GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

MAY 2019

ENCLOSED

Safety Topic: GAWDA Sample Safety Policies

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

Traffic Bulletin: Hazardous Materials Registration Program (Virtually ALL Distributors are affected)

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1 FAQ: I do not fill my own food/beverage gases. Do I need to register with the FDA to warehouse food/beverage gases? What about medical gases?

FAQ: What should I do if an FDA investigator asks me to sign an affidavit?

2. Recent FDA Observations: Buildings

3. May Medical Gas Roundtable (31 May 2019): Subpart E – Control of Components Training.

Specialty Gas – Making Your Own Working Calibration Gas Standard ;

Food Gas Roundtable- CGMP Training – Part 117 Subpart C – Hazard Analysis and Risk Prevention Controls (HARPC) – General Program

4. 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 _____

GAWDA Sample Safety Policies

The GAWDA Safety Committee has put together sample safety policies. Here is an example of one of the many available off the member resources portion of the GAWDA website. Recently one of our members had a near miss with a liquid nitrogen cylinder in an elevator when the power went off while the driver was in the elevator with the cylinder. Thankfully they called the fire department and the driver was extracted from the elevator before the cylinder needed to vent off any pressure.

PURPOSE	To provide guidelines for the safe transportation of pressurized cryogenic liquid containers in an elevator
RESPONSIBILITY	All individuals transporting pressurized cryogenic liquid containers in freight elevators
AUTHORITY	Plant Manager and/or Distribution Manager

Transport of Pressurized Cryogenic Liquid Containers in an Elevator (Insert Company Name Here)

Key Considerations

1. Pressurized cryogenic liquid cans are equipped with pressure relief devices that operate in order to keep the container in safe operating condition. Special precautions shall be taken in order to ensure container pressure relief devices do not function during transportation in an elevator. Such condition may cause an unsafe atmosphere in the elevator.

2. Cryogenic liquid containers are considered bulky packages. Special consideration shall be taken in order to provide safe transport in an elevator. Such precautions are, but not limited to, preventing container from tipping over and preventing container from moving during transport in the elevator.

3. Containers that appear to be damaged shall not be transported in an elevator unless it has been determined there is no product in container.

4. Always wear the proper personal protective equipment. Recommended personal protective equipment includes, but not limited to:

- Safety Glasses
- Leather or other suitable gloves
- Safety Shoes
- Personal oxygen monitor

5. Due to the potential of an unsafe atmosphere in an elevator, it is recommended that unoccupied freight elevators are used to transport pressurized cryogenic liquid containers. However, there may not be a freight elevator available. Recommendations are provided below for reducing the hazards associated with transporting pressurized cryogenic containers in a freight elevator, as well as, a passenger elevator.

Transportation of a Pressurized Cryogenic Liquid Container in a Freight Elevator

1. Inspect container for damage prior to transport in elevator. Damaged containers shall not be transported in an elevator unless it has been determined that it is free of product.

2. Verify pressure of container is at least 3 psig below the equipped pressure relief valve. If not vent liquid container to at least 5 psig below the equipped pressure relief setting per manufacturer's instructions.

3. It is recommended that transporting a cryogenic liquid can in a freight elevator be unoccupied. In order to minimize the efforts, it is suggested that at least two people conduct this job task.

a. Second person shall be stationed at the receiving floor elevator door.
b. First person shall position the container in the elevator. Container shall be on an approved cart with the wheels chocked or locked to prevent movement during transport. If the container is equipped with wheels or casters, a cart may not be used; however, the wheels or casters shall be properly locked or chocked.
c. First person shall place a sign on container or in elevator stating, "Please do not enter while freight in transport" or similar.
d. First person shall press the appropriate floor button on the elevator and leave the elevator.
e. Second person shall wait for the elevator to arrive at floor. When door opens, the person shall inspect the elevator to ensure container is still in upright position and appears to be secure.
f. Once inspected and deemed safe, container is ready to be removed from elevator.

Transportation of a Pressurized Cryogenic Liquid Container in a Passenger Elevator

In the event a freight elevator is not available, and a passenger elevator must be used, these steps are recommended.

1. Inspect container for damage prior to transport in elevator. Damaged containers shall not be transported in an elevator unless it has been determined that it is free of product.

2. The attendant must possess a supplemental breathing apparatus (PPE) in case of a catastrophic release of product into a confined area—no other personnel are allowed in the elevator other than the attendant

3. The Dewar (liquid can) must be secured in the elevator with either wheel brakes or chocks and the attendant must stand opposite the container with an escape route in the event of movement

4. Once the floor is attained and the can is deemed safe, then the container is ready to be removed from the elevator.

Again, the purpose of this sample policy is to reduce accidents in the workplace and to provide our members with a template that they can use to write their own safety policy.

Feel free to contact me if you have any questions.

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Traffic Bulletin

May 2019

HAZARDOUS MATERIALS REGISTRATION PROGRAM

In 1992, the Pipeline and Hazardous Materials Safety Administration (PHMSA) set up a national registration program and annual fee-collection system for a person offering for transport, and transporting, certain hazardous materials depending on the quantity. The annual fee funds a nation-wide emergency response training and planning grant program for states, Indian tribes, and local communities.

In 2000, PHMSA issued a final rule under docket HM-208C, which changed the hazmat and registration fee program. Registration is required for each person that offers or transports **any shipment of hazardous materials that requires placarding.** The final rule was intended to increase funding for the Hazardous Materials Emergency Preparedness (HMEP) grants program.

Virtually All Distributors Are Affected

Applicability

The program's registration and fee requirements apply to any person who offers for transportation or transports - in foreign, interstate, or intrastate commerce - any hazardous materials that require placarding.

How to Register and Fee Requirements

Each person required to register must do so by June 30 of each year. PHMSA will then issue you a Certificate of Registration. The annual registration fee is based on the size of your company. Currently, the fee is $275 ($250 fee plus a $25 processing fee) for any business meeting the Small Business Administration's (SBA) criteria for a small business (less than 100 employees in the company) and $2,600 ($2575 fee plus the $25 processing fee) for all other companies. You may register for one, two, or three registration years by completing a single registration form and submitting the appropriate fees.

Registering Through the Internet

You may register via the Internet by going to https://www.phmsa.dot.gov/registration/registration-overview and registering by one of two methods.

You can register online through the PHMSA Portal https://www.phmsa.dot.gov/registration/online-registration and the website provides tips and

instructions on how to do this. Using the Portal is new this year so be prepared that it is not how you have done it in the past.

You can also go to the first above PHMSA web page and download the Registration Form and Instruction Brochure if you prefer to mail in the registration and fees but this will take about 4 weeks to process and receive your registration.
https://www.phmsa.dot.gov/registration/registration-mail You must have your new registration before July 1st so if you register by mail then you need to do this sometime in May.

What If You Have Failed to Register for Past Years?

If you engaged in any of the hazardous materials activities described in 49 CFR 107.601 (a)(1) through (a)(6), which is also shown as items 1 through 6 on the first page of this bulletin, in any of the registration years 2000-2001 and later, you must register for those years where you offered or transported placarded amounts of hazardous materials.

Penalties for Failure to Register

The requirement to register with DOT is based on federal law. The enforcement of this requirement is conducted cooperatively by federal, state, and local agencies. Federal, state, or local officials may impose penalties for failure to register or failing to meet the recordkeeping requirements. For small companies, the proposed penalty for failure to register is $1,200 plus $600 for each additional year that the company was not registered and then they make you go back and register for each of the years missed. As you can see this can add up real fast.

Recordkeeping

Motor carriers subject to the registration requirements must carry, on board each vehicle that is transporting a hazardous material requiring registration (not including trailers or semi-trailers), a copy of the carrier's current Certificate of Registration. In addition, each company subject to the program must maintain a copy of the registration at their principal place of business for three (3) years from the date of the certificate's issuance.

Feel free to contact me if you have questions.

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin
05/01/2019

Frequently Asked Questions

Q – I do not fill my own food/beverage gases. Do I need to register with the FDA to warehouse food/beverage gases? What about medical gases?

A – If you fill **AND/OR** warehouse food gases, you need to register your food facilities with the FDA. To restate, even a food gas warehouse must register with the FDA.

However, for medical gases, you usually only need to register with the FDA for manufacturing operations (production, repacking, transfilling). Locations that do not manufacture medical gases, but only distribute gases filled by another company, usually must be licensed by the states in which they distribute… but not the federal FDA. Please contact jodie@asteriskllc.com if you would like more information.

Q - What should I do if an FDA investigator asks me to sign an affidavit?

A – We recommend that you never sign an affidavit from an FDA investigator before your corporate counsel approves it. In most cases, your lawyer will not approve the signing of the affidavit. The investigator may ask you to make some corrections or simply acknowledge the affidavit. Once again, we recommend that you politely let the investigator know that you are not permitted to sign, correct or acknowledge the document.

The investigator has been trained to get your signature and/or acknowledgment. For example, see the following section from the FDA's *Investigations Operations Manual:*

> *4.4.8.2 - Refusal to Sign the Affidavit*
>
> *Prepare the statement as described above even if it is apparent the affiant will refuse to sign the affidavit. Have the affiant read the affidavit. If they decline, read it to them. Request the affiant correct and initial any errors in his/her own handwriting. Ask the affiant if the statement is true and correct. Ask him/her to write at the bottom of the statement "I have read this statement and it is true, but I am not signing it because..." in his/her own handwriting.*
>
> *If the affiant still does not sign the affidavit, you should write a statement noting the refusal situation. Write this near the bottom and within the body of the affidavit. Include the actual situation, such as, you recorded the above facts as the affiant revealed them, the affiant read or refused to read the statement and avowed the statement to be true, and the affiant's reason for refusing to sign (e.g., "upon advice of corporate counsel", "per corporate policy", etc.). Sign and date this statement in the body of the document; only sign in the signature block if the affiant signs the affidavit. Once the refusal is documented on the affidavit, it is not necessary to include any additional narrative under the refusals section of the EIR.*

Be polite and respectful to the inspector, but do not sign, initial or acknowledge an affidavit unless instructed by your corporate counsel. The affidavit is designed to help the FDA and not to help you.

Recent FDA Observations

Please see these excerpts from actual FDA inspections at medical gas companies. Consider if these observations could happen at your facility and correct the problem, if needed. For the full list of recent FDA observations and a training record, contact tom@asteriskllc.com.

Medical, Food/Beverage and Specialty Gases Bulletin

Please forward a scanned copy of any FDA inspections you receive. We will remove any company identification and include in the recent FDA activity report.

Buildings

Form 483 Observation-03-03 - Buildings used in the manufacturing and holding of a drug product are not maintained in a good state of repair. Specifically,

- There was dirt and debris located on the floor in the ___ Fill Manifold area where the filling operations for the Liquid Oxygen USP product occurs.
- There was a 4 to 5 inch hole at the bottom of the dock door next to the area where their Liquid Oxygen USP product filling operations occur.

How to prevent this from showing up in your inspection?

Daily sweep up the fill area and maintain the building to a reasonable standard. We are not going to be able to have a perfect pest exclusion system, however, we can repair the obvious rodent entry holes.

May Medical Gas Roundtable - Subpart E – Control of Components Training

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, May 31, we will cover **Subpart E – Control of Components Training**. This training covers the qualification of your raw materials (including bulk products) used in making medical gases.

In addition, we will be conducting the following additional training on May 25:

- ***Specialty Gas*** - Making Your Own Working Calibration Gas Standards
- **Food Gas Roundtable** –
  - CGMP Training – Part 117 Subpart C – Hazard Analysis and Risk Prevention Controls (HARPC) – General Program
  - The latest information about food gas regulations is reviewed –
  - The sample Food Gas SOPs are available for downloading during the seminar.

If you would like to receive invitations to the training webinars, just send an email to jodie@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. **Dead Ring Test –** Verify that the dead ring test is actually being performed on high-pressure steel oxygen cylinders. Of course, the dead ring test should not be performed on aluminum cylinders.

Medical, Food/Beverage and Specialty Gases Bulletin

2. **Certificate of Analysis (CoA) –** Be sure that the CoAs you receive for your bulk medical product and for your Servomex span/zero gas cylinders have the following mandatory items:

   - ❑ Name and address of the calibration standard supplier
   - ❑ Name of the product
   - ❑ Lot number or unique identification number specific for each cylinder
   - ❑ Analytical methodology used to assay the calibration standard
   - ❑ Actual analytical results (for example, 99.9 percent nitrogen)
   - ❑ The responsible person's signature and the date signed

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