GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

NOVEMBER 2020

ENCLOSED

Safety Topic

Bloodborne Pathogens

CGA Posters

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

Traffic Bulletin

Post Trip Vehicle Inspection Report

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQs: FDA Drug Listings
2. Recent FDA Observations
3. November Medical Gas Roundtable (11/20/2020): Subparts H & I – Holding and Distribution, Laboratory Controls
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/ ****

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

November 2020

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 _____

Bloodborne Pathogens

Did you know that if you have a first aid responder then you must have a Bloodborne Pathogen Program?

The Bloodborne Pathogen Standard covers many types of employees, from health care workers to first aid responders, that may be exposed to bloodborne pathogens or other potentially infectious material (like COVID-19).

First aid responders may experience “occupational exposure” to pathogens. OSHA defines occupational exposure as “reasonably anticipated contact” (with blood or other potentially infectious materials) while performing their stated duties. However, employees who are not designated first aiders who perform unanticipated "Good Samaritan" acts are excluded from coverage by the standard since such an action does not constitute "occupational exposure", as defined above.

In order to reduce or eliminate the hazards of occupational exposure to bloodborne pathogens, an employer must develop a Bloodborne Pathogen Program, which includes:

*Employee Protection Measures
*Engineering and Work Practice Controls
*Personal Protective Equipment
*Medical Surveillance
*Hepatitis B Vaccinations
*Employee Training

and other provisions as required by OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030).

The GAWDA Safety Committee has published proposed guidelines for the bloodborne pathogen program for welding distributors and fill plants. The guideline may be found on the GAWDA website in the Members Only section under Sample Safety Practices/Bloodborne Pathogen Program (9/2020).

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CGA Posters

CGA publishes guidance on the safe filling and handling of our gaseous and liquid hazardous materials. This month they have published safety posters. They have a Dry Ice Safety Poster that is free to all and they have Home Oxygen, Liquid Nitrogen and Medical Oxygen Safety posters free to companies that subscribe to the GAWDA CGA Subscription Program. (The program application instructions are on the GAWDA website, under the Resources tab.)

The posters NOW available through the CGA website.

Dry Ice Safety Poster: http://www.cganet.com/dry-ice-safety/
Home Oxygen Safety: https://www.cganet.com/home-oxygen-safety/
Liquid Nitrogen Safety: https://www.cganet.com/liquid-nitrogen-safety/
Medical Oxygen Supply: https://www.cganet.com/wp-content/uploads/CGA-Poster_Medical-Oxygen-Supply_Cylinder_11x17.pdf

If you have any questions regarding the program or if you should have a program, please feel free to contact me, my contact information is listed at the bottom of this article.

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Traffic Bulletin

November 2020

Post Trip Vehicle Inspection Report

Part 396 .11 requires a driver of a Commercial Motor Vehicle to prepare and sign a written vehicle inspection report at the completion of each day's work on each vehicle operated and each trailer that was used. A separate report must be prepared for each power unit operated during the day's work. The report must cover at least the following parts and accessories:

1. Service brakes including trailer brake connections
2. Parking (hand) brake
3. Steering mechanism
4. Lighting devices and reflectors
5. Tires
6. Horn
7. Windshield Wipers
8. Rear vision mirrors
9. Coupling devices
10. Wheels and rims
11. Emergency equipment

No specific format is required; however, provisions must be made for three signatures:

- The driver's signature preparing the report (396.11(b)).
- The motor carrier's, mechanic's, etc. signature certifying the reported defects or deficiencies have been corrected or that no correction is necessary (396.11(c)(1)); and
- The reviewing driver's signature acknowledging the corrective action taken by the carrier (396.13(c)). The next driver of the vehicle signs the report, only if defects or deficiencies were noted by the driver who prepared the report, to acknowledge that the driver has reviewed it and that there is a certification that the required repairs have been performed.

If you need a post trip inspection form that you can use as is or modify to your company needs then just contact me and I'll be happy to send you the form in Word format.

Traffic Bulletin

Record Retention
Motor carriers must maintain the original of each vehicle inspection report and the certification of repairs for at least 3 months (396.11(c)(2)). You are not required to carry the report on the vehicle the next day.

Exemptions
Driver vehicle inspection reports are not required of the following operations:

- Driveaway–towaway (Tow truck) operations as specified in 396.15.
- A motor carrier operating only one motor vehicle (396.11(d)), or
- A private motor carrier of passengers (nonbusiness) (396.11(d)).

Completing the Report
Using the example report provided, the driver completes the first portion of the report at the end of the day. If no defects are noted, the driver checks the provided spot, signs the report and you are finished. If any of the "DOT Regulated Safety Items" are checked as defective, the items must be corrected before driving on the next trip. If any of the "Maintenance Items" are defective, then you ask yourself if the vehicle is safe to operate. If yes, then you can correct the items at your next convenient opportunity. When sending the vehicle in for repairs, send the report along with the vehicle so the mechanic can sign the report after completing the repairs. If the repair facility does not sign or refuses to sign the inspection form, then the motor carrier can sign the inspection report. The report would then come back with and be left in the vehicle so the next driver could then sign the report to acknowledge that the driver has reviewed it and that there is a certification that the required repairs have been performed. Remember, this last signature only happens if there were noted defects and the defects were corrected.

Please note that currently DOT does not require a written post trip inspection report if no defects were noted during the inspection but many companies have decided that they want the driver to complete one so they have documentation showing the inspection was done.

If there are any questions regarding this Bulletin, please contact:

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical, Food and Specialty Gas Bulletin
11/01/2020

Frequently Asked Questions – FDA Drug Listings

Q – Must I register my facility if I am only warehousing product and not filling the cylinders at this location?

A – This answer depends on whether the cylinders are drugs or food/beverage gases.

- **Food/Beverage Gases** – Warehousing and production locations must both be registered with the FDA if they handle food/beverage gases. The registration process is exactly the same, except that the facility type is marked as a warehouse or a manufacturing location. Keep in mind that many states also require licenses/permits to produce or distribute food gases.
- **Drug gases** – Only ***production*** locations need to be registered with the FDA. If you are simply warehousing drug gas cylinders at a location, you may need to license with your state board of pharmacy even though you are **not** required to be registered with the federal FDA.

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.

Annual Record Review

Form 483 Observation-03-02 - Written procedures are not followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected. Specifically, your firm does not perform an annual product review of each medical gas by reviewing the batch records, complaints, returned products, investigations and or recalls to determine the need for changes in the process or control procedures for the following medical gases: _____

How to prevent this from showing up in your inspection?

Document your Annual Records Review. Contact tom@asteriskllc.com for a sample SOP and Annual Records Review form.

Medical, Food/Beverage and Specialty Gases Bulletin

November Medical Gas Roundtable (11/20/2020) – Subparts H & I – Holding and Distribution, Laboratory Controls

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In November we will be discussing warehousing and laboratory operations.

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

- ***Specialty Gas*** - Measuring and Controlling Uncertainty in Gas Chromatographs (ISO 6143)
- **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. **Servomex Filter -** Verify that you have records that the filter on the Servomex has been inspected according to the frequency in your instrument manual. Keep in mind that Servomex allows a longer inspection period for analyzing clean, dry gases (medical gases). Read the manual or your SOP carefully.
2. **Segregation** – Be sure your full medical gas cylinders are segregated from your industrial gas cylinders.

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