

SAFETY & TECHNOLOGY ORGANIZER

NOVEMBER 2016

ENCLOSED

Safety Topic: Carbon Monoxide Please contact Mike Dodd, GAWDA DOT, Security, OSHA & EPA Consultant for more information.

Traffic Bulletin: Railroad Crossings Please contact Mike Dodd for more information.

Medical Gas Bulletin:

- **1. Medical Gas Expiration Dates**
- 2. Medical Gas Roundtable (11/18/2016) Subparts H & I Holding and Distribution, Laboratory Controls
- 3. Webinars: QSR/ISO 17025 Internal Audits and Management Reviews; Specialty Gas -
- Measuring and Controlling Uncertainty in Gas Chromatographs (ISO 6143)
- 4. Food Gas Roundtable Part 117 Subpart F Records Policy
- 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.

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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Railroad Crossings

392.10 Railroad grade crossings; stopping required.

Except as provided below, the driver of a commercial motor vehicle that is placarded shall not cross a railroad track or tracks at grade unless he/she first:

- Stops the commercial motor vehicle within 50 feet of, and not closer than 15 feet to, the tracks;
- thereafter listens and looks in each direction along the tracks for an approaching train; and ascertains that no train is approaching.
- When it is safe to do so, the driver may drive the commercial motor vehicle across the tracks in a gear that permits the commercial motor vehicle to complete the crossing without a change of gears.
- The driver must not shift gears while crossing the tracks.

A stop need not be made at:

- A streetcar crossing, or railroad tracks used exclusively for industrial switching purposes, within a business district, as defined in §390.5,
- A railroad grade crossing when a police officer or crossing flagman directs traffic to proceed,
- A railroad grade crossing controlled by a functioning highway traffic signal transmitting a green indication which, under local law, permits the commercial motor vehicle to proceed across the railroad tracks without slowing or stopping.
- An abandoned railroad grade crossing which is marked with a sign indicating that the rail line is abandoned,
- An industrial or spur line railroad grade crossing marked with a sign reading "Exempt." Such "Exempt" signs shall be erected only by or with the consent of the appropriate State or local authority.

Traffic Bulletin

Law enforcement officials deal very harshly with any infractions dealing with railroad crossings. Here is a table listing the penalties for each infraction.

383.51 (d) Disqualification for railroad-highway grade crossing offenses. Table 3 to §383.51 contains a list of the offenses and the periods for which a driver must be disqualified, when the driver is operating a CMV at the time of the violation, as follows:

If a driver is convicted of operating a CMV in violation of a Federal, State or local law because	For a first conviction a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a second conviction of any combination of offenses in this Table in a separate incident within a 3-year period a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a third or subsequent conviction of any combination of offenses in this Table in a separate incident within a 3-year period a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for
 The driver is not required to always stop, but fails to slow down and check that tracks are clear of an approaching train. 	No less than 60 days	No less than 120 days	No less than 1 year.
(2) The driver is not required to always stop, but fails to stop before reaching the crossing, if the tracks are not clear.	No less than 60 days	No less than 120 days	No less than 1 year.
(3) The driver is always required to stop, but fails to stop before driving onto the crossing.	No less than 60 days	No less than 120 days	No less than 1 year.
(4) The driver fails to have sufficient space to drive completely through the crossing without stopping.	No less than 60 days	No less than 120 days	No less than 1 year.
(5) The driver fails to obey a traffic control device or the directions of an enforcement official at the crossing.	No less than 60 days	No less than 120 days	No less than 1 year.
(6) The driver fails to negotiate a crossing because of insufficient undercarriage clearance.	No less than 60 days	No less than 120 days	No less than 1 year.

Traffic Bulletin

Feel free to contact me on any of these items if you have questions.

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Medical Gas Bulletin 11/01/2016

Frequently Asked Questions – Expiration Dates

Q - What is the latest FDA thinking on medical gas expiration dates?

A – The FDA has formally acknowledged their policy on expiration dates for medical gases in guidance to its inspectors: <u>Click here.</u>

See PART V - REGULATORY/ADMINISTRATIVE STRATEGY, C(2) page 26:

If a firm chooses not to include expiration dating (21 CFR Part 211.137) on the label, no action will be taken. If a firm labels a gas with an expiration date it must be supported by data (stability studies), which is subject to review during a site inspection. Lack of an expiration date should not be included on a Form FDA 483 unless prior concurrence has been given by CDER.

Stability studies (21 CFR Part 211.166) are not required unless a firm labels a gas with an expiration date.

In other words... don't use an expiration date on medical gases.

November Medical Gas Roundtable (11/18/2016) – Subparts H & I – Holding and Distribution, Laboratory Controls

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In November we will be discussing warehousing and laboratory operations.

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

- QSR/ISO 17025 Internal Audits and Management Reviews
- Specialty Gas Measuring and Controlling Uncertainty in Gas Chromatographs (ISO 6143)
- Food Gas Roundtable Part 117 Subpart F Records Policy

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. **Servomex Filter -** Verify that you have records that the filter on the Servomex has been inspected according to the frequency in your instrument manual.
- 2. **Segregation** Be sure your full medical gas cylinders are segregated from your industrial gas cylinders.

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