GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

JULY 2020

ENCLOSED

Safety Topic

Heat Illness Prevention Plan

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

Traffic Bulletin

DOT Compliance Review: Would you have the answers to their questions?

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. MRI – Updated Cylinder Labeling Information - Correction
2. Recent FDA Observations
3. GAWDA Professional Compliance Seminars: Summer -- July 27th-31st Afternoon Webinar; Fall -- October 27th-29th Webinar
4. July Medical Gas Roundtable: CGMP – Subpart F – Production and Process Controls
5. 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/ ****

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 _____

GAWDA GASES AND WELDING DISTRIBUTORS ASSOCIATION

Heat Illness Prevention Plan

COVID-19 is not the only threat to our employee's health, most of our workforce do not work in air conditioned environments. According to OSHA, "Millions of U.S. workers are exposed to heat in the workplace and thousands become sick from occupational heat exposure, and some cases are fatal." Creating a Heat Illness Prevention plan and training employees concerning the signs/symptoms, prevention and personal factors that can make employees more susceptible to heat illness can help keep your business running well.

A Heat Illness Prevention plan should include:

- Who will provide daily oversight during hot weather; including monitoring heat advisory reports.
- What engineering controls and work practices will be used; e.g. summer weight uniforms, cold kerchiefs, shift changes
- Who will be responsible to monitor workers, including those returning from vacation
- Who will train employees. Training should identify heat hazards, signs and symptoms of heat rash/stress/stroke, how/when to call for medical assistance and personal factors that can make employees more susceptible to heat illness (obesity, diabetes, high blood pressure, heart disease, and level of physical fitness and other medical conditions (e.g. COVID-19)).
- What will be the first aid and medical assistance plan

Below are two links to OSHA information that can serve as a guide to your Heat Stress Plan and training.

- OSHA Heat Stress Guide
- OSHA Heat Stress Quick Card

Please contact me if you would like to discuss this plan or any other DHS, EPA or OSHA issue.

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Traffic Bulletin

Traffic Bulletin

July 2020

DOT Compliance Review: Would you have the answers to their questions?

You have just received a phone call from the U.S. Department of Transportation (USDOT), Federal Motor Carrier Safety Administration stating that you have been scheduled for a Compliance Review. They have scheduled their visit for 2 weeks from the phone call. DOT must give you at least 2 days to gather your information and files, but they usually give you longer notice. They have faxed you several pages of items and questions they want you to have available during their review, which could last from a few hours to several days depending on the size of your company or what items they discover. **That was the old method and it is still going to be used but you need to know about the new method, the Remote Carrier Compliance Review.** DOT started doing this method as a test as far back as 2010 in 10 states and in 2019 they started doing this in all 50 states. FMCSA said the operational test documented a number of promising statistics:

- About 60% of new entrant carriers were eligible for, and received, off-site audits.
- Off-site safety audits take 33% less time to conduct than on-site audits.
- Off-site safety audits save 58% on agency travel costs.
- The average efficiency of off-site audits increased by about 20%.

DOT ramped up the remote reviews this year because of the COVID-19 concerns. We have had some of our members go through this type of review. So be prepared to answer questions over the phone, be directed to an audit website program, and or email or fax documentation back to the review officer. They may not be visiting you in-person but they will be asking the usual questions.

You **may** be requested to send the following records and documents:

1. Current list of drivers
2. Current list of equipment (CMV trucks and trailers)
3. Accident Register listing all USDOT recordable accidents (i.e. fatality, injury and/or tow truck needed) for the last 3 years
4. Insurance Company “Loss Run” report for the last 3 years
5. MCS-150 (your DOT number letter or updates, required every 2 years)
6. MCS-90 (Liability Insurance) coverage (either $1,000,000 or $5,000,000 depending on hazard class or quantity being carried)
7. HM registration (for the past 3 years as applicable)

8. Unified Carrier Registration (only if interstate commerce)
9. A copy of the written education materials that you are required to give to your CDL drivers regarding the misuse of Alcohol and Controlled Substances that cover the 11 required elements in 382.601
10. Summaries of Alcohol/Controlled Substances Testing for the last 5 years.
11. Name, address, and telephone number of Drug Testing Consortium – if applicable
12. Documentation of Brake Inspector/Adjuster training (if your drivers are adjusting their vehicle brakes)
13. Documentation of Annual Inspector qualifications (if a certified garage is not used)
14. Documentation of HM Training for drivers and hazmat employees showing that they have been trained within the past 3 years
15. Documentation of security awareness training within the past 3 years for all employees handling or that have access to hazardous materials.
16. Shipping papers / manifests review and keeping for 2 years
17. Commercial Motor Vehicle (CMV) maintenance records: a) vehicle identifying information, b) roadside inspection reports, c) driver post-trip inspection reports (last 3 months), d) Periodic inspection of CMV (original copy kept 14 months from report date)
18. Schedule of inspection, maintenance & repair programs for vehicles
19. Copy of previous Compliance Review report or enforcement actions from State or Federal DOT Agency – if applicable
20. Hours of Service documentation for last 6 months (driver logs, detailed timecards or hours summary sheets)
21. Driver Qualification Files for employees who are drivers of Commercial Motor Vehicles
22. Copies of leases for vehicles that are under a maintenance lease
23. Able to provide a copy of the Federal Motor Carrier Safety Regulations (FMCSR)
24. Able to provide a copy of the hazardous materials regulations
25. Have a system to show you are aware of when driver's license and medical card will expire
26. Driver files are in a locked authorized access only area
27. Hazmat security plan only if required to have one.
28. Placards available to give out to customers that need them
29. Current copies of any special permits that you are using and documentation that you have trained any employee that handle the special permitted package

This list is not all-inclusive but will assist you in having the majority of the necessary documents ready during your Compliance Review.

Traffic Bulletin

Will you be ready when you get your call for a Compliance Review?

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

Medical Gas Bulletin
07/01/2020

MRI – Updated Cylinder Labeling Information - Correction

In September 2018, we published information about labeling cylinders and containers for MRI service. The CGA SA-32 reference (updated in 2019) and the important requirements for testing were not included in the earlier article. The additional information you need is highlighted in yellow, below.

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

A – Short answer…. No. The Magnetic Resonance (MR) task group of the American Society for Testing and Materials (ASTM) International has developed a set of MR safety terms that have been used since 2005. Before 2005, the MR definitions were less consistent.

The new 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. The "MR Safe" icon consists of the of the letters "MR" in green in a white square with a green border - or - the letters "MR" in white in a green square.

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 "MR Conditional" icon consists of the letter "MR" in black inside a yellow triangle with a black border. 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.

For more details, see:

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

Clearly HP and Liquid cylinders are metallic and electrically conducting and therefore do not qualify for the “MR Safe” label. 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”.

Medical, Food/Beverage and Specialty Gases Bulletin

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.

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.

Upcoming Training

- Summer - GAWDA Professional Compliance Seminar – July 27 to 31, 2020 – Afternoon Webinars: Click here for details.
    - FDA Food Gas Essentials
    - FDA Medical Gas Essentials
    - OSHA - Facility Emergency. Response Plan (FERP)
    - LPG Cylinder Requalification
    - HP/Cryo Cylinder Visual Inspections

- Fall - GAWDA Professional Compliance Seminar – October 27 to 29, 2020 – Webinar hosted by Weldcoa – DOT, OSHA and FDA Audit Survival

Medical, Food/Beverage and Specialty Gases Bulletin

July Medical Gas Roundtable (07/31/2020) – 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.

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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Medical, Food/Beverage and Specialty Gases Bulletin

Compressed Gas Association
The Standard For Safety Since 1913

SAFETY ALERT

SA-32—2019

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HAZARDS OF COMPRESSED GAS CYLINDERS IN THE MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT

Compressed gas cylinders, cylinder valves, cylinder regulators, other assemblies included with cylinders, or any other equipment used to supply compressed gases shall not be present in the same room as an MRI device unless proven nonmagnetic and/or tested and deemed suitable for this environment.

Serious personal injury and property damage has resulted from the use of steel gas cylinders in close proximity to MRI devices. One incident resulted in the death of a six-year-old boy when a steel cylinder was brought into a room containing an operating MRI unit. The magnetic forces generated by the MRI drew the cylinder across the room, striking the boy in the head.

This is an area of serious concern to the Compressed Gas Association and the focus of this safety alert is to notify personnel who handle, use, transport, or store compressed gas cylinders and equipment to this hazard.

If there are any questions as to whether a piece of equipment is suitable for use in the MRI environment, the equipment manufacturer or supplier should be contacted.

Marking of cylinders, valves, regulators, and other compressed gas equipment as suitable for MRI environments should be done according to nationally or internationally recognized standards. For specific details on markings, see ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment* [1].

Reference

Unless otherwise specified, the latest edition shall apply.

[1] ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*, ASTM International. www.astm.org

Medical, Food/Beverage and Specialty Gases Bulletin

PLEASE NOTE:

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This document is subject to periodic review, and users are cautioned to obtain the latest edition. The Association invites comments and suggestions for consideration. In connection with such review, any such comments or suggestions will be fully reviewed by the Association after giving the party, upon request, a reasonable opportunity to be heard. Proposed changes may be submitted via the Internet at our web site, www.cganet.com.

This document should not be confused with Federal, state, provincial, or municipal specifications or regulations; insurance requirements; or national safety codes. While the Association recommends reference to or use of this document by government agencies and others, this document is purely voluntary and not binding.

A listing of all publications, audiovisual programs, safety and technical bulletins, and safety posters is available via the Internet at our website at www.cganet.com. For more information contact CGA at Phone: 703-788-2700, ext. 799. E-mail: customerservice@cganet.com.

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Medical Equipment Committee

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