



OCTOBER 2020

ENCLOSED

Safety Topic

Carbon Monoxide

Please contact Marilyn Dempsey, GAWDA DHS, EPA, & OSHA Consultant for more information.

Traffic Bulletin

Drug and Alcohol Clearinghouse

Please contact Mike Dodd, GAWDA DOT Consultant for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQs
2. GAWDA Professional Compliance Webinar: Fall -- October 27th-29th Webinar;
October Medical Gas Roundtable (10/30/2020): Subpart G – High Pressure Prefill
Inspection and Filling High Pressure Cylinders
3. Micro-Audit Suggestions

Please contact Tom Badstubner, GAWDA FDA Food, Medical & Specialty Gases Consultant for more information.

**** Visit GAWDA's COVID-19 Resource Center at www.gawda.org/covid-19/ ****

Here you will find information on Live GAWDA Consultant Covid -19 Roundtables, Safety Alerts, and Members-Only links.

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

Cold weather will soon be upon us and we need to remember to take necessary precautions to protect our employees from the serious effects of Carbon Monoxide. Carbon monoxide is a colorless, odorless, and tasteless flammable gas that is slightly less dense than air. It is toxic to animals that use hemoglobin as an oxygen carrier when encountered in concentrations above about 35 ppm.

Every year, workers die from carbon monoxide poisoning, usually while using fuel-burning equipment, like forklifts. However small gasoline-powered engines and tools also present a serious health hazard. They produce high concentrations of carbon monoxide (CO) which is a poisonous gas that can cause illness, permanent neurological damage, and death. Because it is colorless, odorless, and non irritating, CO can overcome exposed persons without warning.

This can be especially true during the winter months when employees use equipment in indoor spaces that have been sealed to block out cold temperatures and wind. Symptoms of carbon monoxide exposure can include everything from headaches, dizziness and drowsiness to nausea, vomiting or tightness across the chest. Severe carbon monoxide poisoning can cause neurological damage, coma and death.

Employers can reduce the chances of CO poisoning in the workplace by doing the following:

- Install an effective ventilation system that will remove CO from work areas.
- Maintain equipment and appliances, such as water heaters, space heaters, and cooking ranges that can produce CO in good working order to reduce CO formation.
- Consider switching from gasoline-powered equipment to equipment powered by electricity, batteries, or compressed air if it can be done safely.
- Prohibit the use of gasoline-powered engines or tools in poorly ventilated areas.
- Provide personal CO monitors with audible alarms if potential exposure to CO exists.
- Test air regularly in areas where CO may be present, including confined spaces.
- Install CO monitors with audible alarms.
- Educate workers about the sources and conditions that may result in CO poisoning as well as the symptoms and control of CO exposure.



In addition, if your employees are working in confined spaces where the presence of CO is suspected, you must ensure that workers test for oxygen sufficiency before entering.

Here are some guidelines you can train your workers to use to prevent CO poisoning:

- As a rule, gasoline-powered engines or tools should not be used inside buildings or in partially closed areas unless gasoline engines can be located outside and away from air intakes.
- Report any situations that might cause CO to accumulate.
- Be alert to ventilation problems-especially in enclosed areas where gases of burning fuels may be released.
- Always substitute less hazardous equipment if possible.
- Use equipment that allows for the placement of gasoline-powered engines outdoors at a safe distance from air entering the building.
- Avoid overexertion if you suspect CO poisoning and leave the contaminated area.
- Report any complaints of dizziness, drowsiness, or nausea promptly.
- Tell your doctor that you may have been exposed to CO if you get sick.

For more information, see OSHA Fact Sheet [Carbon Monoxide Poisoning](#).

Please contact me if you would like to discuss the hazards of Carbon Monoxide or any other DHS, EPA or OSHA issue.

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Traffic Bulletin

Traffic Bulletin

October 2020

Drug and Alcohol Clearinghouse

This Bulletin is a repeat from December 2019. **Please remember that you must run at least an unlimited query on all your CDL drivers by 1-6-2021.** You must do an unlimited query on all CDL drivers at least annually. Also, remember that you must do a full query on any new hires when doing the hiring process as of 1-1-2020.

CDL Drug and Alcohol Clearinghouse final rule became mandatory on January 6, 2020. FMCSA has placed new compliance resources on its website, www.clearinghouse.fmcsa.dot.gov, It is suggested that while visiting the website that you sign up for updates. Also highly suggested is to read all the FAQs. DOT has done a great job with the questions and answers found in those FAQs. Motor carriers looking to hire driver applicants must query the online database for past three years of drug and alcohol test results; current employers must upload any positive tests or refusals to test, or other D&A testing violations, into the online database

What to do to comply

- Register with Clearinghouse FMCSA web portal
- Beginning January 6, 2020, run full query on all CDL drivers pre-employment
- Beginning January 6, 2020, run full or limited query on all current CDL drivers once a year (and full query if data is available)
- Upload info to database on any positive tests or refusals to take drug or alcohol tests (or other D&A testing violations) on or after January 6, 2020
- Upload info on completion of return to duty requirements for drivers who were referred to Substance Abuse Professionals

Registration

- All motor carriers must register through FMCSA portal (www.fmcsa.dot.gov) to participate in Clearinghouse
- Register by company name and USDOT number
- Company registration is effective for 5 years
- CDL drivers must register with Clearinghouse as well to provide consent for carrier database queries and to review their own records

Registration of others

- Carriers must register one company representative to be the main contact to the database; may register additional company personnel to have access to database info ("Clearinghouse Assistants")
- Substance Abuse Professionals, Medical Review Officers (MRO), and Service Agents (Testing Consortia or Third-Party Administrators (C/TPA)) must also register with the Clearinghouse to participate



Traffic Bulletin

Consent for Queries

- Drivers must give written or electronic consent for carriers to access the driver's info in Clearinghouse database
- Written (general) consent acceptable for limited queries; may be for indefinite period, such as duration of employment; no specific form required
- Electronic (specific) consent through the FMCSA portal is necessary for full queries—requires driver to register with Clearinghouse
- Consent is a condition of employment—companies may not allow drivers who have refused consent to perform any safety sensitive functions

Pre-Employment Queries

- Company (or C/TPA) must conduct full query of driver's record in Clearinghouse database before allowing new hire CDL driver to perform safety sensitive functions (SSF)
- Driver must provide electronic consent for query (requires driver to register with Clearinghouse)
- If driver's record in Clearinghouse database shows positive drug or alcohol tests, refusal to take a test, or other D&A violations, without completing return to duty process, company may not allow driver to perform SSF

Annual Queries

- Company (or C/TPA) must conduct annual query for all CDL drivers to determine if there are violations in the database (might be working for other carriers)
- Annual queries may be limited queries—Is there info in the database on this driver? If no, the query stops. If yes, then conduct a full query to access the driver's violation history
- All queries cost \$1.25 per transaction; companies may purchase queries in bulk

Full Query Report

- Driver details, including name, date of birth, contact information, CLP/CDL information, and eligibility status
- Information about the driver's employer who ordered the test or reported a violation to the Clearinghouse
- Test details, including the type of test, violation details, and test result
- Information about who entered the test result
- Return to Duty (RTD) activity information

Reporting Info to Database

- Information must be reported to Clearinghouse database on a CDL driver's positive drug or alcohol test, refusal to take a test, or other D&A violations
- Within 2 business days of determination, MRO must report a verified positive, adulterated, or substituted controlled substances test result, or refusal-to-test determination by the MRO



Traffic Bulletin

MRO Reporting Data

- Reason for the test;
- Federal Drug Testing Custody and Control Form specimen ID number;
- Driver's name, date of birth, and CDL number and State of issuance;
- Employer's name, address, and USDOT number, if applicable;
- Date of the test;
- Date of the verified result; and
- Test result. The test result must be one of the following:
 - (A) Positive (including the controlled substance(s) identified);
 - (B) Refusal to test: Adulterated;
 - (C) Refusal to test: Substituted; or
 - (D) Refusal to provide a sufficient specimen

Employer Reporting to Database

- Within 3 business days following the date on which it obtained that information, employer or C/TPA must report to database:
 - (i) An alcohol confirmation test result with an alcohol concentration of 0.04 or greater;
 - (ii) A negative return-to-duty test result;
 - (iii) A refusal to take an alcohol test;
 - (iv) A refusal to test determination; and
 - (v) A report that the driver has successfully completed all follow-up tests as prescribed in the SAP report

Other Violation Reports

- For each violation, the employer must report the following information:
 - (i) Driver's name, date of birth, CDL number and State of issuance;
 - (ii) Employer name, address, and USDOT number, if applicable;
 - (iii) Date the employer obtained actual knowledge of the violation;
 - (iv) Witnesses to the violation, if any, including contact information;
 - (v) Description of the violation;
 - (vi) Evidence supporting each fact alleged in the description of the violation, including but not limited to, affidavits, photographs, video or audio recordings, employee statements, correspondence, or other documentation; and
 - (vii) A certificate of service or other evidence showing that the employer provided the driver with all information reported

Substance Abuse Professional (SAP) Reporting

- SAPs must report to the Clearinghouse, for each driver who has completed the return-to-duty process, the following information:
 - (i) SAPs name, address, and telephone number;
 - (ii) Driver's name, date of birth, and CDL number and State of issuance;
 - (iii) Date of the initial substance-abuse-professional assessment; and
 - (iv) Date the SAP determined that the driver demonstrated successful compliance and was eligible for return-to-duty testing



Traffic Bulletin

Additional Clearinghouse Info

- After 3 years, this process will eliminate need to request drug and alcohol test history directly from prior employers; in the meantime, must complete both procedures
- Violations prior to January 6, 2020 are not reportable to the database
- Non-DOT test results are not reportable, either
- FMCSA proposed 3-year extension of State queries to Clearinghouse before issuing, renewing, upgrading or transferring a CDL; States may voluntarily query the database during that period

I want to say a special thank you to Rick Schweitzer, GAWDA General Counsel, for providing the above information.

Feel free to contact me if you have questions.

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical, Food and Specialty Gas Bulletin 10/01/2020

Frequently Asked Question

Q - Can I sell medical oxygen for aircraft use?

A - The specifications for the oxygen used on an aircraft depend on the "intended use" of the oxygen. Here are some follow-up questions:

- ***Is the customer planning on using the oxygen for the pilot's use?*** If so, then you may want to supply Aviator Breathing Oxygen (ABO) with very low moisture (6.6 ppm H₂O and 99.5% O₂) and NOT Oxygen, USP. Note that if the customer wants ABO with according to SAE or the MilSpec, there is SIGNIFICANT additional testing required. Contact tom@asteriskllc.com if you need more information about the MilSpec, SAE specification or procedures for filling ABO. Assure that the customer's requirements and your specifications are the same.
- ***Is the customer planning on using the oxygen for a patient?*** If so, you must sell Oxygen, USP. You should also have a prescription or medical license on file in order to sell the drug.
- ***Does the customer simply want the oxygen available in case of a medical emergency for a potential patient?*** If so, you can sell the Oxygen USP without a prescription or medical license under the "emergency use" exemption. The FDA allows medical oxygen to be dispensed without a prescription to properly trained individuals for oxygen deficiency and resuscitation, as long as the following conditions are met:
 - A high-pressure cylinder filled with medical oxygen and used for oxygen deficiency and resuscitation must have the "emergency use" statement present on the drug label.
 - The equipment intended for such use must deliver a minimum flow rate of 6 liters of oxygen per minute for a minimum of 15 minutes and include a contents gauge and an appropriate mask or administration device.
 - Proper training documentation is on file that an individual has received training within the past 24 months, or other appropriate interval, in the use of emergency oxygen, including providing oxygen to both breathing and non-breathing patients, and safe use and handing of emergency oxygen equipment. Training may be obtained from any nationally recognized professional organization, such as the National Safety Council, the American Heart Association, the American Red Cross, etc.
 - Under no circumstances can emergency oxygen be used to fill high-pressure cylinders or be used in a mixture or blend.

Once all of these conditions are met, an individual or firm may have access to medical oxygen without a prescription.

Medical, Food/Beverage and Specialty Gases Bulletin

GAWDA Professional Compliance Seminar – Audit Survival

GAWDA Professional Compliance Webinar – Audit Survival

DOT, OSHA and FDA (Food/Beverage and Medical Gases) – Audit Survival Seminar
October 27 to 29, 2020 - Webinar hosted by Weldcoa

[Click here for information or to register](#)

October Medical Gas Roundtable (10/30/2020) – 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 C Food Safety Plan

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.

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