GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

JANUARY 2019

ENCLOSED

Safety Topic: **Chemical Inventory Reporting**

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

Traffic Bulletin: **DRUG and ALCOHOL RECORDKEEPING**

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. **FDA Compliance ToDo List: 1. Food Supplier Qualification 2. Medical Gas Supplier Qualification**
2. **GAWDA Professional Compliance Seminars – 2019 : dates and places**
3. **January Medical Gas Roundtable (25 January 2019): 21 CFR 211 Subparts A & B - Organization and Personnel.**
4. **Webinars: Specialty Gas - Gas Chromatography Method Development ; Food Gas Roundtable – FSMA: introducing Part 117 & Registration**
5. **Micro Audit Suggestions**

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

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
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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 _____

January 2019 Safety Topic

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

Feel free to contact me if you have any questions.

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Traffic Bulletin

January 2019

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.

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.

Traffic Bulletin

- 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

Medical Gas Bulletin
01/01/2019

FDA Compliance ToDo 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
    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. Suppler 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 for checklists and sample procedures to qualify your supplier in accordance with current FDA expectations.

Medical, Food/Beverage and Specialty Gases Bulletin

GAWDA Professional Compliance Seminars - 2019
- March 19 - 21, 2019 - Ball Ground, GA (at Chart)
- October 29 - 31, 2018 - Aurora, IL (at Weldcoa)
Hold the date... more details later

January Medical Gas Roundtable (25 January 2019)

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** – FSMA: introducing Part 117 & Registration - Free resources, procedures and training for your food gas compliance including the latest Food Safety Modernization Act regulations and how to comply with 21 CFR 117.

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.

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.

Medical, Food/Beverage and Specialty Gases Bulletin

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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