



SAFETY & TECHNOLOGY ORGANIZER

JANUARY 2013

ENCLOSED

Safety Topic: “Chemical Inventory Reporting”

Please contact GAWDA's OSHA and EPA Consultant, Mike Dodd for more information.

Traffic Bulletin: “Shipping Papers– Frequent Citations”

Please contact GAWDA's DOT and Security Consultant, Mike Dodd for more information.

Medical Gas Bulletin: FAQs, Medical Gas Roundtables, and Micro-audit

Please contact GAWDA Medical Gas Consultant, Tom Badstubner 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



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)

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.)

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, to download the Tier 2 Submit 2008 software, and the Facility Submission Guide:

<http://www.epa.gov/emergencies/content/epcra/tier2.htm>

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.



You can also use this website to search for information on your LEPC. Contact your SERC to find out the contact information for your LEPC.

http://www.epa.gov/emergencies/content/epcra/serc_contacts.htm

The EPCRA hotline for free help is 800-424-9346 or you can email them by going to this website: http://www.epa.gov/emergencies/contact_us.htm

Here is the EPCRA Frequent Questions website:

<http://www.epa.gov/emergencies/content/epcra/epcra-qa.htm>

Additional information related to SARA Title III can be found in the GAWDA EPA Manual in sections 5, 6, 7 and 8. (Remember, the GAWDA Reference Manuals are available to all members as a part of their membership.)

Feel free to contact me if you have any questions.

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TRAFFIC BULLETIN

January 2013

Shipping Papers – Frequent Citations

Have you reviewed your shipping paper lately? Several things have changed in the past several years. Here is a quick rundown of the changes:

- As of January 1, 2013, the identification number (UN number) must be immediately in front of the shipping name.
- In 2005, a change was made that required certain gases to show the subsidiary hazard class. If the material (other than combustible liquids) has a subsidiary hazard class shown in column 6 of the hazardous materials table found in 172.101, then it must be entered in parenthesis immediately following the primary hazard class or division number on the shipping paper. For example, oxygen gas will be shown as: UN1072, Oxygen, compressed, 2.2 (5.1).
- A couple of years ago, DOT added the requirement to have your company name on your shipping papers. This is in addition to already showing the emergency response company and phone number that you are using.

The following items are the most common mistakes that DOT finds on shipping papers:

- Failing to prepare a shipping paper.
- Failing to properly identify hazardous entries on a shipping paper that also includes non-hazardous entries.
- Failing to include the proper identification number, shipping name, hazard class, and/ or packing group.
- Listing an improper proper identification number, shipping name, hazard class, and/ or packing group.
- Including unauthorized information.
- Listing information out of sequence.
- Failing to properly identify "RQs".
- Failing to provide the total quantity.
- Failing to provide the type of package.
- Listing a package type not authorized or defined by DOT.
- Failing to include technical name(s) when required.





TRAFFIC BULLETIN

Common mistakes DOT finds on shipping papers(continued):

- Failing to list applicable exemption or special permit number(s).
- Failing to include or sign the required certification.
- Failing to include a 24-hour emergency response number .
- Failing to staff the listed number .
- Listing a fraudulent 24-hour number .
- Listing a number which is not working or is incorrect.
- The required response information is not listed on, or provided with, the shipping paper .
- The response information provided is inappropriate for the material.

The penalties for **these mistakes can run into the thousands of dollars**. If you have not reviewed your shipping paper recently, you should. I would be happy to review your shipping paper for you. I can spot mistakes very quickly and explain how to make the needed corrections. Just email me your shipping paper and I'll be happy to look it over.

Feel free to contact me on any of these items if you have questions.

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MEDICAL GAS BULLETIN

01/01/2013

Frequently Asked Questions

Q – What is the new Medical Gas Certification all about?

A – One of the important provisions of the Medical Gas Safety Act was to give the core medical gases the same status as “approved drugs”. The goal of Congress was to give us this protection **without** the costly drug user fees that all other drug manufacturers pay. In order for the FDA to process this request as simply as possible, the FDA has proposed a relatively form to “certify” medical gases.

This new certification process will not apply to most GAWDA members. The form is to be used by the **original manufacturer** of the medical gas. For oxygen and nitrogen, the original manufacturer is the Air Separation Unit. All subsequent manufacturers (most GAWDA members) will not need to submit the certification form.

If you make Medical Air, USP by blending Oxygen, USP and Nitrogen, NF, you will not need to complete the certification form. If you make Medical Air, USP with an air compressor, you are the original drug manufacturer and will need to complete the certification form.

This is one of the subjects we will cover in the online medical gas training in January. If you have any questions, send an email to tom@asteriskllc.com or plan on attending the training on January 4.

January Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On January 4, we will cover **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 on January 4:

- Medical Device Gases (QSR)** - Subparts A & B – Quality Systems Requirements
- Specialty Gas** - Gas Chromatography Method Development

These and other webinars are also 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 juliet@asteriskllc.com.





MEDICAL GAS 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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