



## JANUARY 2020

### ENCLOSED

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#### Safety Topic

**Chemical Inventory Reporting: Emergency Planning and Community Right-to-Know Act (EPCRA)**

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

#### Traffic Bulletin

##### CDL Driver License Notifications

*Please contact Mike Dodd for more information.*

#### Medical, Food/Beverage and Specialty Gases Bulletin

1. Safety Posters Available
2. FDA Compliance To Do List
3. GAWDA Professional Compliance Seminars 2020: March 10-12 & 17-19, Ball Ground, GA and October 27-29 & November 3-5, Aurora, IL; January Medical Gas Roundtable (1/31/20) - 21 CFR 211 Subparts A & B – Organization and Personnel.
4. Micro Audit Suggestions

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

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*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 \_\_\_\_\_



## Chemical Inventory Reporting

### Emergency Planning and Community Right-to-Know Act (EPCRA)

#### Bulk Storage Tanks or Bulk Trailers at Customer Sites

Do you own any bulk tanks at a customer site? An owner of bulk installations at a customer site has a duty under EPA regulations (Section 312) to notify the customer of their obligation to file Tier Form reports for each hazardous chemical that meets or exceeds the threshold planning quantities. **The reminder must be mailed to an appropriate customer representative by February 15, each year.** The supplier must document its efforts to notify its customers of these requirements.

If the customer owns the bulk unit, then you are not required to remind or notify them on their reporting obligations.

Hospitals are exempted from the notification and reporting obligations. (Section 311(e)(4) of EPCRA and 40 CFR 370.2 and 355.20 of the regulations exclude from the definition of "hazardous chemical" any substance to the extent it is used in a research laboratory or a hospital or other medical facility under the direct supervision of a technically qualified individual.)

A letter from the EPA Office of Enforcement dated March 4, 1991 states that "industrial gas suppliers who retain ownership of gas storage tanks or bulk trailers located on the premises of their customers" must make a good faith effort to notify such customer of the annual inventory reporting requirement. **This language does not include notifying customers who merely store gas in supplier-owned cylinders on the customer's property, however.**

Where the supplier does have a gas storage tank or bulk trailer on the customer's property, a good faith effort to notify the customer includes the following:

1. **Contract Language.** All new, reopened, renewed, or modified gas supply contracts must explicitly state the following language:

It is a responsibility of the Buyer to comply with all relevant reporting obligations under the Emergency Planning and Community right-to-Know Act of 1986, 42 U.S.C. §§11001-11049 (EPCRA, also commonly known as Title III of the Superfund Amendments Reauthorization Act of 1986 (SARA Title III)) resulting from the presence of the chemicals supplied under the agreement. Further, it is



a responsibility of the Buyer to warn and protect its employees and others exposed to the hazards posed by the Buyer's storage and use of the product.

**2. Customer Notification.** Industrial gas suppliers must remind their customers by separate mail of the EPCRA reporting obligations the customer may incur from the presence of the chemicals supplied under the agreement, and provide in the reminder a source of EPCRA compliance information such as the EPCRA hotline (1-800-535-0202). The reminder must be mailed to an appropriate customer representative by February 15 of each year. The supplier must also document its efforts to notify its customers of these requirements.

### **SARA Title III Reporting**

**March 1 is the filing deadline for your Hazardous Chemical Inventory Report.** This report usually is submitted on a Tier I or Tier II Form. Keep in mind that your state may require one of these forms be used over the other or even have its own special form. Your state may even have different reporting quantities. Check with your State Emergency Response Commission (SERC) if you have questions regarding what form to use or other possible state requirements.

Please use the following website to check on your state reporting requirements:  
<https://www.epa.gov/epcra/state-tier-ii-reporting-requirements-and-procedures>

If you submitted this report last year, use it as a guide. The report(s) must be submitted to your Local Emergency Planning Committee (LEPC), your SERC and the local fire department with jurisdiction over the facility. Use the above website to see how each state wants to receive their reports and get information on the SERC and LEPC reporting procedures.

Contact your SERC to find out the contact information for your LEPC.  
<http://www.epa.gov/epcra/state-emergency-response-commissions-contacts>

The EPCRA hotline for free help is 800-424-9346 or you can email them by going to this website: <http://www.epa.gov/epcra/forms/contact-us-about-emergency-planning-and-community-right-know-act-epcra>

Here is the EPCRA Frequent Questions website:  
[https://emergencymanagement.zendesk.com/hc/en-us#\\_ga=1.223967193.377971968.1446741998](https://emergencymanagement.zendesk.com/hc/en-us#_ga=1.223967193.377971968.1446741998)

Feel free to contact me if you have any questions.

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# Traffic Bulletin

**January 2020**

## **CDL Driver License Notifications**

There are two regulations that require CDL drivers to notify their employer about driving violations. The first, 383.31 (b), says that if the driver is convicted of any motor vehicle traffic control violation (other than a parking ticket) in any type of vehicle, they must notify their employer within 30 days after the conviction. The “date of conviction” is either the day they appear in court and are convicted or the day they sign the ticket pleading guilty and send in the fine.

This notification to the employer must be made in writing per 383.31 (c) and contain the following information:

1. Driver's full name;
2. Driver's license number;
3. Date of conviction;
4. The specific criminal or other offense(s), serious traffic violation(s), and other violation(s) of State or local law relating to motor vehicle traffic control, for which the person was convicted and any suspension, revocation, or cancellation of certain driving privileges which resulted from such conviction(s);
5. Indication whether the violation was in a commercial motor vehicle;
6. Location of offense; and
7. Driver's signature.

The second regulation regarding driver notifications is found in 383.33. It requires the driver to notify the employer by the end of the next business day whenever the driver has had their license suspended, revoked, or canceled or has been disqualified from operating a commercial motor vehicle for any period of time.

I have made up two forms that you may use for this program. The first makes a great driver meeting where you remind the driver of these rules that they are already subject to as a CDL driver. This form is not required but I think it makes a great addition to the driver's qualification file to show that you have discussed this requirement for the driver to notify you. The second is a form you can use to give to the driver and him them fill it out and return to you. This meets the driver's requirement to notify you in writing per 383.31 above.

If you have any questions about these requirements or use of the forms, please contact:

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# Traffic Bulletin

## **Notification of Traffic Convictions 383.31 And License Suspension, Revocation or Cancellation 383.33**

(383.31) Each person who operates a commercial motor vehicle, who has a commercial driver's license issued by a State or jurisdiction, and who is convicted of violating, in any type of motor vehicle, a State or local law relating to motor vehicle traffic control (other than a parking violation) in a State or jurisdiction other than the one which issued his/her license, shall notify an official designated by the State or jurisdiction which issued such license, of such conviction. The notification must be made within 30 days after the date that person has been convicted.

**The driver shall notify his/her current employer within 30 days of such conviction. The notification to the State official and employer must be made in writing and contain the following information:**

- Driver's full name;
- Driver's license number;
- Date of conviction;
- The specific criminal or other offense(s), serious traffic violation(s), and other violation(s) of State or local law relating to motor vehicle traffic control, for which the person was convicted and any suspension, revocation, or cancellation of certain driving privileges which resulted from such conviction(s);
- Indication whether the violation was in a commercial motor vehicle;
- Location of offense; and
- Driver's signature.

(383.33) Each employee who has a driver's license suspended, revoked, or canceled by a State or jurisdiction, who loses the right to operate a commercial motor vehicle in a State or jurisdiction for any period, or who is disqualified from operating a commercial motor vehicle for any period, shall notify his/her current employer of such suspension, revocation, cancellation, lost privilege, or disqualification. The notification must be made before the end of the business day following the day the employee received notice of suspension, revocation, cancellation, lost privilege, or disqualification.

**Driver Certification: I certify that I have read and understood the above requirements.**

Driver's Name (printed): \_\_\_\_\_

Driver's Signature: \_\_\_\_\_ Date: \_\_\_\_\_



# Traffic Bulletin

## CDL Driver License Notice of Violation Form

This form may be used by a driver of commercial motor vehicles to notify his or her employer or state official regarding convictions for traffic offenses (other than parking violations, equipment, or hours of service offenses and size and weight violations). **383.31 and 383.33 require this notification to be in writing and contain the following items:**

**Driver's full name;** \_\_\_\_\_

**Driver's license number;** \_\_\_\_\_

**Date of conviction;** \_\_\_\_\_

The specific criminal or other offense(s), serious traffic violation(s), and other violation(s) of State or local law relating to motor vehicle traffic control, for which the person was convicted and any suspension, revocation, or cancellation of certain driving privileges which resulted from such conviction(s):

- ☐ **Traffic Violation in any type of motor vehicle (must notify employer within 30 days of conviction)**
- ☐ **License suspension, revocation, cancellation, or disqualification (must notify employer by the end of the next business day)**

**Describe the violation here:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Was the violation in a commercial motor vehicle? YES NO**

**Location of offense:** \_\_\_\_\_

**Driver's signature:** \_\_\_\_\_

**Date of this notification:** \_\_\_\_\_





# Medical, Food/Beverage and Specialty Gases Bulletin

01/01/2020

## Safety Posters Available

The Compressed Gas Association has published eleven outstanding safety posters that you can download and post in your plant.

Check out: <https://portal.cganet.com/Publication/Index.aspx?mode=SP> Each poster is available in English and French.

- CGA SP-I Separating Incompatible Gases
- CGA SP-J Proper Cart Usage for Liquid Cylinders
- CGA SP-K Wear Recommended Personal Protective Equipment
- CGA SP-L Enclosed Spaces Can Be Unsafe (in English and French)
- CGA SP-M Misuse of Adaptors Can Be Dangerous
- CGA SP-N Plan Your Trip to Avoid a Tip
- CGA SP-C Valve Protection Caps
- CGA SP-D Securing Cylinders by Nesting
- CGA SP-E Oxygen and Oil Don't Mix
- CGA SP-F The Sleeping Giant
- CGA SP-H Transfilling Cylinders

## FDA Compliance To Do List

1. **Food Supplier Qualification** – Obtain a certificate of Conformance from your bulk food gas suppliers.
  - a. Assure that your bulk product meets one of the following grades:
    - i. For Carbon Dioxide –
      - FCC (Food Chemical Codex)
      - CGA G-6.2 Commodity Specification for Carbon Dioxide QVL H or I
      - ISBT (International Society of Beverage Technologists)
    - ii. For Nitrogen –
      - FCC
      - NF (National Formulary)
      - ISBT
      - CGA G-10.1 Commodity Specification for Nitrogen QVL B
    - iii. Other gases
      - FCC (Food Chemical Codex)
      - Another acknowledged food specification
  - b. Verify that your supplier is registered with the FDA for food production
  - c. Verify that your supplier is not passing food safety hazards to you



# Medical, Food/Beverage and Specialty Gases Bulletin

- d. Document your food/beverage gas supplier qualification in accordance with CGA F-3 and GAWDA sample supplier qualification procedures and checklist.

2. **Medical Gas Supplier Qualification** – assure that your
  - a. Contract actually specifies USP/NF (Medical Gas)
  - b. Supplier is registered with the FDA and licensed in your state
  - c. Supplier has a valid NDA (New Drug Application) and NADA (New Animal Drug Application)
  - d. Assess the type of verification needed for your incoming medical gas
  - e. Document the existence of a “Quality Agreement” with your supplier
  - f. Document your medical gas supplier qualification in accordance with CGA M-7 and GAWDA sample qualification procedures and checklist.

Contact [tom@asteriskllc.com](mailto:tom@asteriskllc.com) for checklists and sample procedures to qualify your supplier in accordance with current FDA expectations.

## **GAWDA Professional Compliance Seminars - 2020**

**March 10 – 12 and 17 – 19 - Ball Ground, GA (at Chart)**

**October 27 – 29 and November 3 – 5 - Aurora, IL (at Weldcoa)**

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

### **January Medical Gas Roundtable (31 January 2020)**

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In this roundtable, we will cover **21 CFR 211 Subparts A & B - Organization and Personnel**.

This presentation will include discussions about the responsibilities, authorities and procedures of the Quality Control Unit. We will also review the types of training required for operators, drivers and counter personnel.

For your information, we are also conducting the following webinars that day:

- **Specialty Gas** - Gas Chromatography Method Development
- **Food Gas Roundtable** – Allergen Awareness & Personal Hygiene

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 [tom@asteriskllc.com](mailto:tom@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. **Quality Control Unit Training** – Verify that your QCU has received CGMP training within the last year. This training should be documented. The GAWDA Medical Gas Roundtables are examples of CGMP training.
2. **Personnel Training** – Verify that your operations personnel and drivers have received documented CGMP and function specific training.

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