GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION


# DECEMBER 2022

## ENCLOSED

### Safety Topics

***OSHA 300A***

***Facility Securement***

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. **Compliance ToDo List – Review your Drug Listings**
2. **FAQs – CGA SB-26 now CGA V-23**
3. **December Medical Gas Roundtable (12/30/2022) – *Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products***
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 **December 7th** @ 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**

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# SAFETY TOPIC

**December 2022 *(rev)***

**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

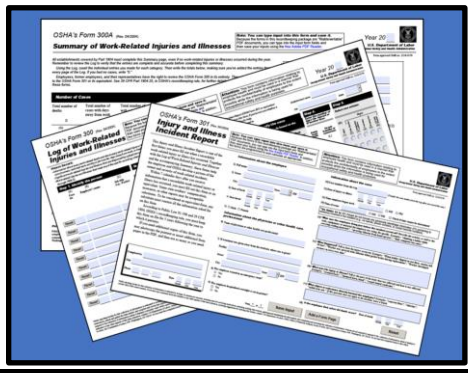
**We are happy to provide you with a monthly topic for your agenda.**

**ROUTE TO:**

- ☐ General Manager
- ☐ Safety Coordinator
- ☐ Supervisor Dept. _____
- ☐ Other _____
- ☐ Date of Meeting _____

## December 2022

## OSHA 300 Series




As the end of the year approaches it's a good time to gather your injury and illness records in preparation for the 300A posting (and electronic submission for most GAWDA members).

The OSHA 300A Summary must be completed even if there were NO work-related injuries or illnesses during the calendar year.

Overview for Recording Work-Related Injuries and Illnesses
Workplace Injuries and Illnesses must be recorded and the process includes THREE forms:

- **OSHA Form 300** – Log of Work-Related Injuries and Illnesses
  any medical treatment beyond First Aid must be recorded on an OSHA 300 Log of Work-Related Injuries and Illnesses.

**What must be recorded?**

- Any medical treatment beyond First Aid must be recorded.
- Death
- Loss of consciousness
- Days away from work
- Restricted work activity or job transfer

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**When?**

- Within 7 days after being informed of injury or illness
- EXCEPTION:
  - Death - within 8 hours
  - Hospitalization, amputation, loss of eye - within 24 hours

•**OSHA Form 301** – Injury and Illness Incident Report (or equivalent form) that records The detailed information about an injury/illness . For most states A Worker's Compensation Report of Injury would be equivalent to the OSHA 301 because the Worker's Compensation Report of Injury contains the same information as the OSHA 301 form.

•**OSHA Form 300A** – Summary of Work-Related Injuries and Illnesses
By the end of January, of each year, a summary of Injury and Illnesses (OSHA 300a) must be completed, reviewed, certified and posted (Electronically and Physically)

**Physical posting due Feb. 1, of the next calendar year.**
**Electronic Submission due March 2 of the next calendar year**
**(example: 2022 OSHA 300A must be posted by Feb. 1, 2023.)**
**https://www.osha.gov/injuryreporting/**

**Process:**

1. **Complete OSHA 300A using data from OSHA 300 log**

2. **End of the year review:**
   - Review the OSHA 300 log for accuracy
   - Correct any mistakes
   - Create the Annual Summary (Form 300A)
   - Certify the summary

3. **Certify the summary**
   - An owner of the company (only if the company is a sole proprietorship or partnership);
   - An officer of the corporation;
   - The highest-ranking company official working at the establishment; *or*
   - The immediate supervisor of the highest-ranking company official working at the establishment

4. **Post OSHA 300A:**
   - Physical posting:
     OSHA 300A should be where notices to employees are usually posted.

   - Electronic reporting:

   Any employer with establishments with 250 or more employees must report electronically. Employers that have 20 or more employees and are deemed to be **HIGH RISK** by OSHA must also report electronically.

   **HIGH RISK** industries include those companies that fill cylinders, requalify cylinders, sell compressed gases or welding supplies.

   NAICS codes of **HIGH RISK** industries include:
   325120- industrial gas manufacturing
   423840- industrial supplies Merchant; Welding Supply wholesalers
   424690- welding gases, other chemical and Allied products Merchant Wholesalers
   454390- other direct selling establishments.

Complete OSHA list of NAICS codes that must file electronically (20-250 employees)

**INSPECTIONS:**
OSHA 300A records are generally reviewed by an OSHA inspector and there are five common mistakes:

1. Combining locations onto one OSHA 300A. Each physical location must have an OSHA 300A completed and posted.
2. If a location is opened anytime during the year, a 300A must be completed and posted; even if it is opened on the last day of the year.
3. If a location is closed anytime during the year then a 300A is NOT required to be completed.
4. A company executive has not signed the form.
   A company executive may be:
   - An owner of the company (only if the company is a sole proprietorship or partnership)
   - An officer of the corporation;
   - The highest-ranking company official working at the establishment; *or*
   - The immediate supervisor of the highest-ranking company official working at the establishment.
5. The 300A form must be posted from Feb 1 to Apr 30 each year, even if filed electronically.
6. The 300A form must be posted in an area where employees are likely to view it; e.g. next to the OSHA safety posters or time clock.

## Facility Securement

In day-to-day business operations we often forget the importance of facility securement even though many are located in "rough" areas. The GAWDA Safety Committee created a Facility Securement suggested safety practice. This template can be adapted for your company and used as a monthly or quarterly security audit. The complete document is available on the GAWDA website/ Members Only Document page/ Facility Securement.

GAWDA GASES AND WELDING DISTRIBUTORS ASSOCIATION

**Facility Securement**
(Insert Company Name Here)

| | |
|---|---|
| **PURPOSE** | **To provide a set of proposed guidelines for facility securement of welding distributors and fill plants.** |
| **RESPONSIBILITY** | **All personnel of the facility** |
| **AUTHORITY** | **Facility manager and or fill plant manager** |

1. Building
   a. Evaluate current facility design, use and limitations to determine specific access needs and requirements during regular hours of operation and after-hours usage.
   b. Minimize the number of entrances without compromising emergency egress. This can be accomplished by using door hardware that only opens from the inside.
   c. Magnetic locks can help to ensure doors fully close and latch after entry or egress is made.
   d. Limit key distribution and, if possible, use electronic card key access to monitor entry.
   e. Ensure all exits and entrances are properly marked properly and remain visible to facility personnel.
   f. Utilize camera/DVR system to ensure consistent monitoring of the facility with security system with alarm.
   g. Have an established hours of operation posted for all to see.
   h. Post signs on exit doors that state visitor sign-in requirements and warn that violators could be charged with trespassing.
   i. Provide communication devices such as intercoms or buzzers so that management can be alerted if a trespasser is present in a restricted area.
   j. Create a visitor sign-in, sign-out, and escort procedure.
   k. Use visitor ID badges.
   l. Secure custodial and delivery doors and keep records of deliveries.
   m. Have a protocol for securing the facility when closing.
   n. Assign specific tasks to specific personnel for securing facility.

2. Perimeter
   a. Establish total perimeter fencing with locking gates. When closed, the gap beneath a gate should not exceed 4 inches.
   b. Walls can be used to provide perimeter while limiting visual access to the property.
   c. Fencing and gates can be reinforced and protected from vehicular damage by using curbs, bollards, or guardrails.
   d. Maintain a clear zone of 5-10 feet on both sides of the fence. Materials and equipment should not be

positioned within the clear zone and decorative vegetation should be kept to heights of less than 2 feet.

e. Lighting of the perimeter and outdoor areas can be used to improve safety, deter access, and promote detection and monitoring of unauthorized intrusion.
f. Utilize camera/DVR system to ensure consistent monitoring of the outdoor areas, focusing on likely points of access.
g. Position signage on perimeter fencing to address marking requirements for hazardous materials.
h. Secondary fencing or additional security may be required for certain chemicals.

3. Vehicle Parking
   a. Do not park vehicles within the fencing clear zone.
   b. Remove vehicle keys and lock doors after parking.
   c. Remove high value items, such as data tablets or computers, from vehicle cab.

4. Electronic and Internet Security
   a. Firewall system in place for securing internet.
   b. Protocol in place for backing up the day's receipts, preferably off-site.
   c. Program for changing passwords at predetermined intervals.
   d. Provide employees with training to recognize and avoid phishing scams and similar attempt of cyber intrusion.

If you have any questions about either of these topics, how to subscribe to the CGA program or Any other OSHA, EPA or DHS questions please contact me.

Marilyn Dempsey
GAWDA DHS,EPA,OSHA Consultant

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# Traffic Bulletin

**December 2022**

## Drug and Alcohol Clearinghouse

***This Bulletin is a repeat from October 2020 and September of 2021 because of the number of contacts that I am getting on this topic and more importantly the number of members that have called and were not registered into the Clearinghouse system.***

Any GAWDA members that have CDL drivers must register with the Clearinghouse. 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, 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 the Clearinghouse
- 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 the result comes back with the driver prohibited)
- 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 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 queries 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

**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 on any of these items if you have questions.

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# Medical, Food/Beverage and Specialty Gases Bulletin

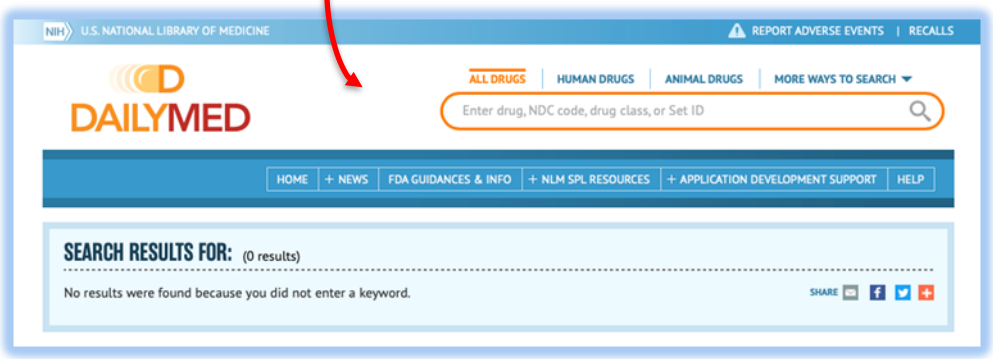
**12/01/2022**

## 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 Device Gases – UDI Barcodes

*This section of the Medical gas Bulletin applies ONLY to medical device gases (Lung Diffusion Mixtures, Clinical Blood Gas Mixtures, etc.) This does not apply to drug gases (Oxygen, Nitrogen Drug Gas Mixtures, etc.)*

On September 24, 2013, the FDA published a final rule establishing a Unique Device Identification (UDI) system designed to adequately identify devices through distribution and use. Implementation of the regulatory requirements for typical medical device gases was phased in and delayed until December 8, 2022. The applicable medical device gases are classified as Class 1 and include:

- Lung Diffusion Mixtures
- Clinical Blood Gas Mixtures
- Laser Gas Mixtures
- Calibration Gas Mixtures

GAWDA and CGA met with the FDA to discuss the UDI issue for medical device gases and sought to become exempt from the rule. Our position is that the UDI does not contribute to public safety for medical device gases. There have been significant technical challenges with this rule at FDA and the agency has issued and revised guidances at least four times. The FDA has not addressed our request and the extended deadline for implementation in quickly approaching (12/8/2022).

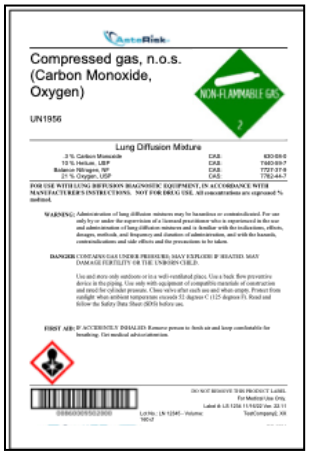
# Medical, Food/Beverage and Specialty Gases Bulletin

The UDI Rule requires a device to bear a unique device identifier (UDI Barcode) on its label and packages. The UDI Rule also requires that data pertaining to the key characteristics of each device be submitted to FDA's GUDID (21 CFR 830.300). GUDID provides a repository of device safety information for FDA. Most of the information submitted to GUDID is also available to the public through AccessGUDID. AccessGUDID enables healthcare providers and patients to obtain safety information on specific devices, such as sterility requirements and MRI compatibility information. For more information see:

- FDA UDI Resource - https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system
- GAWDA Safety Manager's Safety Meeting (11/09/2022) - https://attendee.gotowebinar.com/recording/6393315295878628097
- AccessGUDID - https://accessgudid.nlm.nih.gov

## Sample label with UDI barcode

The UDI is the machine-readable barcode and the human-readable number below the barcode. This is a sample showing a possible label format using the Specialty Gas Manager software.




## 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.*

# Medical, Food/Beverage and Specialty Gases Bulletin

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 (12/30/2022) – 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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