GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

OCTOBER 2019

ENCLOSED

Safety Topic: GAWDA Sample Safety Policy: Regulatory Agency Visit Guidelines

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

Traffic Bulletin: Shipping Papers – Frequent Citations

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQ's: Medical Oxygen for Emergency Use - CORRECTION
2. Recent FDA Observations: Food Gases
3. GAWDA Professional Compliance Seminar – Audit Survival: DOT and FDA (Food/Beverage and Medical Gases) – Train the Trainer Training (10/29-31/19); October Medical Gas Roundtable: (10/25/2019) – CGMP – High Pressure Prefill Inspection and Filling High Pressure Cylinders; Food Gas Roundtable- Part 117 Subpart D & E - Modified Requirements and Qualified Facility Exemption; Specialty Gas Operations - High Pressure Prefill Inspection and Filling High Pressure Cylinders.
4. 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 a recent one that has been completed. This is an example of one of the many available off the member resources portion of the GAWDA website.

GAWDA GASES AND WELDING DISTRIBUTORS ASSOCIATION

Regulatory Agency Visit Guidelines

(Insert Company Name Here)

PURPOSE	**To provide a set of proposed guidelines for an on-site visit by regulatory agencies**
RESPONSIBILITY	**All pertinent personnel**
AUTHORITY	**General manager**

Site visits by regulatory agencies such as, but not limited to, Occupational Safety and Health Administration (OSHA), Federal Drug & Administration (FDA), Environmental Protection Agency (EPA), and Fire Marshal, are common. Site visits typically are a result of a report of routine inspection program or a complaint. It is of great importance to ensure locations are prepared for expected and unexpected site inspections by regulatory agencies. Listed below are some, but not all, guidelines to assist in an on-site visit.

General Information:

1. Designate and train applicable personnel to accompany an inspector
2. Ensure proper housekeeping
3. Ensure pedestrian pathways are identified and clearly marked
4. Ensure compliance records are current and maintained per required retention timeframes.
5. Ensure employee training records are current

Before the inspection – pre-planning:

The least painful and most effective measures you can take are to assure that you are in compliance ***before*** the inspection. Similar to all other critical parts of your business, you need a plan for compliance and then you execute the plan. Your compliance plan should include the following elements:

6. Consider prior inspections – The agencies have a record of your prior inspections. They expect that prior inspectional observations are permanently corrected. Agencies have taken severe compliance action when violations have recurred.
7. Well written procedures – Assure that you have clear, well-written procedures. Consider GAWDA sample procedures.
8. Training –Assure that your personnel are qualified before working… Be sure the qualification is documented.
9. Calibrations – Assure your gauges, thermometers, scales, etc. are within calibration date and that you have a record of the calibration.
10. Records – Incomplete records are a source of violations. Be sure each required record has been properly completed and approved.

Greeting Inspector:

11. Be honest, courteous and cordial
12. Verify inspector credentials. Ask for business card and/or governmental identification. It is advisable to contact inspector's office to confirm site inspection
13. Workspace – Take the investigator to a convenient work area (e.g. conference room, office, etc.). Be sure the compliance records are not in the room. When the investigator asks for records, bring in the specific records he/she requests.
14. Determine the reason for inspection. If inspection is due to a complaint, request a copy of the complaint
15. If assigned and trained personnel for regulatory inspections are not on-site and unavailable, ask inspector if there is a possibility of delaying inspection until appropriate company representation arrives
16. Never leave inspector unattended
17. Review site visitor rules, such as, required PPE, emergency response procedures, smoking policy, photograph policy, etc.
18. Request inspector to conduct an opening conference to explain purpose and expectations
19. Request inspector to conduct a closing conference to review findings and next steps

During the Inspection and Walk-Around

20. Do not volunteer unsolicited information
21. Have relevant records available, surrendering only those requested
22. Agree to the scope of an inspection before the walkthrough
23. Escort regulatory representative to areas of location that are of importance to the investigation. Determine most direct route to these areas. Try to avoid deviating from direct path. This could change the scope of initial inspection
24. Take notes and photographs on all observations an inspector makes and pictures that inspector takes
25. Duplicate all pictures inspector takes during inspection
26. List any violations that the inspector noted during the inspection
27. Keep records of documents provided inspector during visit

28. Correct small items identified immediately demonstrating good faith
29. Clarify – There are times when the inspector simply misunderstands our vocabulary or even misinterprets the agency's own enforcement interpretations. Seek to have any misunderstandings corrected before the final report is delivered.

Closing Conference

30. Reinforce the company's commitment to safety and compliance
31. Confirm with inspector that the scope of inspection was met
32. Have inspector review findings and next steps
33. Take all potential violations under advisement. Do not agree to any violations or corrective actions. In addition, do not become confrontational on any potential violations listed.
34. Advise the inspector of any items that may have been addressed during the inspection along with any proof/evidence
35. Request copy of any notes/draft report prior to inspector leaving site
36. If the inspector asks you to sign an affidavit, politely explain that it is company policy that you are not authorized to sign affidavits without permission from the company counsel. Ask to have a copy of the affidavit to forward to top management and company counsel.
37. The inspection may require a written response. Be certain to understand the time limits for responding to the inspection.

Again, the purpose of this sample policy is to give suggested guidance on how to handle regulatory agency visits.

Feel free to contact me if you have any questions.

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Traffic Bulletin

Traffic Bulletin

October 2019

Shipping Papers – Frequent Citations

Have you reviewed your shipping paper lately? Several things have changed in the past several years. Here is a quick rundown of the changes:

- As of January 1, 2013, the identification number (UN number) must be immediately in front of the shipping name.

- In 2005, a change was made that required certain gases to show the subsidiary hazard class. If the material (other than combustible liquids) has a subsidiary hazard class shown in column 6 of the hazardous materials table found in 172.101, then it must be entered in parenthesis immediately following the primary hazard class or division number on the shipping paper. For example, oxygen gas will be shown as: UN1072, Oxygen, compressed, 2.2 (5.1).

- A couple of years ago, DOT added the requirement to have your company name on your shipping papers. This is in addition to already showing the emergency response company and phone number that you are using.

The following items are the most common mistakes that DOT finds on shipping papers:

- Failing to prepare a shipping paper.
- Failing to properly identify hazardous entries on a shipping paper that also includes non-hazardous entries.
- Failing to include the proper identification number, shipping name, hazard class, and/or packing group.
- Listing an improper proper identification number, shipping name, hazard class, and/or packing group.
- Including unauthorized information.
- Listing information out of sequence.
- Failing to properly identify “RQs”.(Reportable Quantity)
- Failing to provide the total quantity.
- Failing to provide the type of package.
- Listing a package type not authorized or defined by DOT.
- Failing to include technical name(s) when required.
- Failing to list applicable exemption or special permit number(s).
- Failing to include or sign the required certification.
- Failing to include a 24-hour emergency response number.
- Failing to staff the listed number.
- Listing a fraudulent 24-hour number.
- Listing a number which is not working or is incorrect.

- The required response information is not listed on, or provided with, the shipping paper.
- The response information provided is inappropriate for the material.

The penalties for these mistakes can run into the thousands of dollars. If you have not reviewed your shipping paper recently, you should. I would be happy to review your shipping paper for you. I can spot mistakes very quickly and explain how to make the needed corrections. Just email me your shipping paper and I'll be happy to look it over.

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

10/01/2019

Frequently Asked Questions - Medical Oxygen for Emergency Use - CORRECTION

Last month we said:

The FDA allows medical oxygen to be dispensed without a prescription to properly trained individuals for oxygen deficiency and resuscitation, as long as the following conditions are met:

1. *A high-pressure cylinder filled with medical oxygen and used for oxygen deficiency and resuscitation must have the "emergency use" statement present on the drug label.*
2. *The equipment intended for such use must deliver a minimum flow rate of 6 liters of oxygen per minute for a minimum of 15 minutes and include a content gauge and an appropriate mask or administration device.*
3. *Proper training is documentation that an individual has received training within the past twenty-four months or other appropriate interval, in the use of emergency oxygen including providing oxygen to both breathing and non-breathing patients, and safe use and handing of emergency oxygen equipment. Training may be obtained from any nationally recognized professional organization, such as the National Safety Council, the American Heart Association, the American Red Cross, etc.*
4. *Under no circumstances can emergency oxygen be used to fill high-pressure cylinders or be used in a mixture or blend.*

Once all of these conditions are met, an individual or firm may have access to medical oxygen without a prescription. Keep in mind that some states may have additional requirements.

Correction to Item 4

Item number 4 should read: "***4. Under no circumstances can emergency oxygen be used to fill a mixture or blend.***" The reason for this correction is that Emergency Services/Ambulance companies, routinely top off their own emergency oxygen cylinders and the original statement would prohibit them from doing so.

Recent FDA Observations – Food Gases

We are seeing more FDA food inspections lately. The number one concern is sanitation and housekeeping. Please be sure:

1. Your cylinder filling and storage areas are clean and well organized.

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2. There is no “evidence of infestation”. This includes spider webs and bird/rodent droppings.
3. You have a documented inspection schedule with procedures. Contact tom@asteriskllc.com if you need a sample procedure/checklist.
4. Your bathroom is clean, has hot water and you have a sign stating that all employees must wash their hands before returning to work. These signs are under $10 at Amazon: https://www.amazon.com/Employees-Must-Hands-Before-Returning/dp/B07H5R5GG7/ref=sr_1_3?crid=3ST4ISGIIEME7&keywords=all+employees+must+wash+hands+sign&qid=1568748301&sprefix=sign+employees+was%2Caps%2C154&sr=8-3

GAWDA Professional Compliance Seminar – Audit Survival

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

October Medical Gas Roundtable (10/25/2019) – 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.

Medical, Food/Beverage and Specialty Gases Bulletin

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

- ***Specialty Gas Operations*** - 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 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. **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.

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