

SAFETY & TECHNOLOGY ORGANIZER

MAY 2013

ENCLOSED

Safety Topic: “Nitrous Oxide Safety”

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

Traffic Bulletin: “Hazardous Materials Training”

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.



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 _____

Nitrous Oxide Safety

Recently, one of our members brought to the attention of the GAWDA Safety Committee a recent incident of nitrous oxide abuse at a music concert. The 3 day concert had about 20,000 people floating around for the weekend. The sheriff's dept. contacted the member and asked if he could dispose of 63 small nitrous oxide cylinders they confiscated. The cylinders they dropped off were mostly CO2 but some were actual nitrous with the proper CGA valve. All apparently had been refilled by someone, most had wrong labels or no labels, some were within hydro, and some just recently reconditioned. The police told the member to Google "nitrous mafia", which he did and found the following website: <http://www.villagevoice.com/2010-07-06/music/hippie-crack-nitrous-mafia-boston/>. It is a long article with foul words but it unfortunately is very insightful to the extent of the problem.

There was an excellent article published in the November 2010 Welding & Gases Today Online entitled "***Who Is Accountable For Product Abuse? And Other Conundrums...***" I highly suggest reading or refreshing your memory with this article. <http://www.weldingandgases.com/index.php/2010/11/who-is-accountable-for-product-abuse-and-other-conundrums/>

CGA has a Safety Bulletin, SB-6 - 2008, *Nitrous Oxide Security and Control* that has very good guidelines on the security and sales of nitrous oxide. It will offer you guidelines on storage, securement of the cylinders on your property, reporting incidents, suggested security measures to take, and sales to customers.

Additional security guidance can be found in the following publications:

CGA P-50, *Site Security Standard*, which provides guidance to the compressed gas industry for assessing security risks and identifying and implementing preventive security measures at fixed sites;

CGA P-51, *Transportation Security Standard for the Compressed Gas Industry*, which provides guidance for securing product during shipment; and

CGA P-52, *Security Standard for Qualifying Potential Customers of Compressed Gases*, which provides guidance to the compressed gas industry for qualifying potential customers who purchase products that are considered at risk for illegal use.



Unfortunately, nitrous oxide theft and abuse is still with us. Therefore, we need to use proper due diligence to minimize the risk to our membership.

If you have signed up for the CGA / GAWDA, then you can download these publications and more for free. If you need to sign up, then go to this website:

<http://www.cganet.com/customer/gawda.aspx>

Feel free to contact me if you have questions.





TRAFFIC BULLETIN

May 2013

Hazardous Materials Training

Overview

49 CFR 172.700-704 requires that each hazardous materials employer train its hazmat employees to safely load, unload, handle, store and transport hazardous materials.

A hazmat employer must train, test and certify every hazmat employee who, in the course of employment, has any function that directly affects hazardous materials transportation safety.

Definitions

A **hazmat employer** refers to a person who uses one or more employees in connection with:

- Transporting hazardous materials in commerce;
- Causing hazardous materials to be transported or shipped; or
- Representing, marking, certifying, selling, offering, manufacturing, reconditioning, testing, repairing, or modifying containers, drums, or packagings as qualified for use in the transportation of hazardous materials

A **hazmat employee** refers to an individual, including a self-employed individual, who, during the course of employment:

- Loads, unloads, or handles hazardous materials;
- Manufactures, tests, reconditions, repairs, modifies, marks or otherwise represents containers, drums or packagings as qualified for use in the transportation of hazardous materials;
- Prepares hazardous materials for transportation;
- Is responsible for safety of transporting hazardous materials; or
- Operates a vehicle used to transport hazardous materials.





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Types of Training

Hazardous materials training must include:

- **General Awareness/Familiarization** - Each hazmat employee must receive general awareness/familiarization training designed to provide familiarity with the HMR requirements and to enable the employee to recognize and identify hazardous materials consistent with the hazard communication standards in the regulations.
- **Safety** - Each hazmat employee must receive safety training concerning emergency response information, measures to protect the employee from the hazards associated with materials to which he may be exposed to in the workplace, and methods and procedures for avoiding accidents.

Note: A hazmat employee who repairs, modifies, reconditions, or test packagings as qualified for use in the transportation of hazardous materials, and who does not perform any other function subject to the regulations, does not have to receive safety training.

There is a provision under the regulations that if you have conducted safety training under OSHA or EPA requirements, then you don't have to duplicate the training for DOT.

- **Security Awareness** – Each hazmat employee must receive security awareness training. This training must include an awareness of security risks associated with hazardous materials transportation and methods designed to enhance transportation security. A component covering how to recognize and respond to possible security threats must be included.

DOT has issued a revised CD that covers the security awareness training very well. The new version has feature of allowing an employee to sign in, watch the CD to receive the training, answer questions, and then print a training document for your file. It is found on the Hazmat Digipack and is available for free at https://hazmatonline.phmsa.dot.gov/services/Pub_Free.aspx

On the same website is a free hazmat general awareness / familiarization training CD.

Completion of these training modules and the interactive test will meet the hazmat and security awareness-training requirements.





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- **Function-specific** - Each hazmat employee must receive function-specific training concerning the regulations specifically applicable to the functions the employee performs. The specific training will vary depending on the individual's specific job functions. What is needed by a shipping clerk, a driver, the compliance officer, even the person who prepares the shipping papers, will vary in the detail according to what functions they are performing.

Our members that either fill cylinders and/or requalify cylinders must train, test and certify their employees in their specific jobs.

- **Driver Training** - In addition to the above training, each mode of transport (highway, rail, air, or water) has additional training requirements. For example, by highway, driver training is required for a hazmat employee who drives a vehicle transporting hazardous materials. The driver must be trained on the safe operation of the motor vehicle and the applicable requirements of the Federal Motor Carrier Safety Regulations.

Training Timetables

A new hazmat employee, or a hazmat employee who changes job functions must be trained, tested and certified before they perform the hazmat work. Those employees may perform those functions prior to the completion of training provided the employee performs those functions under the direct supervision of a properly trained and knowledgeable hazmat employee; and the training is completed within 90 days after employment or a change in job function.

Each hazmat employer must train, test and certify each hazmat employee at least once every three years.

However, if a new regulation is adopted or an existing regulation is changed, that relates to a function performed by a hazmat employee, that employee must be trained, tested and certified on the new or revised regulations. This training must be completed before the employee performs the function and before the three year recurrent training is required. The employee only needs to be instructed on the new or revised requirements.

Transferability of Other Employment Training

Relevant training received from a previous employer or other source may be used to satisfy the training requirements, provided a current record of training is obtained from the hazmat employee's previous employer.





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Record of Training

A record of current training must be in writing and must include the following elements on the certification:

1. The hazmat employee's name;
2. The most recent training completion date of the hazmat employee's training;
3. A description, copy, or the location of the training materials used to do the training;
4. The name and address of the person providing the training; and
5. Certification that the hazmat employee has been trained and tested, as required by this subpart.

You must keep the certification for as long as that employee is employed and for 90 days after they leave your employment.

Training Sources

There are also training programs available from several vendors, such as JJ Keller and CGA.

I also conduct hands-on training for your employees at your location. I have programs for the hazmat General Awareness, Safety, and Security Awareness as well high-pressure, liquid containers, LPG and acetylene cylinder filling as well as programs for high-pressure, low pressure, and acetylene cylinder requalification.

Training is the best way to ensure the safety of your employees and your customers.





MEDICAL GAS BULLETIN

04/01/2013

Frequently Asked Questions

Q – What is going on with the new FDA medical gas "certification"?

A – The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. Among other provisions, FDASIA provides a framework for approving “designated medical gases.”

Congress designated the core medical gases (and their mixtures) to have status similar to “approved” drugs. These gases are oxygen, nitrogen, air, helium, carbon dioxide, nitrous oxide and carbon monoxide. In order to grant approval status to these drug gases, the FDA requires a simple “certification” process.

Medical Gas Certification applies **ONLY** to the “**original**” manufacturer of the medical gas:

- Air Separation Plants and CO₂/N₂O/Helium plants
- GAWDA members who make medical air with a compressor. (If you make medical air by blending oxygen and nitrogen, you will **not** need to certify.)

If you are filling oxygen cylinders (or other medical gases) with bulk product supplied by an air separation plant, **Medical Gas Certification does not apply** to you.

The instructions for certifying are found in the draft “*Guidance for Industry - Certification Process for Designated Medical Gases.*” See:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM332136.pdf>

The application (FDA Form 3864) is found after page 12 of the draft guidance. If you would rather have us complete your certification form, just let Juliet know (Juliet@asteriskllc.com). This is a free benefit to all GAWDA distributor members.... Even if your registration is handled by others.

We recommend that GAWDA members who make Air, USP by compression complete their FDA Form 3864 by May 9, 2013. This will give the FDA plenty of time to evaluate the certification application before their July 2013 deadline. Be sure to keep a copy of your certification application and send it to the FDA with a certified/signed delivery. If the FDA does not send you a response to your application, you are automatically granted certification after 60 days.

In late 2013, we will have a process in place to verify the certification of your supplier.





MEDICAL GAS BULLETIN

May Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, May 3, 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 3:

- **Medical Device Gas** - QSR Subparts G, H, I & J - Production and Process Controls, Acceptance Activities, CAPA, Non-Conforming Product
- **Specialty Gas** - Making Your Own Working Standards
- **Food Gas Roundtable** – 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 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. **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. This simple item has appeared in recent FDA audits.
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)
3. The responsible person's signature and the date signed

