



NOVEMBER 2019

ENCLOSED

Safety Topic: Carbon Monoxide

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

Traffic Bulletin: Shipping Papers, Part II

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Medical, Food/Beverage and Specialty Gases Bulletin

1. Recent FDA Observations: Annual Record Review
2. FAQ's: FDA Drug Listings
3. *November Medical Gas Roundtable (11/22/2019) – Subparts H & I – Holding and Distribution, Laboratory Controls; Specialty Gas - Measuring and Controlling Uncertainty in Gas Chromatographs (ISO 6143); Food Gas Roundtable – Part 117 Subpart F – Records Policy*
4. Micro-Audit Suggestions

Please contact Tom Badstubner, GAWDA FDA Food, Medical & 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 forklift, 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 forklifts 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.

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Shipping Papers, Part II

Last month, I talked about some changes and some typical mistakes found on shipping papers. This month I will talk about some additional items on shipping papers.

Basic Description

As discussed last month, the basic description consists of the identification number, full proper shipping name, hazard class number (and subsidiary hazard class numbers as applicable), and the packing group, if assigned. There can be no distributor information, such as codes, stock numbers, etc., inserted in the above order. You may place any other descriptive information after the basic description. I find product descriptions being abbreviated such as CO₂ or C-25. No abbreviations are allowed in the proper shipping name unless specified in the Hazardous Materials Table (e.g., "n.o.s.").

The quantity of the hazardous materials may be listed by the number of cylinders (hazard class 2 only), the volume in cubic feet, or the weight in pounds. The metric system is an option. A common mistake is to show cubic feet or pounds next to liquid product descriptions and then show only the number of containers shipped. If you use cubic feet or pounds, then you have to show the actual cubic feet or the total pounds of the package and product shipped. The easiest quantity description would have been cylinders. Abbreviations may be used to express units of measurement and types of packages.

RQ

Sometimes I find the letters "RQ" preprinted on the shipping paper with a particular product. This is all right to do provided at least one of the packages contains the reportable quantity or more. If the package being shipped doesn't contain the reportable quantity of the product and your shipping paper shows "RQ", then you would be in violation.

DOT Special Permits

Each shipping paper issued in connection with a shipment made under a special permit must bear the notation "DOT-SP" followed by the special permit number assigned and located so that the notation is clearly associated with the description to which the special permit applies.



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Shipper's Certification

I find wrong or misspelled words in the shipper's certification. The words must be exactly as shown in the regulations. For highway transportation this statement must be:

"This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation." (The words "herein-named" may be substituted for the words "above-named".)

There are several exceptions and there are alternate certifications to use depending on the mode of transportation. Please read 172.204 for all the details. Remember, distributors do not have to certify shipments on their own vehicles. Many distributors do certify their own vehicles to avoid conflicts with roadside inspectors that are unaware of this exception.

Shipping Names

Nitrous oxide no longer has the word "compressed" in the shipping name.

Do you still show rare gas descriptions on your shipping paper? These descriptions have been gone for many years. All the rare gas descriptions reverted back to the compressed gas, n.o.s. descriptions.

Do you ship any mixtures with oxygen greater than 23.5%? Remember to use the description "UN 3156, Compressed Gas, oxidizing, n.o.s., (oxygen, *the other gas*), 2.2 (5.1)" that describes the hazardous properties of the mixture more accurately.

If you ship LPGs, be sure your shipping paper description matches the description on the cylinder decal. There are several correct descriptions so long as they both match.

Are your shipping papers readable? I find some pretty poor copies being run off of copying machines.

Engine Drive Welders

A common question is, "How do I properly describe our engine drive welders on our shipping papers?"

The quick answer is you don't put it on your shipping paper because you are not required to so long as you have the battery securely installed and in an upright position. A fuel tank containing a flammable liquid fuel must be drained and securely closed, except that up to 500 ml (17 ounces) of residual fuel may remain in the tank, engine components, or fuel lines provided they are securely closed to prevent leakage of fuel during transportation. If you have a welder where the battery is not properly secured or you have left too much fuel in the tank, then the regulations are not being followed and you would be open for citations.



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The long answer is that the best shipping name description in the hazardous materials table is “Battery, wet, filled with acid or alkali with vehicle or mechanical equipment containing an internal combustion engine, see **Vehicle**, etc. or **Engines, Internal combustion**, etc.” When you go to the “UN3166, Engines, internal combustion, flammable liquid powered, 9” you will see an exception listed as 173.220, which is, (c) *Wet battery powered or installed*. Wet batteries must be securely installed and fastened in an upright position. Batteries must be protected against short circuits and leakage or removed and packaged separately under 173.159. Battery powered vehicles, machinery or equipment including battery powered wheelchairs and mobility aids are excepted from the requirements of this subchapter when transported by rail, highway or vessel. (This means the hazardous materials regulations do not apply to our welders as long as batteries are securely fastened upright, the fuel is less than 17 ounces in the closed tank, and you don’t ship them by air.)

I have an example of a good shipping paper. If you need one, just ask.

If there are any questions or concerns with your shipping paper and you would like to have me review it, then send me a copy and I will be happy to look it over for you.

Feel free to contact me if you have questions.

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Medical, Food/Beverage and Specialty Gases Bulletin

11/01/2019

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.

Annual Record Review

Form 483 Observation-03-02 - Written procedures are not followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected. Specifically, your firm does not perform an annual product review of each medical gas by reviewing the batch records, complaints, returned products, investigations and or recalls to determine the need for changes in the process or control procedures for the following medical gases: _____

How to prevent this from showing up in your inspection?

Document your Annual Records Review. Contact tom@asteriskllc.com for a sample SOP and Annual Records Review form.

Frequently Asked Questions – FDA Drug Listings

Q – Must I register my facility if I am only warehousing product and not filling the cylinders at this location?

A – This answer depends on whether the cylinders are drugs or food/beverage gases.

- **Food/Beverage Gases** – Warehousing and production locations must both be registered with the FDA if they handle food/beverage gases. The registration process is exactly the same, except that the facility type is marked as a warehouse or a manufacturing location. Keep in mind that many states also require licenses/permits to produce or distribute food gases.
- **Drug gases** – Only **production** locations need to be registered with the FDA. If you are simply warehousing drug gas cylinders at a location, you may need to license with your state board of pharmacy even though you are not required to be registered with the federal FDA.



Medical, Food/Beverage and Specialty Gases Bulletin

November Medical Gas Roundtable (11/22/2019) – 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:

- **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. Keep in mind that Servomex allows a longer inspection period for analyzing clean, dry gases (medical gases). Read the manual or your SOP carefully.
2. **Segregation** – Be sure your full medical gas cylinders are segregated from your industrial gas cylinders.

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