GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

DECEMBER 2021

ENCLOSED

Safety Topics

EPA Definitions

Delivery Safety

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

Traffic Bulletin

Drug and Alcohol Recordkeeping

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. **Medical Gases and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)**
2. **Compliance To Do List – Review your Drug Listings**
3. **FAQS: CGA SB-26 now CGA V-23**
4. **December Medical Gas Roundtable (12/17/2021) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products**
5. **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 December 8th @ 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.

GASES AND WELDING DISTRIBUTORS ASSOCIATION
One Oakwood Blvd., Suite 195, Hollywood, FL 33020 P(954)367-7728 F(954)367-7790

SAFETY TOPIC

December 2021

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 _____

December 2021

EPA definitions

Delivery Safety

Many GAWDA member companies are servicing extraction facilities and other industries that use significant amounts of hazardous materials. If you have quantities equal to/ greater than the reporting quantity or if you have Extremely Hazardous Substances as listed in the *List of Lists* (see hyperlink) then you will have to comply with one or more of these EPA statutes.

The EPA not only uses acronyms, but they throw in numbers to further confuse us. Below is a chart of the acronyms and *What actions are necessary* for you to be compliant with EPA regulations.

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EPA Title #	Requirement	Actions necessary
302	Emergency Planning	Local governments are required to prepare chemical emergency response plans, and to review plans at least annually.
		State governments are required to oversee and coordinate local planning efforts. .
		Facilities that maintain Extremely Hazardous Substances (EHS) on-site in quantities greater than corresponding threshold planning quantities (TPQs) must cooperate in emergency plan preparation
304	Emergency Release	Facilities must immediately report accidental releases of EHSs and "hazardous substances" must be reported to state and local officials. Any releases of these substances in quantities greater than their corresponding Reportable Quantities (RQs) must be reported to state and local officials.
311/312	SDS and Inventory (SARA Tier II)	Facilities handling or storing any hazardous chemicals must submit Safety Data Sheets (Safety Data Sheets, SDSs) to state and local officials and local fire departments.
		Facilities must also submit an inventory form for these chemicals, to state and local officials and local fire departments.
313	Toxic release Inventory	Facilities must complete and submit a toxic chemical release inventory form (Form R) annually. Form R must be submitted for each of the over 600 TRI chemicals that are manufactured or otherwise used above the applicable threshold quantities.
112 (r)	RMP	Certain listed regulated flammable and toxic substances are required to develop a Risk Management Program, which includes a(n):
		Hazard assessment that details the potential effects of an accidental release, an accident history of the last five years, and an evaluation of worst-case and alternative accidental releases scenarios;
		Prevention program that includes safety precautions and maintenance, monitoring, and employee training measures; and
		Emergency response program that spells out emergency health care, employee training measures and procedures for informing the public and response agencies (e.g., the fire department) should an accident occur.
Resource:	List of lists	

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SAFETY TOPIC

December 2021

Safe Delivery Practices for Liquid Dewars

If you're in the compressed gas business, then liquid dewar deliveries are probably part of your normal delivery routes. Dewars are heavy, cumbersome and, depending on the wheel configuration, unstable.

Delivery of these packages should be addressed prior to signing the account. However, when that does not happen, the driver should have the last call on if the manual delivery route is safe. Some obstacles that could prevent manual delivery include stairs, unsafe ramps and unsafe delivery surfaces (gravel or broken concrete) or elevators. The GAWDA Safety Committee has published two Best Safety Practices* to assist training your employees:

Sample Cylinder Delivery at Locations with Stairs or Ramps (2020)
Transport of Pressurized Cryogenic Liquid Containers in an Elevator (2021)
And the Delivery Survey

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Both of these Safety Practices discuss the steps employees should take to ensure a safe delivery; these include:

#1 Complete a Delivery Survey prior to first delivery!

- Inspect the dewar before transporting
- Verify pressure is 5 psi below PRD rating
- Check to ensure the pressure builder is off
- Special precautions must be made if transporting a dewar on an elevator

**Best Safety Practices may be found on the Member's Only Document page of the GAWDA Website.*

If you have any questions about these topics, or any other DHS, EPA or OSHA topic, please contact:

Marilyn Dempsey
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Marilyn@SafetyDragons.com

Traffic Bulletin

December 2021

DRUG and ALCOHOL RECORDKEEPING

What records must employers keep?

I have compiled the drug and alcohol recordkeeping requirements for 49 CFR Part 40 and Part 382 into the following information. Sorry for the length and amount but there are a lot of requirements.

As an employer, you must keep the following records for the following periods of time:

Five Years

- Records of alcohol test results indicating an alcohol concentration of 0.02 or greater;
- Records of verified positive drug test results;
- Documentation of refusals to take required alcohol and/or drug tests (including substituted or adulterated drug test results);
- Substance Abuse Professional reports; and
- All follow-up tests and schedules for follow-up tests.
- Calibration documentation,
- Records related to the administration of the alcohol and controlled substances testing programs, and
- A copy of each annual calendar year summary required by §382.403. The Federal Motor Carrier Safety Administration (FMCSA) requires a motor carrier to prepare an annual summary only if a carrier is notified by FMCSA. A motor carrier is also required to submit a summary upon demand of a federal, state, or local official with proper authority as part of an inspection, investigation, or special study.

Three Years

- Information obtained from previous employers under §40.25 concerning drug and alcohol test results of employees. This will go away on 1-6-2023 because there will be 3 years of data in the Clearinghouse.
- Clearinghouse 382.701; Employers must retain for 3 years a record of each query and all information received in response to each query made under this section.

Two Years

- Records of the inspection, maintenance, and calibration of EBTs.
- Records related to the alcohol and controlled substances collection process.

One Year

- Records of negative and cancelled drug test results and alcohol test results with a concentration of less than 0.02.

Indefinite period

- Records related to the education and training of breath alcohol technicians, screening test technicians, supervisors, and drivers shall be maintained by the employer while the individual performs the functions which require the training and for two years after ceasing to perform those functions.
- See “Other Records” below.

You do not have to keep records related to a program requirement that does not apply to you (*e.g.*, a maritime employer who does not have a DOT-mandated random alcohol testing program need not maintain random alcohol testing records).

You must maintain the records in a location with controlled access.

A service agent may maintain these records for you. However, you must ensure that you can produce these records at your principal place of business in the time required by the DOT agency. For example, as a motor carrier, when an FMCSA inspector requests your records, you must ensure that you can provide them within two business days.

If you store records electronically, where permitted by this part, you must ensure that the records are easily accessible, legible, and formatted and stored in an organized manner. If electronic records do not meet these criteria, you must convert them to printed documentation in a rapid and readily auditable manner, at the request of DOT agency personnel.

Other Records

The 49 CFR 382.401 (c) has the following records being maintained but doesn’t say for how long, therefore I would keep them indefinitely. The following specific types of records shall be maintained. "Documents generated" are documents that may have to be prepared under a requirement of this part. If the record is required to be prepared, it must be maintained.

- Records related to the collection process:
  - Collection logbooks, if used;
  - Documents relating to the random selection process;
  - Calibration documentation for evidential breath testing devices;
  - Documentation of breath alcohol technician training;
  - Documents generated in connection with decisions to administer reasonable suspicion alcohol or controlled substances tests;
  - Documents generated in connection with decisions on post-accident tests;
  - Documents verifying existence of a medical explanation of the inability of a driver to provide adequate breath or to provide a urine specimen for testing; and
- Records related to a driver's test results:
  - The employer's copy of the alcohol test form, including the results of the test;
  - The employer's copy of the controlled substances test chain of custody and control form;
  - Documents sent by the MRO to the employer, including those required by §382.407(a).
  - Documents related to the refusal of any driver to submit to an alcohol or controlled substances test required by this part; and
  - Documents presented by a driver to dispute the result of an alcohol or controlled substances test administered under this part.
  - Documents generated in connection with verifications of prior employers' alcohol or controlled substances test results that the employer:
    - Must obtain in connection with the exception contained in §382.301 of this part, and
    - Must obtain as required by §382.413 of this subpart.
- Records related to other violations of this part.
- Records related to evaluations:
  - Records pertaining to a determination by a substance abuse professional concerning a driver's need for assistance; and
  - Records concerning a driver's compliance with recommendations of the substance abuse professional.
- Records related to education and training:
  - Materials on alcohol misuse and controlled substance use awareness, including a copy of the employer's policy on alcohol misuse and controlled substance use;
  - Documentation of compliance with the requirements of §382.601 (Company written drug and alcohol policy, see Traffic Bulletin May 2001), including the driver's signed receipt of education materials;
  - Documentation of training provided to supervisors for the purpose of qualifying the supervisors to make a determination concerning the need for alcohol and/or controlled substances testing based on reasonable suspicion, §382.603;
  - Documentation of training for breath alcohol technicians as required by §40.51(a) of this title, and
  - Certification that any training conducted under this part complies with the requirements for such training.

- Administrative records related to alcohol and controlled substances testing:
    - Agreements with collection site facilities, laboratories, breath alcohol technicians, screening test technicians, medical review officers, consortia, and third party service providers;
    - Names and positions of officials and their role in the employer's alcohol and controlled substances testing program(s);
    - Quarterly laboratory statistical summaries of urinalysis required by §40.29(g)(6) of this title; and
    - The employer's alcohol and controlled substances testing policy and procedures.

The information collection requirements of this part are found in the following sections: Section 40.333, 382.105, 382.113, 382.301, 382.303, 382.305, 382.307, 382.309, 382.311, 382.401, 382.403, 382.405, 382.407, 382.409, 382.411, 382.413, 382.601, and 382.603.

There are a lot of recordkeeping items for drug and alcohol, and I hope this has not confused you. As always, if there are any questions, just ask.

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Medical, Food/Beverage and Specialty Gases Bulletin

12/01/2021

Medical Gases and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

The CARES Act requires medical gas firms to submit their monthly and annual drug gas volumes to the FDA. The purpose of the Act is to help the FDA mitigate drug shortages by enhancing FDA's visibility into drug supply chains. The timeline for reporting medical gas releases is:

- 2020 volumes to be reported by February 15, 2022.
- 2021 volumes to be reported by May 16, 2022.

You will list your releases by NDC Code. Each cylinder size of each medical gas has a unique NDC Code. You can get your NDC Codes by reviewing your FDA Drug Listing… see below. If you need assistance, contact jodie@asteriskllc.com.

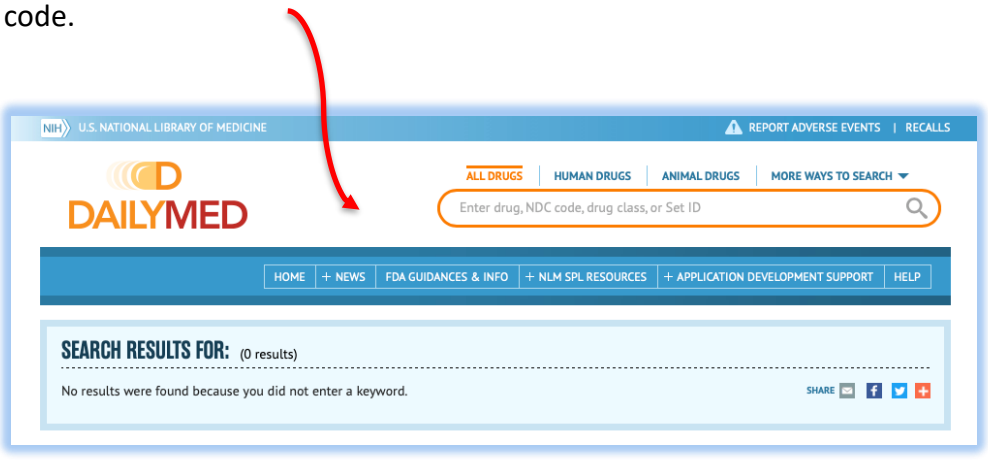
We discussed this subject at the GAWDA Safety Managers Safety Meeting. To watch that presentation, click here: https://attendee.gotowebinar.com/recording/4420977245062474768

Compliance ToDo List – Review your Drug Listings

The FDA drug registration and listing regulations (21 CFR 207) require drug manufacturers to review their online drug labels in June and December each year. Look for obsolete labels, "unapproved medical gas" statements, or errors in the submission.

To verify your Drug Listing log on to: https://dailymed.nlm.nih.gov/dailymed/search.cfm

Enter your NDC Code (Labeler Code). Let jodie@asteriskllc.com know if you would like to look-up your labeler code.



Medical, Food/Beverage and Specialty Gases Bulletin

Frequently Asked Questions – CGA SB-26 now CGA V-23

Q – Is CGA SB-26, *Cylinder Connections on Portable Liquid Cryogenic Cylinders*, still in effect since the FDA adopted the new container and closure rules?

A – Yes. The relevant portion of the new FDA regulations specify:

> *Portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (e.g., those that have been silver- brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the containers' use) except by the manufacturer.*

CGA SB-26 was developed in 2000 following several tragic incidents where cryogenic container outlet connections had been switched to connect the wrong gas to a customer's distribution system. In 2017, the FDA has adopted the principles behind CGA SB-26.

In 2020, CGA re-issued SB-26 as a standard publication. The new publication is CGA V-23, *Standard for Cylinder Connections on Portable Cryogenic Liquid Cylinders.*

We strongly encourage you to get your own copy of CGA V-23 and follow its guidance. This publication is available for free to GAWDA members who participate in the CGA safety program (www.cganet.com). If you are not a part of the CGA safety program, this would be a good time to join. Otherwise, the publication's cost is only $9.00.

We have developed a training course that you can use for your cryogenic cylinder fillers and drivers to reinforce these basic safety principles and regulations.
Medical Gas Liquid Container Valve Outlet and Labeling Regulations

December Medical Gas Roundtable (12/17/2020) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products.

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In December, we will be discussing the various records required by the FDA. In addition, we will have an easy to use handout about how to document your Annual Records Review.

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

- ***Specialty Gas*** - Fuel/Oxidizer - Alternative Approaches (CGA P-58)
- **Food Gas Roundtable** – 21 CFR 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.

Medical, Food/Beverage and Specialty Gases Bulletin

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. **Complaints -** Verify that your complaint file has any instances of customers asking for credit because they thought the cylinder was not full. (Even if the complaint was found to be without merit).
2. **QCU Review -** Verify that your QCU reviews all complaints.
3. **Other Lots? –** Be sure your complaint investigations consider whether any other cylinders from the same or different lots should be investigated. Document your decision to not investigate other cylinders/batches on the complaint record.

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