

SAFETY & TECHNOLOGY ORGANIZER

OCTOBER 2016

ENCLOSED

Safety Topic: Control of Hazardous Energy (Lockout/Tagout)

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

Traffic Bulletin: Safety Management System

Please contact Mike Dodd for more information.

Medical Gas Bulletin:

Prefill inspections and filling cylinders

- 1. Food Safety Modernization Act – Implementation and Myths**
- 2. Food & Beverage Gas Myths**
- 3. GAWDA Professional Compliance Seminar: (October 18 to 20, 2016) focuses on certified DOT and FDA CGMP (Food/BevGas/Drug) Training**
- 4. Medical Gas Roundtable (10/28/2016) – CGMP - High Pressure Prefill Inspection and Filling High Pressure Cylinders**
- 5. Webinars: QSR/ISO 17025 - Internal Audits and Management Reviews; Specialty Gas - High Pressure Prefill Inspection and Filling High Pressure Cylinders; Food Gas Roundtable – Part 117 Subpart D & E – Modified Requirements and Qualified Facility Exemption**
- 6. Micro Audit Suggestions**

Please contact GAWDA Medical Gas Consultant, Tom Badstubner 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 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 _____

Control of Hazardous Energy (Lockout/Tagout)

"Lockout/Tagout (LOTO)" refers to specific practices and procedures to safeguard employees from the unexpected energization or startup of machinery and equipment, or the release of hazardous energy during service or maintenance activities. The Occupational Safety and Health Administration (OSHA) regulates lockout/tagout through the Control of Hazardous Energy standard, found at 29 CFR §1910.147. This standard mandates training, audits, and recordkeeping to ensure that workers will not be unintentionally injured by the unexpected energization, start-up, or release of electrical, mechanical, hydraulic, pneumatic, chemical, thermal, or any other type of energy.

The OSHA Lockout/Tagout website is found here:

<http://www.osha.gov/SLTC/controlhazardousenergy/index.html>

It will give you detailed information and links in the following areas:

- Standards
- Directives
- Standard Interpretations
- Lockout/Tagout Concepts
- Training

There is an OSHA e-Tool found at this website

<http://www.osha.gov/dts/osta/lototraining/index.html>

and it includes selected references for training and interactive case studies. The program has three major components. You can go through these components at your own pace and in any sequence:

Tutorial: Explains the standard in a question/answer format. **Hot topics:** Contains five abstracts with a detailed discussion of major issues. Relevant highlighted sections of the all-inclusive documents are linked here. **Interactive case studies:** Seven simulated LOTO inspections are presented. You will be making decisions on the application of the LOTO standard, based on information presented on the screen.



Here is a very brief overview of Lockout/Tagout:

Controlling Energy Sources

There are a wide variety of energy sources on which lockout/tagout must be used to protect workers from the release of hazardous energy. Some of these energy sources include: Electrical, Mechanical, Pneumatic, Fluid and Gases, Hydraulic, Thermal, Water under pressure, and Gravity.

Lockout/tagout must be used to protect employees from the potentially dangerous effects of hazardous energy. Some of the problems of hazardous energy include:

- Accidental start-ups
- Electric shock
- Disabling injuries and death

Remember, these accidents are usually the result of someone taking a short cut when servicing a piece of machinery, or they occur when a worker doesn't understand the equipment or procedures.

The Lockout/Tagout Procedure

The lockout/tagout procedure covers the following:

- How to prepare for and perform the shutdown,
- How to isolate the equipment,
- How to apply and remove lockout devices,
- How to safely release stored energy to assure that a zero energy state exists, and
- How to verify that the machine or equipment is isolated from its energy supplies.

Training

OSHA requires that all authorized employees be trained in the recognition of hazardous energy sources, the type and amount of hazardous energy sources available in the facility, and how to perform the lockout/tagout procedures. OSHA also requires that all affected employees must be trained in the purpose and use of lockout/tagout.

OSHA requires that all other employees whose work operations are or may be in an area where lockout/tagout procedures *may be* used must be instructed on the purpose of the plan and that no one can attempt to restart or reenergize equipment that's locked or tagged out.



Retraining

OSHA requires that retraining be done when there are changes in equipment, job assignment, or procedures, when an audit shows deficiencies with the procedure, and when the employer feels the procedures should be reviewed.

Audits

The OSHA standard calls for periodic inspections or audits. All audits must be performed by an authorized employee other than the ones who are using the energy control procedure being inspected. Each audit must be documented. The periodic inspections must contain at least two components: 1) a visual observation of each energy control procedure, and 2) a review of lockout procedures with all the authorized employees who use the procedure (but each of those authorized employees does not need to be observed performing the procedure as part of the inspection).

Each energy control procedure must be separately inspected at least annually to ensure that the energy control program is being properly utilized. Energy control procedures used less frequently than once a year need be inspected only when they are used. Machines and equipment with the same type and magnitude of hazardous energy and which have the same or similar type of controls can be grouped and inspected by the type of procedure, if all of the procedures in the grouping have the same or similar:

1. Intended machine/equipment use;
2. Procedural steps for shutting down, isolating, blocking, and securing machines or equipment;
3. Procedural steps for the placement, removal, and transfer of the lockout or tagout devices and the responsibility for them; and
4. Requirements for testing a machine or equipment to determine and verify the effectiveness of lockout/tagout devices and other control measures.

The inspector must be able to determine whether: 1) the inspected procedures are adequate; 2) they are understood; and 3) they are being followed by employees.

Tagout

In very rare cases, a power source cannot be physically locked out. If an energy isolating device is not capable of being locked out, the employer's energy control program must use a tagout system where procedures are developed so that warning tags are applied to warn employees not to operate the energy isolating devices. When tagout is used, use additional safety measures such as the removal of an isolating circuit element, blocking of a controlling switch, opening of an extra disconnecting device, or the removal of a valve handle to reduce the likelihood of inadvertent energization. If tagout is used, the procedures must be



reviewed with both authorized and *affected* employees during the procedures' periodic audits.

As you can see, this can be a very complicated program and this affects most of our members. There are several companies that sell training programs and all the locks, tags, and other equipment needed to do this program.

Feel free to contact me if you have questions.

Michael Dodd
GAWDA DOT, Security, EPA, & OSHA Consultant
P.O. Box 93
Poplar Bluff, MO 63902
(573) 718-2887
Email: MLDSafety@hotmail.com



Traffic Bulletin

October 2016

Safety Management System

This is another installment of how to check your company record for accidents and inspections. This is another way for you to look up your record and then to look into the details of items such as your roadside inspections.

Have you received a warning letter from DOT asking you to review your record and improve your overall score? Several of our members have received their letters. This is not a letter that you want to get. It is a warning letter that in so many words mean that if you do not improve your score, then you may be visited, another way of saying that you may get an audit.

You may look at your overall record by going to the Safety Management System (SMS) website at this address: <https://ai.fmcsa.dot.gov/SMS/>

Type in your USDOT number or your company name and your profile will come up after selecting your company.

From your carrier information page, you can get more detail by either clicking on the "Complete SMS Profile" tab on the left or by clicking on any of the "BASIC" items shown on the left side of the page. You will only see information if they have entered something into one of the BASIC items. This is one of those "no news is good news" things. If there is no information under an item, that is great. You have not been written up in that area.

If there is information in one of the BASIC items, then you can look into even more detail by clicking on "Inspection History Report #" link. This will let you see the actual items that were written up on the inspection.



Traffic Bulletin

Why should a motor carrier log in to the SMS?

Logging into the SMS provides additional functionality. Motor carriers that log in can view areas and information not available to the public. You will also get to see the driver name for each item written up.

If you need a PIN, please obtain one by following the links on the SMS websites or if you cannot locate your PIN or were never assigned one, please go to the link below and then follow the instructions to request a new one: https://i-public.fmcsa.dot.gov/LIVIEW/PKG_PIN_START.PRC_INTRO .

Once you complete the PIN registration process, a notification letter with your PIN will be generated and mailed to the address that was submitted on your most recent Form MCS-150. You should receive this letter within two weeks.

Assistance with PIN issues can be obtained by calling FMCSA technical support at 1-800-832-5660 during normal business hours. Please note that you need a USDOT Number PIN, not the Docket Number PIN.

If you receive a warning letter from DOT and would like me to help you review the data, then please send me an email or give me a call. I would be happy to help you through the websites and the data.

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

**Michael Dodd
GAWDA DOT, Security, EPA, & OSHA Consultant
P.O. Box 93
Poplar Bluff, MO 63902
(573) 718-2887
Email: MLDSafety@hotmail.com**





Medical Gas Bulletin

Medical Gas Bulletin
10/01/2016

Food Safety Modernization Act – Implementation and Myths

The Food Safety Modernization Act (FSMA) regulations are in place with specific compliance requirements and defined implementation dates. (see 21 CFR Part 117 or ask tom@asteriskllc.com for an annotated copy of the regulations.)

Help to comply with the FSMA regulations

The new Food Gas regulations generally follow the old regulations ... with the following new requirements:

- Hazard Analysis and Risk Prevention Controls (HARPC)
- Supply-Chain Program •Allergen and Sanitation Training
- Etc.

We have developed the following resources to help develop a compliance program specific to your company's needs:

- Sample Written Operating Procedures
- Allergen/Sanitation Training
- Food/Bev Gas Current Good Manufacturing Practice Training
- HARPC's for
 - CO₂ cylinder filling
 - CO₂ Micro-bulk
 - Beer Gas and other high-pressure gases
- Monthly Food Gas Roundtables
- Self-Assessment Checklist Spreadsheet
- Registration Instructions

These resources are available at no cost to GAWDA members to help establish a solid foundation for an effective Food/BevGas compliance program.

Quick Compliance Highlights

- **Registration** – All production, distribution and warehousing facilities must be registered with the FDA and appropriate state agencies where required.
- **Raw material qualification** – Annually obtain a certificate of conformance from each bulk food gas supplier as a part of your material controls. Additional details will follow from the FDA.
- **Lot Numbers** – A lot numbering system to track food/beverage gas cylinder or bulk shipments to your customer.





Medical Gas Bulletin

- **Housekeeping/Pest Control** – A documented housekeeping and pest control program to look for cleanliness and for evidence of pests (spider webs, rodent droppings, etc.).
- **CGMP/Allergen/Sanitation Training** – Documented personnel training in Food GMP's, allergen and sanitation requirements. Asterisk conducts free monthly Food Gas Roundtable to satisfy many of these needs.
- **Risk Assessments** – Conduct and document a Hazard Analysis and Risk Prevention Control analysis to insure that any risk of contamination to food grade products has been considered and mitigated. Asterisk can offer sample HARPC's for many products.
- **Product Testing** – Your risk assessment would determine whether or not your bulk product or full cylinders would require analysis over and above your supplier qualification.

Food & Beverage Gas Myths

- **Bulk Tank Annual Testing** – Cylinder and micro-bulk plants are not required by the FDA, CGA or ISBT to have their Food/BevGas bulk tank tested by an outside lab annually or any other time. You may decide to have your tank tested if it becomes contaminated or if your risk assessment/procedures require testing.
- **Bulk Tank Testing Upon Delivery** - Cylinder and micro-bulk plants are not required by the FDA, CGA or ISBT to test their Food/BevGas bulk tanks each time they are filled by the supplier, unless your risk assessment or procedures require testing. An annual letter of conformance from the supplier may be adequate.
- **Full Cylinder Testing** - Cylinder and micro-bulk plants are not required by the FDA, CGA or ISBT to test their finished product... unless your risk assessment/procedures require testing.
- **Consultants** - Cylinder and micro-bulk plants are not required to have a consultant implement their Food/BevGas compliance program or conduct periodic audits. Even the largest end users have provisions for you to develop your own program and conduct your own audits.
- **The FDA Requires Cylinder Inversion** – The truth is that the FDA does not explicitly require cylinder inversion or RPV valves. The new regulations require that you consider the food safety risks of your products. Both CGA and ISBT have published guidelines about inverting cylinders or using residual pressure valves. (See the sample written procedures or CGA/ISBT publications for additional details.)





Medical Gas Bulletin

Due to historical safety and contamination issues, both CGA and ISBT have identified serious corrosion and safety risks with customers backing up water/syrup into your cylinders. Cylinder inversion/RPV valves are the recommended means to mitigate the risks. In short – the FDA requires you to consider the risk and CGA/ISBT provide the recommended solutions. We also recommend that you follow CGA guidelines.

- **Food Compliance Is Hard To Achieve** – There are certainly some specific new requirements (HARPC, Allergen Training, etc.). However, the resources you have available can make the compliance implementation process smooth.
- **USP Products used for Food Gas Applications** - A company cannot offer USP grade products in lieu of food grade for food applications. First, the customer would require the appropriate credentials to receive medical products, such as registration with FDA or a doctor's prescription. Second, the USP product may not have the appropriate controls as required by the FSMA or may not have been appropriately tested in accordance with the Food Chemical Codex or other food gas requirements.
- **Industrial Grade products for Food Gas applications** - A company cannot offer industrial grade products in lieu of food grade for food application. The industrial product may not have the appropriate controls as required by the FSMA or may not have been appropriately tested in accordance with the Food Chemical Codex or other food gas requirements.

GAWDA Professional Compliance Seminar

Hold The Date (October 18 to 20, 2016)... GAWDA Professional Compliance Seminar at Weldcoa, Aurora, IL. This seminar focuses on certified DOT and FDA CGMP (Food/BevGas/ Drug) training. In addition, we will review the latest FDA enforcement trends. [Click here to register.](#)





Medical Gas Bulletin

October Medical Gas Roundtable (10/28/2016) – CGMP - High Pressure Prefill Inspection and Filling High Pressure Cylinders

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In October we will be discussing basic procedures to conduct a prefill inspection and how to fill medical high-pressure cylinders.

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

- **QSR/ISO 17025** - Internal Audits and Management Reviews
- **Specialty Gas** - High Pressure Prefill Inspection and Filling High Pressure Cylinders
- **Food Gas Roundtable** – Part 117 Subpart D & E – Modified Requirements and Qualified Facility Exemption

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 tom@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. **Filling Procedures** – Copy the fill procedure from the SOPs and watch a cylinder filling operator actually perform the procedure. This is the same technique the FDA uses to see if we are following our fill procedures.
2. **Documented Training** – Complete a training record for the cylinder filling operator that was observed. Attach a copy of the completed SOP to the training record.

Tom Badstubner
GAWDA Medical Gas Consultant
Telephone: 508-883-0927
Fax: 508-883-3558
Email: tom@asteriskllc.com

