

## ***SAFETY & TECHNOLOGY ORGANIZER***

**MARCH 2018**

### ***ENCLOSED***

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**Safety Topic: Cylinder Loading Dock Safety**

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

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

*Please contact Mike Dodd for more information.*

### **Medical, Food/Beverage and Specialty Gases Bulletin**

- 1. Recent FDA Observations, ie Lot Stickers, etc.**
- 2. Medical Gas Roundtable (Friday, March 30) including Specialty Gas and Food Gas Roundtable topics.**
- 3. GAWDA Professional Compliance Seminars – 2018.. dates and places.**
- 4. Micro Audit Suggestions**

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

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*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 \_\_\_\_\_

## Cylinder Loading Dock Safety

This month's Safety Topic is one of the sample safety practice developed by the GAWDA Safety Committee. To see all the published sample safety practices, please see the GAWDA website under the "Resources" tab and then the "Members Only Reference Materials" and then log in with your ID and password.

The purpose of this sample safety practice is to bring awareness to cylinder loading docks and the dangers they pose. This is an inspection criterion that may be used to inspect docks and loading areas to help reduce injuries on loading docks.

### Dock Safety

- Make sure walkways, barriers including dock edges are marked or identified. Example would be yellow paint (as in picture below) yellow tape or any other means of identification.
- Display "authorized personnel only" sign
- Keep cylinders out of walkways
- Safety chains can be used for railing in the event a permanent railing system is not practical
- Anchor posts for railing chains must withstand at least 200 pounds of force from any direction
- Docks of 4' or higher must be protected by a standard railing system (not required for working side)
- Ensure area is clean by removing accumulated debris and containing spills
- Eliminate fall hazards in the loading dock area to reduce slips and trips
- Inspect area to ensure emergency equipment is not blocked or damaged
- Ensure dock and loading area are properly lighted
- Prevent jumping from ground to dock, dock to dock, or dock to ground
- Use appropriate ladders or walkways to access the dock



- Verify ladders from dock floor to dock surface meet current OSHA specifications



### Dock to Vehicle Safety

- Ensure that dock plates, if provided, are designed for appropriate loads
- Toe cleats or similar are needed for dock plates to prevent movement during loading
- Dock levelers, if provided, are returned to a level, stored position after use
- Inspect trailer or truck floor before entering it with a forklift
- Provide cover to keep rain or snow off loading docks
- Identify and mark overhead hazards such as pipes, doors, or electric wires
- Keep a safe distance from the edge of the dock
- Avoid backing to the edge of the dock
- If loading by forklift, provide wheel chocks for vehicles and enforce their usage
- If trailer is spotted at your dock, inspect landing gear and jack stands for integrity

Many thanks to the members of the Safety Committee for the work on items like the above.

Michael Dodd

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# Traffic Bulletin

## Traffic Bulletin

### **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.

You **may** be requested to present 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



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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 time cards 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 in having the majority of the necessary documents during your Compliance Review.

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.

Michael Dodd

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# 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](mailto: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.

## Lot Stickers

**Form 483 Observation-03-01** - Procedures designed to assure that correct labels are used for drug products are not written and/or followed. Specifically, the labels which you include in your batch records (lot stickers) for your Liquid Oxygen USP product, which contain lot number information, are not maintained and controlled as numerous labels (>25) were observed on the floor by filling manifold no. \_\_\_\_, where the liquid oxygen are filled and labeling operations for these "lot stickers" occur. These labels (lot stickers) were used on Liquid Oxygen USP lot \_\_\_\_ which was filled and distributed on \_\_\_\_.

**Form 483 Observation-01-04** - Strict control is not exercised over labeling issued for use in drug product labeling operations. Specifically, labels are not properly reconciled by your firm. For example, during the walk-through on \_\_\_\_, we viewed returned product lot labels on the floor of the production area.

### ***How to prevent this from showing up in your inspection?***

Assure your pumpers clean the old lot numbers off the floor after each cylinder filling activity.

## GAWDA Professional Compliance Seminars - 2018

- March 20 - 22, 2018 - Ball Ground, GA (at Chart)

- October 16 - 18, 2018 - Aurora, IL (at Weldcoa)

[Click here for information or to register](#)

## March Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, March 30, we will cover **Subparts D - Equipment**. *Sample equipment maintenance records will be available for downloading during the training.*

In addition, we will be conducting the following additional training that day:

- **Specialty Gas** – Measuring and Controlling Uncertainty in Gravimetric Fill Systems (ISO 6142).
- **Food Gas Roundtable** –
  - CGMP Training – Part 117 Subpart A - Qualified Individuals, Exemptions
  - The latest information about food gas regulations is reviewed –
  - The sample Food Gas SOPs are available for downloading during the seminar.

# Medical, Food/Beverage and Specialty Gases Bulletin

If you would like to receive invitations to the training webinars, just send an email to [jodie@asteriskllc.com](mailto: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 Check** – Verify that the filter inspection record is current for your Servomex oxygen analyzer. The frequency of inspection is listed in the operator's manual for your instrument.
2. **Calibrations** – Be sure that your thermometers, vacuum gauges and high-pressure gauges are calibrated according to your SOPs.
3. **Daily Vacuum Gauge Verification** – Be sure you have a record that your vacuum gauge needles read zero at atmospheric pressure. This record should be made each day the vacuum gauge is used.

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