GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

AUGUST 2019

ENCLOSED

Safety Topic: GAWDA Sample Safety Policy: Mechanical Lifting Devices

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

Traffic Bulletin: Auditing Your Hydrotest Vendor

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. Florida Compliance: medical gas company banking records being reviewed by DBPR
2. Recent FDA Observations: Labels and Labeling
3. FAQ's: Do I need to have my Servomex span gas certified?

4. GAWDA Professional Compliance Seminar – DOT and FDA (Food/Beverage and Medical Gases) – Train the Trainer Training (dates); August Medical Gas Roundtable: (08/30/2019) – CGMP – Practical validation for the cylinder plant; Specialty Gas – Fuel/Oxidizer Safe Practices (2000 BTU & CGS P-36); Food Gas Roundtable- Part 117 Subpart C - Corrective actions and corrections, Verification, Validation.

5. Micro Audit Suggestions

Please contact Tom Badstubner, GAWDA FDA Food, Medical & 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 _____

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.

GAWDA GASES AND WELDING DISTRIBUTORS ASSOCIATION

Mechanical Lifting Devices

(Insert Company Name Here)

Purpose	To provide a set of proposed guidelines for using mechanical lifting devices in the fill plant.
Responsibility	Material handling personnel
Authority	Facility manager and fill plant manager

Mechanical lifting devices such as hoists and slings, are an integral part of a fill plant operation which raise and lower items vertically and or horizontally. These devices are time savers if used wisely. The following guidelines will assist the operator to move cylinders and other large items safely and efficiently.

Installation, Maintenance, and Preparation for Use

1. Install, maintain, and inspect all mechanical lifting devices in accordance with the manufacturer's guidelines and federal, state, and local codes.
2. Never attempt to modify or alter the power unit, pulleys, lifting cable or chains, or hooks.
3. Do not remove or obscure any warning labels or markings on the equipment. The lifting capacity of the mechanical lifting device should be visible to the operator.
4. Identify personal protective equipment requirements for equipment operation (PPE).
5. Ensure that all operators are trained and qualified to operate the lifting equipment.

Hoists

Many locations have small overhead hoist devices that are hand-chain operated or electric-powered that are used for vertical lifting and lowering of freely suspended loads that are affixed to a monorail or beam.

The weight capacity of the device, trolley, and beam to which the lifting device is attached must be clearly marked on the device and beam and be visible to the operator.

Ensure that all components have sufficient capacity so that any component of the system (beam, trolley, hoist) is not overloaded (e.g., the hoist is not rated for more than the capacity of the beam).

The hook at the end of the chain must be affixed with a serviceable safety latch and have sufficient weight capacity to coincide with the capacity of the hoist and the structure to which it is attached.

Lifting devices must be included in the facility's preventive maintenance program, which should be based on the equipment manufacturer's recommendations.

A visual inspection prior to use each shift day is required. The inspection must cover the operating mechanism, hoist upper limit switch, braking system, hook and safety latch, and chain to ensure proper and safe operation.

If using an electric hoist, it must be compatible with the electrical classification of the area in which it operates.

Slings

Each day, prior to using a sling, a competent person (designated by the employer) shall inspect the sling and all fastenings and attachments for damage or defects. Additional inspections shall be performed during sling use, where service conditions warrant. Immediately remove damaged or defective slings from service.

Any chain, rope, sling, or hooking device that shows any defect must be immediately removed from service and destroyed. Refer to local regulations and manufacturer’s recommendations for fit-for-use criteria.

Hooks, rings, oblong links, welded or mechanical couplings links, or other attachments shall have a rated capacity at least equal to the chain. If not, do not use the sling in excess of the rated capacity of the weakest component.

During Operation

1. Ensure that proper PPE and warning devices, such as safety cones are employed during the operation
2. Avoid man-baskets
3. When performing lifts, keep loads as low to the ground as reasonably safe
4. Secure the load once it has been lifted into place and return the lifting device to a properly stowed position.
5. During hoisting, care must be taken so there is no sudden acceleration or deceleration while moving the load
6. NEVER allow people under or near a supported load.
7. Never leave the controls when the load is suspended
8. Never use mechanical lifting devices for side pulls

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

Traffic Bulletin

August 2019

Auditing Your Hydrotest Vendor

Do you know if the cylinders that you send out for requalification are being done properly and that the facility is in compliance?

Use the checklist on the following 3 pages as a guideline for auditing vendors.

Some additional questions to ask are:

- Are they using an oxygen compatible thread lubricant?
- Are they applying the "+" and the "five-pointed star" on the proper cylinders?
- Are they using a valving procedure that helps eliminate neck leaks?

A suggested valving procedure for ¾" NPT style valves to help eliminate leaks is as follows:

(Please note: Verify the cylinder really is empty immediately prior to removing any valve from a cylinder. This is done by injecting a hydrocarbon free compatible gas into the valve opening. If gas comes back out, it proves the valve is open and not plugged.)

- Ask yourself the question, "Did this valve come out of this cylinder?" If not, then you need to do what I call double valving.
- Wrap the end of the valve threads with 1 ½ turns of an oxygen compatible Teflon tape. Any more than that is wasting tape and possibly increasing your chances of a leak.
- Insert the valve into the cylinder until snug with a gloved hand. The valve must be in at least 4 turns and no more than 8 turns. This will leave 1 thread left showing. If you want 2 threads left, then limit the number by hand to 7 turns.
- Tighten the valve 3 more turns with a wrench or valving machine.
- If this is the first time this valve has been in this cylinder, then remove the valve and repeat these steps again.

The first valving mates the valve threads to the cylinder threads but it still has a good chance of being a leaker. The second valving takes a properly mated valve and installs it with a seal that will help eliminate most neck leaks. Try it; it works.

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

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Traffic Bulletin

Facility Name: _____

Physical Address: _____

RIN: _____ Primary Contact: _____

Phone: _____ Fax: _____

Date of Review: _____ Reviewed By: _____

	Review Item	Satisfactory	Unsatisfactory	Conditional
1	Is the facility registered with the DOT? (You should see the DOT letter of approval posted near or next to the testing equipment. Check the date of the approval. It is valid for 5 years past the date of the approval.)			
2	Is the equipment, management, hydrotest operators, etc. the same as when the third party inspector performed their review? (You will find this information in the application letter. 107.805(g) Each holder of a current RIN shall report in writing any change in its name, address, ownership, testing equipment, or management or personnel performing any function under this section, to the Associate Administrator (DHM-32) within 20 days of the change. If any of the above have changed, did they send in the update letter?)			
3	Does the facility maintain current copies of 49 CFR that pertain to hydrotesting? (This will be the 49 CFR 100-185 and Part 180 is the section on requalification. The CFR should be within 2 years.)			
4	Does the facility maintain the current copies of the CGA Pamphlets? (They should have C-1, C-5, and then based the type of cylinder then might require the following pamphlets: C-6 for steel, C-6.1 for high pressure aluminum, C-6.2 for fiber reinforced cylinders, and C-8 for 3HT cylinders. Check the CGA website for the current versions available. There may be other pamphlets as needed.)			
5	Does the operator understand how to handle cylinders marked with DOT exemption numbers E 6498, E 7042, E 8107, E 8364, and E8422? (Must be stamped 3AL above the E XXXX number.)			
6	Are the markings stamped on the cylinders legible?			
7	Are cylinders hydrotested to the required test pressure? (Check the cylinder specification stamped on the cylinder and then look at the table found in 180.209 or on the DOT exemption.)(Special permit cylinders will have the test pressure specified in the actual special permit.)			
8	Is the test pressure maintained for at least 30 seconds or longer if the cylinder is still expanding? Some special permits require 60 seconds. (The 30 second hold time starts after the pressure and expansion have stopped.)			

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	Review Item	Satisfactory	Unsatisfactory	Conditional
9	Does the facility have a clock, timer, etc. that is used to measure the test holding time? (There must be something for the operator to check to make sure the 30 or 60 seconds have passed.)			
10	Does the facility have the proper equipment to perform a visual inspection? Such as high intensity light, mirrors for aluminum and composite cylinders, etc.?			
11	Does the facility have the ability to shot blast cylinders?			
12	Are bands/footrings loosened or removed prior to testing?			
13	Is the pressure-indicating device able to read within 1% accuracy?			
14	Is the equipment capable of proving 1% accuracy?			
15	Is their system calibrated daily before testing?			
16	Do they demonstrate calibration within 500 psi. for all test pressures?			
17	Can they demonstrate calibration during the review within the required 1% tolerance? (You should have the operator calibrate the equipment for you.)			
18	Is the equipment capable of reaching the necessary test pressures? Example, if the equipment is only rated at 6,000 psi. do their records document cylinders with a higher test pressure being tested.			
19	Does the facility have the current certificate for the calibrated cylinder? (There should be a letter showing the test pressures and corresponding expansions. The calibrated cylinder is good so long as there is no permanent expansion and the cylinder hits the expansion numbers shown on the letter.)			
20	Does their calibrated cylinder show permanent expansion?			
21	Are their gauges calibrated per the requirements? (CGA C-1, Appendix E, requires every 6 months for the working pressure gauge and every 12 months for a master gauge.)			
22	If they have to repeat a test because of equipment failure, are all successful and unsuccessful tests recorded?			
23	If they have to repeat a test because of equipment failure, is the test repeated at an increase of 100 psi or 10% which ever is less? (The cylinder test can be repeated once, but there is a limit of 10% over the required test pressure. If you exceed this limit, the cylinder must be failed.)			
24	Once a cylinder serial number is entered on the hydrotest report, is the cylinder either passed or failed?			
25	If a cylinder is condemned, do they stamp XXXX's over the DOT specification number and service pressure or stamp it with the word "CONDEMNED"? (180.205 (i)(2) When a cylinder must be condemned, the requalifier must stamp a series of X's over the DOT specification number and the marked pressure or stamp "CONDEMNED" on the shoulder, top head, or neck using a steel stamp. Alternatively, at the direction of the owner, the requalifier may render the cylinder incapable of holding pressure.)			

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	Review Item	Satisfactory	Unsatisfactory	Conditional
26	Do they notify the cylinder owner in writing if they condemn their cylinder? (180.205 (i)(2) … the requalifier must notify the cylinder owner, in writing, that the cylinder is condemned and may not be filled with hazardous material and offered for transportation in commerce where use of a specification packaging is required.)			
27	Does their hydrotesting log record all the DOT required information? (180.215 (b)(2) *Pressure test and visual inspection records*. The date of requalification; serial number; DOT specification or exemption number; marked pressure; actual dimensions; manufacturer's name or symbol; owner's name or symbol, if present; result of visual inspection; actual test pressure; total, elastic and permanent expansions; percent permanent expansion; disposition, with reason for any repeated test, rejection or condemnation; and legible identification of test operator. For each cylinder marked with a "+", the test sheet must indicate the method by which any average or maximum wall stress was computed. Records must be kept for all completed, as well as unsuccessful tests. The entry for a second test after a failure to hold test pressure must indicate the date of the earlier test. (Make sure the actual cylinder dimensions are being written in and not a cylinder "code")			
28	Are 3HT cylinders stamped with low stress stamps, including a low stress RIN?			
29	Can the operators explain the "+" sign? Can they tell you where the criteria is found and the proper use of the "+" sign. (The rules can be found in 173.302a (b).)			
30	Can the operators explain the "star"? Can they tell you where the criteria are found and the proper use of the "star". (The rule can be found in 180.209 (b).)			
31	Can the facility produce current copies of DOT exemptions for any DOT E cylinders tested? (Check the exemption expiration date. The exemption being used must be current.)			
32	Can the facility produce training records in compliance with 49 CFR 172.704, including all DOT exemptions? (172.704 (d)(1) The training certification must show the following: The hazmat employee's name, the most recent training completion date of the hazmat employee's training, a description, copy, or the location of the training materials used to meet the requirements of this section, the name and address of the person providing the training; and certification that the hazmat employee has been trained and tested, as required by this subpart.) (The training record must be within the past 3 years.)			
33	Are foreign cylinders for export marked with a RIN? (The cylinders should be marked with only a month and year.)			

Traffic Bulletin

Other notes:

If the cylinders are being internally cleaned, are they using an oxygen compatible cleaning agent?

Are the valves on aluminum cylinders being properly torqued according to the manufacturer?

Medical, Food/Beverage and Specialty Gases Bulletin

08/01/2019

Florida Compliance

Florida DBPR inspectors have been reviewing medical gas company banking records to be sure licensed customers are actually paying for the prescription drugs (e.g. Oxygen, USP) that they ordered. This can be a problem for GAWDA members if medical Oxygen is sold to a physician (under his/her license) and the physician's clinic actually pays the invoice. If you are selling medical gases in Florida and want additional details about this, please contact tom@asteriskllc.com.

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.

Medical, Food/Beverage and Specialty Gases Bulletin

Frequently Asked Questions

Q – Do I need to have my Servomex span gas certified?

A – Yes. You should have a certificate of analysis (CoA) listing the serial number and the actual purity of the span gas. Since 2014, the Servomex span gas should be 99.99+% Oxygen (typically UHP). Here are the six elements that should be on CoAs for the Servomex span gas:

1. Name and address of the supplier
2. Name of the Product (e.g. Oxygen, UHP)
3. Lot number or unique identification number specific for each cylinder
4. The analytical methodology used to assay the standard
5. The Actual Analytical results obtained, i.e., 99.995% Oxygen.
6. The responsible person's signature and the date signed

GAWDA Professional Compliance Seminar – Certified Training

DOT and FDA (Food/Beverage and Medical Gases) – Train the Trainer Training
October 29 to 31, 2019 at Weldcoa in Aurora, IL.
Click here for more information: GAWDA Professional Compliance Seminar - Fall

August Medical Gas Roundtable (08/30/2019) – 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.

Medical, Food/Beverage and Specialty Gases Bulletin

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 117 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.
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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