GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

JANUARY 2014

ENCLOSED

Safety Topic: *"Chemical Inventory Reporting"*
Please contact GAWDA's OSHA and EPA Consultant, Mike Dodd for more information.

Traffic Bulletin: *"LPG Vendor Filled Cylinders"*
Please contact GAWDA's DOT and Security Consultant, Mike Dodd for more information.

Medical Gas Bulletin: Training Schedule Change, Important Compliance Alert, 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

GASES AND WELDING DISTRIBUTORS ASSOCIATION
8669 NW 36th Street, #130, Miami, FL 33166 (877) 382-6440 Phone (305) 442-7451 Fax

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:
http://www2.epa.gov/epcra-tier-i-and-tier-ii-reporting/state-tier-ii-reporting-requirements-and-procedures

To download the Tier2 Submit 2013 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 2014

LPG Vendor Filled Cylinders

Auditing the vendor

Do you have LPG cylinders being filled by outside vendors? If yes, you should consider auditing them. There is a sample audit checklist at the end of this Bulletin.

Cylinder Decals

DOT marking and labeling

DOT allows several different shipping names to be used as well as using 1075 for the identification number in place of the ID number 1978 shown in the hazmat table. This allowance is shown under special provision 19. The stipulation is that whichever name and ID number you use; you must be consistent on the cylinder decal and on the shipping paper. They must match.

Warning Label

NFPA 58 (2014) 5.2.8.4 requires warning labels for LPG cylinders. Warning labels shall be applied to all cylinders of 100 pounds of LP capacity or less. An example of this warning label is typically found on the 20 pound cylinders and is the rectangular decal with lots of precautionary words and a diagram of the top of a cylinder and valve.

OSHA Warning Label

There is also a suggested label with OSHA warning information on all cylinders used in commercial or industrial service. You typically find these on forklift cylinders and it is the decal with the 3 colored diamonds.

Checking Filled Weights (sampling)

Are you periodically check weighing cylinders filled by your vendor? This is an excellent way to double check that your liquefied gas cylinders are being filled to the proper amounts.

If there are any questions regarding this Bulletin, please contact:

Michael Dodd
GAWDA DOT, Security, OSHA & EPA Consultant
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Liquefied Petroleum Gas (LPG) Cylinder Filling Operations – Audit / Evaluation Checklist – of Third Party Cylinder Filling

(Insert Company Name Here)

Facility Name: _____

Physical Address: _____

Primary Contact: _____

Phone: _____ Email: _____

Date of Review: _____ Reviewed By: _____

	Review Item	Yes	No	Remarks
1	Is the facility registered with the state? (some states require registration – for filling LPG cylinders)			
2	Are employees engaged with filling of LPG cylinders trained? (look for training certificate per 172.704 (d) and test for items that were trained on)			
3	Training documents on file – for one to review? (within 3 years?)			
4	Are LPG cylinders filled by weight – using scale? (All cylinders under WC of 200 lbs. going onto streets must be filled by weight)			
5	If yes, to above, is scale check daily for accuracy? (checking for zero and against known weights)			
6	Is yes, is scale being checked by outside firm periodically – i.e. every six months, once a year per state guidelines?			
7	If no to answer #4 – are LPG cylinders filled by *spit-method*? (If the cylinders have less than 200 lbs. WC and going onto the public streets, they must be filled by weight.)			
8	Does firm have a thorough Standard Operating Procedures (SOP) for filling LPG cylinders?			
9	Is firm willing to share written SOPs with you?			
10	Does firm have a cylinder prefill inspection procedure – i.e. visual inspection of cylinder for defects, cylinder markings, current test date, etc? (Are they using CGA C-6 for steel and C-6.3 for low pressure aluminum?)			
11	Are cylinder fillers aware of LPG cylinder visual testing schedule – outlined by DOT / NFPA 58 – i.e. the first requalification for a new cylinder is required within 12 years after the date of manufacture – then every 5 years thereafter if using the visual method?			
	Review Item	Yes	No	Remarks
12	Does firm perform visual requalification of LPG cylinders?			

13	If yes to #12 – does firm have RIN issued by DOT? (Ask to see the authorization letter and check the expiration date on the authorization letter)			
14	If no to #12 – how does firm handle the visual inspection of LPG cylinders? (Do they send out of test cylinders to another vendor for requalification?) (If yes, then who do they use?)			
15	When LPG cylinders are requalified – are cylinders stamped or is firm using a decal – for current test dates and method – i.e. month-year-E=RIN (3-13 E V123456)?			
16	Does firm have process and procedure in place in the event a cylinder is overfilled?			
17	After cylinders are filled – is firm applying cylinder labels as needed? (DOT decal, OSHA warning decal, consumer warning decal)			
18	Are cylinder labels current with DOT / CGA regulations?			
19	Is the firm using proper Overfilling Prevention Device (OPD) cylinder valve in 4 lb through 40 lb grill-style cylinders?			
20	Does firm purge new cylinders of air and moisture? In addition to new cylinders – are cylinders that have been open to air due to cylinder maintenance shall be purged as well?			
21	Does the vendor confirm the fill weight after disconnecting the fill assembly?			

Remarks:

Items to consider when the vendor is filling LPG cylinders on our property

(Insert Company Name Here_

Please note: The following items are in addition to the preceding pages.

	Review Item	Yes	No	Remarks
1	Are the proper separation distances from other exposures being followed? (i.e., ignition sources, oxidizers, combustibles)			
2	Are they following your company PPE requirements?			
3	Are cylinders with less than 200 lbs. WC that will be going onto public streets being filled on a scale by weight?			
4	The only cylinders allowed to be filled by volume (spitter valve) are cylinders that will be used on the property where they are filled or if they are more than 200 lbs. WC going onto public streets. Is this policy followed?			
5	The preferred method of filling is to never use the spitter valve. Is this procedure being followed?			

Remarks:

MEDICAL GAS BULLETIN

01/01/2014

Training Schedule Change

In the past, the GAWDA Current Good Manufacturing Practices monthly training has been held on the first Friday of each month. We have received feedback that the last Friday would be more convenient. Beginning this month, the monthly training will be generally held on the last Friday of each month:

1-31-14	2-28-14	3-28-14	4-25-14
5-30-14	6-27-14	7-25-14	8-29-14
9-26-14	10-31-14	11-21-14	12-19-14

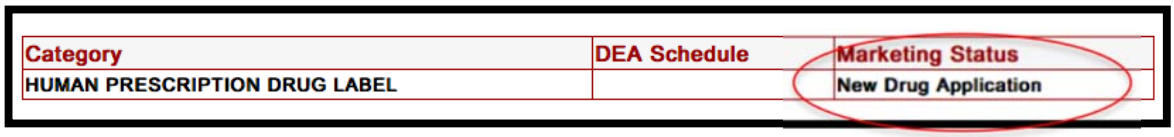
Important Compliance Alert – Medical Gas Certification - NDA

This GAWDA Medical Gas Compliance Alert is to inform GAWDA members that the FDA has developed a process to remove the "unapproved medical gas" label from certain drug listings. Before this process was implemented, the drug listing for medical gases looked like this:

Category	DEA Schedule	Marketing Status
HUMAN PRESCRIPTION DRUG LABEL		unapproved medical gas

NOTE: THIS DRUG HAS NOT BEEN FOUND BY FDA TO BE SAFE AND EFFECTIVE, AND THIS LABELING HAS NOT BEEN APPROVED BY FDA. For further information about unapproved drugs, click here.

Now the drug listing can look like this:



Category	DEA Schedule	Marketing Status
HUMAN PRESCRIPTION DRUG LABEL		New Drug Application

Q&A

1. **Who does this process apply to?** Only the "original manufacturer" of the medical gas can be certified and receive the New Drug Application number from the FDA.
2. **Who is the "original manufacturer"?** The first company to produce the drug is the original manufacturer. For oxygen and nitrogen, this will be the bulk air separation plant. For carbon dioxide, helium and nitrous oxide, the original manufacturer will be the validated plant that produced the product from the non-medical raw material.
3. **What about Medical Air, USP?** It's a little more complicated for medical air. If you produce medical air from the atmosphere with an air compressor, you are the "original manufacturer" of the medical air. If you blend Oxygen, USP and Nitrogen, NF together to make medical air, you are not the "original manufacturer".
4. **What is a "subsequent manufacturer"?** Each company that processes the medical gas after the original manufacturer is the subsequent manufacturer. Most GAWDA members who fill medical gases are subsequent manufacturers. If you fill medical oxygen cylinders and you do not own the ASU, you are a subsequent manufacturer.

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5. What's the regulatory basis for all this? Congress passed the Medical Gas Safety Act about 18 months ago as a part of the FDA reauthorization (FDASIA). One of the provisions of the Act was to remove the "unapproved" status from medical gases.
6. **I fill medical air with a compressor (as the original manufacturer). What do I need to do to remove the "unapproved medical gas" label from my drug listing?**
    a. In the Spring of 2013, you should have completed the medical gas certification application. (If you still need to complete the application, let us know.)
    b. The FDA should have sent you a letter titled "Acknowledge – Medical Gas Certification Request". This letter should have included an NDA number.
    c. Resubmit your listing for medical air and add the NDA number in the pull down menu. If you listing submission fails due to data validation issues, contact the SPL office and give them your "coreid" for the submission. The SPL office can override the data validation error and process your submission. If there are other errors on the X-Form, these errors should be corrected before contacting the SPL office for an override.
    d. If AsteRisk, or another company, processed your FDA Drug Listing, have them resubmit your listing with the NDA number to remove the unapproved medical gas distinction.
7. **How does a subsequent manufacturer (most GAWDA medical gas members) remove the unapproved medical gas from its listing?** The FDA is implementing a process to allow subsequent manufacturers to have the benefits of the "New Drug Application" without going through the certification process of the original manufacturer. Here are the steps:
    a. Ask your bulk medical gas supplier for their NDA number on each bulk medical gas that you buy.
    b. Update your drug product listing with their NDA number.
    c. Handle data validation errors as above.
8. **How can I verify that my FDA drug listing is not an unapproved medical gas?**
    a. Log on to: http://dailymed.nlm.nih.gov/dailymed/search.cfm
    b. Enter your labeler code in the search window and all of your drug listings will be displayed.

If you have questions about this, or other FDA issues, please contact Tom Badstubner: tom@asteriskllc.com.

We are meeting with the FDA next week about these procedures. There is a good chance that some of the items above could be revised by then. **We are scheduling a free GAWDA Compliance Update teleconference at 2:20 PM EST on 31 January 2014 in order to bring all members up to date with this new procedure. We will send teleconference details out to GAWDA members before the teleconference.**

MEDICAL GAS BULLETIN

January Medical Gas Roundtable (31 January 2014)

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.

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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