



MAY 2021

ENCLOSED

Safety Topics

Safety & Regulatory Update

Please contact [Marilyn Dempsey](#), GAWDA DHS, EPA, & OSHA Consultant for more information.

Traffic Bulletin

Qualifying a New Driver

Please contact [Mike Dodd](#), GAWDA DOT Consultant for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQs
2. Recent FDA Observations
3. GAWDA Professional Compliance Training; May Medical Gas Roundtable (5/28/2021)
4. Micro-Audit Suggestions

Please contact [Tom Badstubner](#), GAWDA FDA Food, Medical & Specialty Gases Consultant for more information.

**** Visit GAWDA's COVID-19 Resource Center at www.gawda.org/covid-19/ ****

Here you will find information on Live GAWDA Consultant Covid -19 Roundtables, Safety Alerts, and Members-Only links.

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 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 _____

May 2021

Safety & Regulatory Update

Lock-out/Tag-out is a process to prevent the release of uncontrolled energy during equipment maintenance. In our industry, the Lock-out/Tag-out process should be used when performing maintenance on equipment, e.g., cryogenic pumps, vacuum systems, or any other system with a potential energy release.

OSHA reports that 10% of all serious accidents are due to the failure to lock-out equipment. Failure to lock-out these sources of energy can result in injuries and damaged equipment.

NOTE: The Lock-out process may require more than a single lock out to shut down equipment. One lock may shut down the main energy source however there may be a secondary energy source downstream that requires a second lock-out mechanism.

Hazardous Energy Control (aka, Lockout/ Tagout) Standard does not require a written energy control program; however, the standard does have three requirements that include documentation and certification of records:



1. **Energy Control Procedure.** Paragraph 1910.147(c)(4)(i) states that employers must **document** the procedures used to isolate energy source(s), and render inoperative any machine or equipment prior to servicing, maintenance, or repair. These procedures are necessary if energization, start up, or release of stored energy could injure workers.
2. **Periodic Inspection.** Paragraph 1910.147(c)(6)(ii) requires employees to **certify** the inspection by documenting the date of the inspection and the machine or equipment inspected and the employee who performed the inspection.
3. **Training.** Paragraph (c)(7)(iv) provides that employers must **certify** that individual employees completed the required training, and the training is current. The certification must contain each employee's name and training date. The training should include both Authorized and Affected employees.



Main and Secondary Energy Types

Type of Energy	Example	Potential Hazard	Lock-out
Electrical	Electricity running to Oxygen pump	Electrocution	Close breaker on electrical box. Lock out box. Isolates electrical energy supply.
Pneumatic	Gas pressure in line	Uncontrolled release and injury	Close tank valve, Drain liquid oxygen from line and vent residual gas, lock-out, valve. Isolates/ removes compressed gas in the line.
Chemical	Ammonia leak	Abrasion of respiratory track, burns to the eye.	Isolate area. None recommended, unless company has a trained and properly equipped Emergency Response Team.
Thermal	Oxidizing liquid/gas	Cryogenic burn. Fire/Explosion	Use oxygen clean tools and Drain liquid oxygen from line and vent residual gas.
Hydraulic Line	Hydraulic lift gate pump	Sudden release of pressure and lift gate jumps/falls.	Locate Electrical Disconnect that powers a hydraulic pump. Isolates hydraulic pump motor.
Hydraulic Line	Hydraulic lines for lift gate	Sudden release of pressure and lift gate jumps/falls.	Locate Ball Valve. Stops flow/backflow in hydraulic oil circuits.
Steam	Steam boiler/furnace	Burns	Locate Ball Valve, Gate Valve, Butterfly Valve. Stops supply/return of steam.

Note: There is an exception for minor servicing activities that take place during normal operations, provided other safeguards are in place.

If you have questions about a lock-out/tag-out program, please contact Marilyn Dempsey.



May Heats Up

The end of May in many parts of the United States serves as the unofficial start of summer, with temperatures starting to climb. If you live in a region of the United States that experiences high temperature (or a combination of heat and humidity), you are required, under OSHA's general duty clause, to advise your employees of the heat hazard and train them on methods to avoid heat illness.

Note: Check your local and state regulations for additional requirements, e.g., Indoor Heat Laws in the California Workplace

[Employer Responsibility to Protect Workers \(link\)](#)

Under OSHA law, employers are responsible for providing workplaces free of known safety hazards. This includes protecting workers from extreme heat. An employer with workers exposed to high temperatures should establish a complete heat illness prevention program.

- Provide workers with water, rest and shade.
- Allow new or returning workers to gradually increase workloads and take more frequent breaks as they acclimatize or build a tolerance for working in the heat.
- Plan for emergencies and train workers on prevention.
- Monitor workers for signs of illness.



May 31 is Heat Safety Awareness Day. This day is an excellent opportunity to educate workers not only on the dangers of heat stress in the workplace, but also of the dangers that prolonged exertion in the heat can bring off the job as well. Heat Safety training information (downloadable posters and a short YouTube training link) can be found on this [OSHA link](#).

For further information, please contact:

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Traffic Bulletin

Traffic Bulletin

May 2021

Qualifying a New Driver

What are the things that I need to do to hire a driver? How fast can I put a new driver on the road? What items do I need to have in my hands before letting a driver go out on the road? What should I look for on the motor violation records when deciding to hire a driver? What minimums should I have for hiring a driver? These are some of the questions that I get when someone is trying to put on a new driver. The following guidance assumes that you want a **driver for loads requiring placards**.

Must have items before letting a person drive

1. DOT employment application
2. CDL with hazmat endorsement (if you have a tank(s) bolted to the vehicle with more than 119 gals of capacity, then you need a cargo tank endorsement)
3. Current medical card certification (either a medical card or an MVR showing current medical certification)
4. Medical examiner certification where you have checked the National Registry of Medical Examiners to check that the driver used a certified examiner.)
5. A negative pre-employment drug test
6. Clearinghouse Full Query with no prohibitions
7. Road test form and certificate (391.31(g)), or CDL license or certificate accepted in lieu of road test (391.33),
 - a. A CDL is acceptable.
 - b. Doubles / triples or cargo tankers must have a road test certification for the specific vehicle within the previous 3 years.

Items that you must have within 30 days

1. Motor vehicle record from states (391.23),
 - a. Must be obtained within 30 days of employment
 - b. Must be for the prior 3 years
 - c. Please note that the regulations require this within 30 days, but I suggest that you have this and review it prior to letting the driver drive your vehicles.
2. Previous employer information (391.23),
 - a. Must be obtained within 30 days of employment
 - b. Must be for the prior 3 years
 - c. The information must be verification of employment, any DOT accidents (or any other accidents that the previous employer may want to provide), and the drug and alcohol test results/violations. (The drug and alcohol inquiries from previous employers will be phased out by 1-6-2023. This is being replaced by the Clearinghouse Full Query as it adds 3 years of data to the database.)



Traffic Bulletin

Items needed later down the road

1. Annual review of driving record (391.25),
 - a. Must be done at least annually
 - b. Must keep a copy of the state inquiry results in the file.
 - c. The motor carrier must consider the driver's accident record and any evidence that the driver has violated laws governing the operation of motor vehicles, and must give great weight to violations, such as speeding, reckless driving, and operating while under the influence of alcohol or drugs, that indicate that the driver has exhibited a disregard for the safety of the public
2. List of violations (391.27) (part of the above annual review),
 - a. The driver shall provide a list of driving violations for the previous 12 months. The driver shall sign this list.
 - b. If the driver has already provided this information as required by 383.31, then they don't have to repeat the information. 383.31 requires that drivers notify their carrier within 30 days of any vehicle violations, other than parking tickets, of which they have been convicted. The notification must be in writing and contain the 7 items listed in 383.31.
3. Medical examination kept current, or MVR as required kept current
4. Medical Examiner's Certification kept current
5. Annual limited or full query from the Clearinghouse

Suggested items for the DQ file

1. Not required, but highly suggested is to have a copy of their current driver's license in the file.

Common Question

"What do I do about an existing employee that I want to make a driver?" The easiest and best thing to do is to treat the employee as a brand-new hire. Make sure you have used a DOT driver application form. If not, then have them fill out a new DOT employee application. You still must do the previous employer background checks for the previous 3 years, but you do get to count the time the employee was working for you in that 3-year time period. Be sure to do the pre-employment drug screen.

Driver Eligibility Requirements

Next month, I will have some suggestions to consider for driver eligibility requirements. The suggestions will have some minimum requirements and some items that would possibly disqualify a driver from being considered for a driver position.

Feel free to contact me on any of these items if you have questions.

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Medical, Food/Beverage and Specialty Gases Bulletin

05/01/2021

Frequently Asked Questions

Q – Do beverage or food gas labels have any special requirements?

A – No. Unlike drug or device gases, the appropriate regulations for food gases do not include labeling instructions. Follow CGA C-7, Guide to Classification and Labeling of Compressed Gases for food gas and all gas labeling.

Q – Why do we need to perform the Odor Test?

A – The odor is a quick test to help assure no potentially harmful ingredients are backed-up into the cylinder before filling with:

- Oxygen – medical, industrial, food grade
- Medical gases (except those containing Carbon Dioxide, Nitrous Oxide, Flammable Gases, etc.)

The odor test is designed to protect the patient who will eventually breathe the gas AND the operator who is filling the cylinders. In the past, both medical and industrial cylinders have been contaminated with dangerous ingredients when combined with oxygen.

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.



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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, correct 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. 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.



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GAWDA Professional Compliance Training – HOLD THE DATES

This year, the Fall Professional Compliance Training will be held via Teleconference
October 25 to 29, 2021

May Medical Gas Roundtable - CGMP – Supplier Qualification (CGA M-7)

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, May 28, we will cover **CGMP – Supplier Qualification (CGA M-7)**. This will cover the recent FDA expectations for verifying that your bulk products have been produced by a properly “certified” original manufacturer. We also will have new procedures and forms to assist in your supplier qualification effort.

In addition, we will be conducting the following additional training at different times that day:

- **Specialty Gas** - Making Your Own Working Calibration Gas Standards
- **Food Gas Roundtable** –
 - CGMP Training – Part 117 – Preventive Controls
 - 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.
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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