GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

JULY 2021

ENCLOSED

Safety Topics

Sample Safety Practices: Facility Securement; Control of Hazardous Energy – Lockout/Tagout; Confined Space

Please contact Marilyn Dempsey, GAWDA DHS, EPA, & OSHA Consultant for more information.

Traffic Bulletin

Annual Driver Review 391.25

Please contact Mike Dodd, GAWDA DOT Consultant for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. **MRI – Cylinder Labeling Reminder**
2. **Recent FDA Observations**
3. **July Medical Gas Roundtable (7/30/2021) – CGMP – Subpart F – Production and Process Controls; GAWDA Professional Compliance Training (10/25-29/2021)**
4. **Micro-Audit Suggestions**

Please contact Tom Badstubner, GAWDA FDA Food, Medical & Specialty Gases Consultant for more information.

**** Join us for our Monthly LIVE "Safety Managers' Safety Meeting" ****

Our next meeting is July 14th @ 1PM Eastern.

Visit us at www.gawda.org/safety-meeting/ to learn more and sign up today.

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
One Oakwood Blvd., Suite 195, Hollywood, FL 33020 P(954)367-7728 F(954)367-7790

SAFETY TOPIC

July 2021

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 _____

July 2021

Sample Safety Practices

This month the OSHA, EPA and DHS section of the Safety Organizer is going to focus on three Sample Safety Practices added to the GAWDA website by the GAWDA Safety Committee:

Facility Securement

Control of Hazardous Energy - Lockout/Tagout

Confined Space.

Facility Securement - All member facilities contain hazardous material that can be targets for theft. The Sample Safety Practice "Facility Securement'' provides guidelines for facility securement of welding distributors and fill plants. These guidelines include control of access to the facility, clear perimeter site lines, visitor protocols and surveillance recommendations.

Control of Hazardous Energy - Lockout/Tagout - Every facility has a need for Lockout /Tagout according to OSHA 29 CFR §1910.147; "safeguards must be established to protect workers from the unexpected energization or startup of machinery and equipment, or the release of hazardous energy during service or maintenance activities." Lockout / Tagout programs must be written, employees must be trained, the program must be audited and the audit documented annually.

Confined Space- Confined spaces are defined as areas that have openings large enough for a person to enter but not intended for continuous occupation. Some examples of confined spaces include: acetylene generators, hydrotest pits, lime tanks, cargo trailers with manholes, lime trailers, product storage tanks with manholes or other similar areas. Any confined space that may pose a risk to human health requires a permit process to be included in the Confined Space written program.

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All three of these Sample Safety Practices may be found on the GAWDA website.
To locate the page:

1. Log into the GAWDA website
2. Hover your cursor over “My account” or “Resources” and you will see the ”Members Only Page”
3. Click on “Members Only Page”
4. Under “Member Documents” on the left side of the page, you will see “Sample Safety Practices (alphabetically listed).”
5. Click on “Sample Safety Practices (alphabetically listed)” and scroll/click to the topic of your choice.
6. You can read the document on your computer screen, click Preview, or Download the document for printing or later use.

I would recommend creating or reviewing any one of these programs and using it as a basis for your July Safety training.

If you have any questions, please feel free to contact me.

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Traffic Bulletin

Traffic Bulletin

July 2021

Annual Driver Review 391.25

At least every 12 months, the motor carrier must review the driving record of each driver, including compliance with the Federal Motor Carrier Safety Regulations and the Hazardous Materials Regulations. **This means doing the review on or before the same date next year.** If you go past the date, then DOT during their audit would try to find if you used the driver during the lapse. If they find this, then you will receive a penalty for "allowing and permitting an unqualified driver" to operate a commercial motor vehicle.

This review is a 3-part process. First, you should have the driver certify the previous 12 months of driving violations. Then you would check their records for any violations, one of which should be the appropriate state motor vehicle record (MVR). Finally, you then certify as the carrier whether the driver is qualified or not to continue driving.

You can use third-party companies to do the MVR checks. You can pull the MVR yourself or you can have the driver obtain their own MVR, which is the easiest way many times.

In reviewing each driver's record for the preceding year, attention should be given to any accidents and indications of violations of motor vehicle laws and regulations. Of particular importance are violations indicating a disregard for the safety of the public, such as speeding or operating a vehicle while under the influence of alcohol or drugs.

The reviewer's evaluation of the record should determine whether the driver remains qualified or is disqualified to drive a motor vehicle under the provisions of §391.15 for such infractions as operating a vehicle while under the influence of alcohol or drugs, leaving the scene of an accident involving personal injury or death, etc.

A written record, including the date and the name of the person who reviewed the driving record, must be placed in the driver's qualification file. **This review must be maintained in the driver qualification file for three years after the carrier certification date.** If you need a form to do this documentation, just send me an email and I'll be glad to send you one.

I recommend stapling any paperwork such as the state motor vehicle record and any other reviews that you may have done to the back of the certification form for ease of recordkeeping.

DOT Interpretations:

Question 1: To what extent must a motor carrier review a driver's overall driving record to comply with the requirements of §391.25?

Guidance: The motor carrier must consider as much information about the driver's experience as is reasonably available. This would include all known violations, whether or not they are part of an official record maintained by a State, as well as any other information that would indicate the driver has shown a lack of due regard for the safety of the public. Violations of traffic and criminal laws, as well as the driver's involvement in motor vehicle accidents, are such indications and must be considered. A violation of size and weight laws should also be considered.

Question 2: Is a driver service or leasing company that is not a motor carrier permitted to perform annual reviews of driving records (§391.25) on the drivers it furnishes to motor carriers?

Guidance: The driver service or leasing company may perform annual reviews if designated by a motor carrier to do so.

Question 3: May motor carriers use third parties to ask State agencies for copies of driving records to be examined during the carrier's annual review of each driver's record?

Guidance: Yes. Although an examination of the official driving record maintained by the State is not required during the annual review, motor carriers that choose to do so may use third-party agents, such as driver information services or companies, to obtain the information. However, the motor carrier is responsible for ensuring the information is accurate.

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

07/01/2021

MRI –Cylinder Labeling Reminder

Q – Can I use the “MR Safe” marking on aluminum high-pressure cylinders and stainless-steel liquid containers?

A – Short answer…. **No** – High-pressure cylinders and cryogenic containers do not qualify for the “MR Safe” label.

The applicable ASTM definitions are:

MR SAFE - is an item that poses no known hazards in all MRI environments. Using the new terminology, "MR Safe" items include non-conducting, non-metallic, non-magnetic items such as a plastic Petri dish. Clearly High-pressure cylinders and cryogenic containers are metallic and electrically conducting and therefore do not qualify for the “MR Safe” label.

MR CONDITIONAL - is an item that has been demonstrated to pose no known hazards in a specified MR environment as long as specified conditions of use are met. The item labeling must include the results of testing and the specific conditions of use sufficient to characterize the behavior of the item in the MRI environment.

According to ASTM standards and FDA guidance you could mark your conforming cylinders as “MR Conditional” if your cylinders (including valves) meet the requirements of the ASTM standard and FDA Guidance. Among other things, this will include specific testing and labeling to confirm their safety in the MRI environment. DO NOT label your cylinders to meet MRI requirements without conforming to the ASTM standard and FDA Guidance. Also, be certain that no other magnetic components (valve parts, wheels, etc.) would create a magnetic hazard if your cylinders are marked “MR Conditional”.

For more details, see:

- CGA SA-32-2019, *Hazards Of Compressed Gas Cylinders In The Magnetic Resonance Imaging (MRI) Environment*
- FDA Guidance: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm107708.pdf
- ASTM Publication: https://www.astm.org/Standards/F2503.htm

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.

Medical, Food/Beverage and Specialty Gases Bulletin

QCU and Fill Log Errors

Form 483 Observation-02-02 - The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, the requirements of the SOP ___, titled "Quality Control Unit" have not being followed by QCU personnel as follows: I observed multiple deficiencies in the completion of Fill Log records for medical gas lots manufactured and repacked in ___, which were reviewed and approved by QCU personnel, including the following: The Fill Log record ___ for medical compressed Nitrogen, which was used to document the filling of lots ___ and ___ on ___, does not indicate that the Vacuum Gauge
Operation Check-Zero was performed prior to performing the filling operations, as required by Fill Log ___.

How to prevent this from showing up in your inspection?

Assure QCU knows the importance of correcting ALL errors and omissions on fill logs before signing the record and releasing the lot.

GAWDA Professional Compliance Training – HOLD THE DATES

This year, the Fall Professional Compliance Training will be held via Teleconference

October 25 to 29, 2021

July Medical Gas Roundtable (07/30/2021)
CGMP - Subpart F – Production and Process Controls

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In June we covered how to survive an FDA audit.

In July, we will cover **Subpart F – Production and Process Controls** --- SOPs, filling cylinders, equipment identification, reprocessing, etc.

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

- ***Specialty Gas*** - Making Highly Reliable Gravimetric Mixtures
- **Food Gas Roundtable** – CGMP Training – Part 117 Subpart C - Corrective actions and corrections, Verification, Validation
  - The latest information about food gas regulations is reviewed –
  - The sample Food Gas SOPs are available for downloading during the seminar.

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.

Medical, Food/Beverage and Specialty Gases Bulletin

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. **Authorized Procedures –** Verify that your Quality Control Unit has authorized your SOPs in writing.
2. **Following SOPs –** Be sure that your cylinder filling personnel are strictly following the authorized procedures. This is easily accomplished by taking a copy of the cylinder fill procedure to the manifold and watching the operator fill the cylinders.

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