

SAFETY & TECHNOLOGY ORGANIZER

AUGUST 2018

ENCLOSED

Safety Topic: Forklift Maintenance and Inspection

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

Traffic Bulletin: Hazardous Materials Training

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

- 1. Recent FDA Observations: Excerpts from actual FDA inspections at medical gas companies: Labels & Labeling.
- 2. Frequently Asked Questions: What are the most common violations for FDA food inspections?
- 3. <u>SEMINARS</u>: Upcoming Training & Dates: GAWDA Professional Compliance Seminar (10/16-18): DOT Audit Survival, FDA PCQI & Drug CGMP Training. August Medical Gas Roundtable (08/31/2018) CGMP Practical validation for the cylinder plant. <u>WEBINARS</u>: Food Gas Roundtable Part 118 Subpart C Corrective actions and corrections, Verification, Validation. Specialty Gas Fuel/Oxidizer Safe Practices (2000 BTU & CGS P-36).
- 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.





SAFETY TOPIC

| | Safety | Meetings | are im | portant! |
|--|--------|----------|--------|----------|
|--|--------|----------|--------|----------|

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 | | |
| | S. T. | | |

Forklift Maintenance and Inspection

The OSHA standard for powered industrial truck training requires that an employer provide training to truck operators on a variety of topics. Among these topics are vehicle inspection and maintenance that the operator will be required to perform.

Maintenance

1910.178 (q)(1) Any power-operated industrial truck not in safe operating condition shall be removed from service. All repairs shall be made by authorized personnel.

1910.178 (q)(7) Industrial trucks shall be examined before being placed in service, and shall not be placed in service if the examination shows any condition adversely affecting the safety of the vehicle. Such examination shall be made at least daily. Where industrial trucks are used on a round-the-clock basis, they shall be examined after each shift. Defects when found shall be immediately reported and corrected.

1910.178 (q)(10) Industrial trucks shall be kept in a clean condition, free of lint, excess oil, and grease. Noncombustible agents should be used for cleaning trucks. Low flash point (below 100 deg. F.) solvents shall not be used. High flash point (at or above 100 deg. F.) solvents may be used. Precautions regarding toxicity, ventilation, and fire hazard shall be consonant with the agent or solvent used.

1910.178 (q)(6) Additional counterweighting of fork trucks shall not be done unless approved by the truck manufacturer.

Inspection

The following checklists are being provided as part of OSHA's ongoing effort to assist employers and employees in ensuring that a safe and healthful workplace is provided. The lists serve as a guide only and may not be totally inclusive. Each type of powered industrial truck is unique and checklists pertinent to each type of vehicle should be modified accordingly. It is recommended that the manufacturer's instructions on vehicle maintenance and owner's and operator's responsibilities also be consulted.

Here are two OSHA websites that have sample inspection forms that you can copy into your word processor and modify to your particular powered industrial truck.

This first one is easier to copy from and make your inspection forms:

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http://www.osha.gov/dte/library/pit/daily_pit_checklist.html

This site has information on most types of powered materials handling equipment:

http://www.osha.gov/dte/library/pit/pit_checklist.html

As always, if there are questions or items that I can help you with, please don't hesitate to contact me.

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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.

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.

I can send you a hazmat test with answers along a page where the employee puts their answers which also serves as the training documentation page. You will need our four gas placards, some cylinder decals, and the current emergency response guidebook as training aids while giving the test.

• 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.

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 regualification.

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





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Medical, Food/Beverage and Specialty Gases Bulletin

08/01/2018

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. 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.

Labels and Labeling

Form 483 Observation-02-03 - Strict control is not exercised over labeling issued for use in drug product labeling operations. Specifically, on ____, I observed two rolls of product identification labels for Carbon Dioxide USP left unattended on a desk in Building ____, which is used for filling compressed Carbon Dioxide USP cylinders and is not a controlled label storage location.

How to prevent this from showing up in your inspection?

Assure medical gas labels are secured.

Frequently Asked Questions

Q – What are the most common violations for FDA food inspections?

A – The most common violations we are seeing are sanitation and pest control. If a state or federal inspector observes spider webs or mouse droppings in the production and warehousing areas, you are likely to have a violation. In addition, assure your restrooms are clean at all times. Consider using the facility checklist found in the sample food procedures. If your self-inspections find unclean areas or rodent/insect evidence, take effective corrective action. Also consider hiring a pest control firm for your plant. Assure that the pest control firm is only applying chemicals/processes approved for food production and storage areas.

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GAWDA Professional Compliance Seminar – Audit Survival

Hold The Date (October 16-18, 2018)... GAWDA Professional Compliance Seminar at Weldcoa, Aurora, IL. Click here for more information.

This seminar focuses on:

- DOT Audit Survival
- FDA PCQI and Drug CGMP Training

August Medical Gas Roundtable (08/31/2018) – CGMP – Practical validation for the cylinder plant

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In August we will be discussing practical process validation techniques for cylinder fill operations:

- sample systems
- check valves
- fill processes
- portable fill manifolds

This seminar focuses on ways to save money while improving compliance.

For your information, we are also conducting the following **webinars in August**:

- Specialty Gas Fuel/Oxidizer Safe Practices (2000 BTU & CGS P-36)
- Food Gas Roundtable Part 118 Subpart C Corrective actions and corrections, Verification, Validation

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 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. Portable Oxygen Manifolds – If you are using a portable oxygen manifold, be sure you have validated and documented the manifold.

Medical, Food/Beverage and Specialty Gases Bulletin

2. Automatic, mechanical or electronic equipment – Be sure all major equipment used to produce your medical gases are covered in a maintenance program. The equipment that needs calibration should be within the calibration date (gauges, thermometers, etc.).

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