOT drags their feet, then you get to keep using the SP. If you renew less than 60 days before the

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expiration date, and they drag their feet and the SP expires, then you must cease using the SP until they send you approval letter. The first permit is issued for 2 years and the renewals are issued for 4 years after that.

If there are any questions regarding this Bulletin please contact:

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Medical Gas Bulletin

Medical Gas Bulletin
10/01/2015

Food Safety Modernization Act - Final Rule

On Thursday, 9/17/2015, the FDA published in the Federal Register the “Final Rule” to the Food Safety Modernization Act: "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food”. The new rules are fairly detailed, however, most GAWDA members will not find them to be demanding. And…. we have plenty of time to comply. We are developing templates for the FSMA provisions.

(Download the entire 262 pages by clicking: http://federalregister.gov/a/2015-21920)

This new rule amends the regulations for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food by modernizing requirements, adding requirements including registration, and clarifying the scope for exemptions to registration requirements.

- Some of the previously nonbinding provisions, such as education and training, are now binding.
    - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
    - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.
    - Note that there are similar requirements related to preventive controls.
    - We conduct free CGMP training for GAWDA members as a part of the monthly Food Gas Roundtable.

- The FDA’s longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text. This is not a difficult provision for most GAWDA members and we have the template you can use to provide the allergen training.

One of the new requirements applicable to those establishments that must register as a “food facility” is to implement:

- A written Food Safety Plan;
- Hazard Analysis and Risk-Based Preventive Controls (HARPC), the new Part 117. This would replace the use of Hazard Analysis and Critical Control Points (HAACP) which was developed by the agency to address issues related to seafood, juice and certain other targeted food industries. HARPC is a risk-based evaluation of our operations to prevent food-borne illnesses which would have the establishment institute preventive controls for the mitigation of those identified (*or reasonably foreseeable*) hazards, unless an exemption applies. As a result of the hazard analysis, certain elements will be established:
    - Preventive controls;
    - Monitoring;
    - Corrective actions and corrections;
    - Verification;
    - Recall plan; and
    - Associated records.
    - A newly established 21 CFR 110 Subpart G Supply-Chain Program requires a supplier verification (approval) program.

The final rule also establishes a preventative controls "Qualified Individual" who develops and applies on behalf of the owner, operator, or agent in charge, the Food Safety Plan and oversees the HARPC process. Qualification is established by successfully completing certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system. GAWDA training programs for the qualified individuals are in the works. A qualified individual may be, but is not required to be, an employee of the establishment.

Who or what is exempt from the requirements for hazard analysis and risk-based preventive controls?

The following ''Qualified Facilities'' as defined by FSMA can be exempt from HARPC requirements:

- Business with average annual sales of <$500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or
- Very small business, which the rule defines as a business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

We expect that many GAWDA members could be considered a Qualified Facility.

Note as a "Qualified Facility", modified requirements apply—i.e., a qualified facility is required to:

- Notify FDA about its status; and
- Either:
    - Notify FDA that it is addressing hazards through preventive controls and monitoring; or
    - Notify FDA that it complies with applicable non-Federal food safety regulations, and notify consumers of the name and complete business address of the facility where the food was manufactured or processed.
- The notification is in the form of an attestation, and must be submitted every two years, during the same timeframe as the facility is required to update its facility registration.

A facility solely engaged in the storage of packaged food that is not exposed to the environment (i.e. a Distributor that does not otherwise fill food gases), can also be exempt from HARPC.

Keep in mind that your customer, especially major beverage companies or restaurant chains may still require a HARPC in order to be qualified as an approved supplier.

Templates are being developed for these HARPC's in the CGA Food Gas Committee. The ASU template is nearly complete and then the cylinder filling template will be developed. When completed, these templates will make compliance with HARPC a LOT easier and more consistent. Even if not required, it can be considered a best practice.

Implementation Schedule… this is the good news… we have plenty of time to implement the HARPC and related provisions.

See: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery#Compliance_Dates

For non-HARPC FSMA provisions:

- "Very small businesses" - If your sales of food gases are under a million dollars per year (likely most GAWDA members), you will have three years to be in compliance.
- “Small businesses" - If you have fewer than 500 employees, you will have two years to be in compliance.
- “Large businesses" - You will have one year to be in compliance.

For the new Supply Chain Program (AKA supplier qualification):

- Depending on the size of your food business, you will have six to 24 months to develop your Supply Chain Program
- We are developing standard industry supplier qualification procedures that will make this rule simple to accomplish.

We cover the compliance details and new interpretations of these rules in the free GAWDA Monthly Food Gas Roundtables. The next teleconference will be 2 PM ET on 10/29/2015. We also discuss practical compliance with the regulations in the GAWDA Professional Compliance Seminar, see below.

In the meantime, let Tom Badstubner know if you have any questions (tom@asteriskllc.com).

GAWDA Professional Compliance Seminar

Hold The Date (October 20 to 22, 2015)… GAWDA Professional Compliance Seminar at Weldcoa, Aurora, IL. This seminar focuses on certified DOT and FDA certified training. In addition, we will review the latest FDA enforcement trends. See this link for more details: Click here for registration form and more information

October Medical Gas Roundtable (10/29/2015) – 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 webinars in October:

- ***QSR/ISO 17025*** **-** Complaints, Non-Conformances, Corrective Action/Preventive Action (CAPA)
- ***Specialty Gas*** - Measuring and Controlling Analytical Uncertainty (ISO 6143)
- ***Food Gas Roundtable*** – Free resources, procedures and training for your food gas compliance.

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 amy@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.

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