



SEPTEMBER 2021

ENCLOSED

Safety Topics

Carbon Dioxide Exposure and Asphyxiation

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: DCSA
2. Recent FDA Observations
3. September Medical Gas Roundtable (9/24/2021) – CGMP - High Pressure Prefill Inspection and Filling High Pressure Cylinders; GAWDA Professional Compliance Training (10/25-29/2021)
4. Micro-Audit Suggestions

Please contact [Tom Badstubner](#), GAWDA FDA Food, Medical & Specialty Gases Consultant for more information.

**** Join us for our Monthly LIVE “Safety Managers’ Safety Meeting” ****

Our next meeting is [September 21st](#) @ 1PM Eastern.

Visit us at www.gawda.org/safety-meeting/ to learn more and sign up today.

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 _____

September 2021**Carbon Dioxide Exposure and Asphyxiation**

Carbon dioxide (CO₂) is a colorless, odorless, non-flammable gas that is 1.5x heavier than air at normal atmospheric temperatures. CO₂ can accumulate in low lying areas and confined spaces. Because of these properties it is considered to have NO Warning Properties!

ROUTES OF CARBON DIOXIDE EXPOSURE

Inhalation

Low concentrations are not harmful. Moderate concentrations will affect cognitive abilities. Higher concentrations can affect respiratory function and cause excitation followed by depression of the central nervous system and death. Extremely high concentration will also displace oxygen in the air, causing an oxygen-depleted atmosphere after death has occurred from the toxicity. Symptoms occur more quickly with physical effort.

Skin Contact

Direct contact with the liquefied gas or solid can chill or freeze the skin (e.g., frostbite).

Eye Contact

Gas may cause mild irritation. Direct contact with the liquefied gas can freeze the eye. Permanent eye damage or blindness can result.

Ingestion; Injection; Skin & Ocular Absorption

Not relevant routes of exposure.

Note. Adapted from "Carbon Dioxide," OSH Answers Fact Sheets, by CCOHS, 2017.



Concentration	Effects
5,000 ppm (0.5%)	OSHA Permissible Exposure Limit (PEL) and ACGIH Threshold Limit Value (TLV) for 8-hour exposure
10,000 ppm (1.0%)	Typically, no effects, possible drowsiness
15,000 ppm (1.5%)	Mild respiratory stimulation for some people
30,000 ppm (3.0%)	Moderate respiratory stimulation, increased heart rate and blood pressure, ACGIH TLV-Short Term
40,000 ppm (4.0%)	Immediately Dangerous to Life or Health (IDLH)
50,000 ppm (5.0%)	Strong respiratory stimulation, dizziness, confusion, headache, shortness of breath
80,000 ppm (8.0%)	Dimmed sight, sweating, tremor, unconsciousness, and possible death

Safety precautions to protect against carbon dioxide asphyxiation?

- Employees should receive training and be knowledgeable of the potential sources and symptoms of exposure to CO₂.
- Dry ice and liquid CO₂ can cause tissue damage, proper PPE should be worn when handling dry ice or filling CO₂.
- If you are working near any sources of dry ice or CO₂ filling and develop any of the symptoms of exposure, move to an area of fresh air immediately, and report the incident to your supervisor. (Fresh air or oxygen is the primary remedy for CO₂ exposure.
- If you are pregnant consult with your supervisor and your physician about limiting exposure to CO₂.
- Do not stand directly next to open bins that contain dry ice or in vapors from these bins. Do not touch dry ice or a bin containing dry ice.
- Additional caution should be taken when filling or emptying dry ice bins as high concentrations of CO₂ will be trapped in the bottom of the bin.
- CO₂ cylinders should be vented in a secured position, in an open area (preferably outdoors).
- Employees should never place themselves directly in front of a venting CO₂ valve (for asphyxiation and pressure hazards are present in the gas stream).



Drivers have additional exposure to the hazards of CO₂ and a customer site survey may be necessary to facilitate a safe delivery. Customer site hazards may include:

- Basement deliveries. This may be considered a confined space and again a customer site survey may be necessary to develop a safe delivery plan. Also consider reviewing the GAWDA safe practice for stair delivery (2012-02_ CYLINDER DELIVERY AT LOCATIONS WITH STAIRS AND OR RAMPS, rev.2018).
- Any area that may be deemed a confined space should be equipped with a CO₂ detector and alarm system.
- An interior installation of a CO₂ system should have all venting, relief devices and discharge vents should be piped outdoors.
- Fill connections should be situated on the exterior of the building.
- Signage should be installed on entry doors to the storage area.

Resources:

1. [OSHA.gov](https://www.osha-slc.gov)
2. Staub, Fred D. "Toxic Carbon Dioxide Exposures, the Unacceptable Risk." Professional Safety Journal, July 2021, p.24-36.
3. Compressed Gas Association, Inc. (CGA) pamphlets should be consulted. These pamphlets are designed to assist personnel involved in transferring liquid carbon dioxide, designers, engineers, safety and training personnel, distributors, restaurant personnel, other users, inspectors, and all interested parties.

CGA G-6.5-1992, Standard for Small Stationary Low Pressure, Carbon Dioxide Supply Systems
CGA G-6.4-1992, Safe Transfer of Low Pressure Liquefied Carbon Dioxide in Cargo Tanks, Tank Cars, and Portable Containers

CGA G-6.3-1995, Carbon Dioxide Cylinder Filling and Handling Procedures

CGA G-6-1984, Carbon Dioxide

CGA G-6.2-1994, Commodity Specification for Carbon Dioxide

CGA G-6.6-1993, Standard for Elastomer-Type Carbon Dioxide Bulk Transfer Hose

4. [GAWDA.org](https://www.gawda.org)
5. Dodd, Michael, "Carbon Dioxide Asphyxiation." GAWDA Safety Topic, August 2017.

If you have any questions, please feel free to contact:

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Traffic Bulletin

Traffic Bulletin

September 2021

Drug and Alcohol Clearinghouse

This Bulletin is a repeat from October 2020 because of the number of contacts that I am getting on this topic. **Please remember that you should have run at least a limited query on all your CDL drivers by 1-6-2021.** You must do a limited 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 1-6-2020.

CDL Drug and Alcohol Clearinghouse final rule became mandatory on January 6, 2020. FMCSA has placed new compliance resources on its website, <https://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 and Learning Center. DOT has done a great job with the questions and answers found in those FAQs and a lot of helpful screen shots in the Learning Center examples. 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 refusals to test, any positive test unless you have your testing company doing the upload, 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



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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



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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



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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

08901/2021

Frequently Asked Questions – DSCA

Q – I hear that the Drug Supply Chain Security Act (DSCSA) must be implemented by November 2023. What do I need to do?

A – **Nothing** – DSCA does not apply to medical gases. The definitions in DSCA exempt medical gases. Specifically, in Section 581 of the Federal Food Drug and Cosmetic Act the definitions applicable to DSCA exempt medical gases:

- Paragraph (13) defining the term “product”
- Paragraph (24)(B)(xvii) defining the term “transaction”

If you are being asked for interoperable electronic track and trace systems by your customers, explain that medical gases are exempt from the Drug Supply Chain Security Act.

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.

Employee Training

Form 483 Observation-02-04 - Employees engaged in the manufacture, processing and packing of a drug product lack the training required to perform their assigned functions. Specifically, GMP training records for ____, a Cylinder Filler Operator at the firm, do not exist for the following items as required per SOP ____, revision ____, active ____, titled "Personnel Qualification and Training": FD&C Act; Drug & Device cGMP; FDA Compressed Medical Gas Guidelines and other Guidance; State and Local Requirements; Control of Components; Production and Process Controls; Holding and Distribution Laboratory Controls; Records & Reports/Returned and Salvaged Drug Products; Medical Gas Complaint Procedures.

How to prevent this from showing up in your inspection?

Assure all employees (including pumpers and QCU) are current on their CGMP training.



Medical, Food/Beverage and Specialty Gases Bulletin

GAWDA Professional Compliance Training – HOLD THE DATES

This year, the Fall Professional Compliance Training will be held via Teleconference
October 25 to 29, 2021

September Medical Gas Roundtable (09/24/2021)

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 G - Supply-Chain Program (CGA F-3).

These and other webinars may be 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

For this month, verify these items:

1. **Label Inventory** – Be sure the labels in stock and at your pumper's station are correctly inventoried.
2. **Contents Statement** – Be sure all cylinder and container labels bear the contents statement (liters, cubic feet, etc.). This is a common violation and is easily correctable.
3. **Expiration Dates** – The FDA does not expect medical gas firms to use expiration dates on designated medical gases. Contact jodie@asteriskllc.com for a sample customer notification letter if needed.

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