

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

### **MARCH 2019**

#### ***ENCLOSED***

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**Safety Topic:** Cylinder Delivery at Locations with Stairs and or Ramps

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

**Traffic Bulletin:** Medical Marijuana and CDL Drivers

**Please contact Mike Dodd for more information.**

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

1. FAQ: Color Coding Medical Gases
2. Recent FDA Observations: Lot Stickers; Labeling
3. GAWDA Compliance Seminars (dates, times, places): FDA/DOT Audit Survival
4. March Medical Gas Roundtable (29 March 2019): Subparts D – Equipment Specialty Gas – Measuring and Controlling Uncertainty in Gravimetric Fill Systems (ISO 6142)  
Food Gas Roundtable – CGMP Training – Part 117 Subpart A - Qualified Individuals, Exemptions
5. 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 DELIVERY AT LOCATIONS WITH STAIRS AND OR RAMPS

The GAWDA Safety Committee has published a sample policy that our members can use to reduce potential accidents. This policy along with the customer stair and ramp survey mentioned can be found on the GAWDA website under the Resources tab and then under the Reference Materials link. Here is the body of that sample policy:

It is the position of the Safety Committee that the delivery of cylinders, dewars, and cradles should not be made when stairs or ramps are involved.

This is to insure the safety of the delivery driver, to prevent injuries and to prevent the loss of control of cylinders etc. when stairs and or ramps are involved. Following are some guidelines to help establish a working procedure for these deliveries.

For clarification purposes; A curb or step up is not considered a flight of stairs, more than (1) step with less than (3) ft. of tread length is considered a flight of stairs. A grade rise in excess of 10% would be considered a ramp too steep for cylinder deliveries (see diagram below).

Delivery drivers will inform their supervisor of any issue regarding the delivery of cylinders when it involves stairs or ramps.

### Stair and Ramp Delivery Survey Form

To help identify a problem delivery, the delivery driver will complete a "Stairs and Ramps Delivery Survey" form.

The Stairs and Ramp Delivery Survey form must be turned in to supervisor.

Supervisor, can evaluate, address and resolve problem with customer, or notify the appropriate sales person. Customer should be advised of the problem and offered solutions.



## Stairs

Customers may utilize their personnel to move cylinder either down or up a flight of stairs. Should the customer elect to move cylinders etc. down or up stairs and or ramps a chained area should be made available at or near the stairs or ramp for the delivery of cylinders etc.

If no solution can be agreed on, then it must be determined if it is cost effective to continue doing business with this customer.

## RAMPS

### Grades of 10% or less

Cylinder carts or hand trucks may be used when transporting cylinders on ramps so long as the following applies:

- Ramp has a grade of 10% or less
- Ramp is in good repair
- Person using cylinder cart has the necessary training and is wearing the proper PPE
- Maximum manufacturer load weight of cart is not exceeded

**Warning:** Under no circumstance shall cylinders be rolled up or down a ramp. Losing control of a cylinder can result in serious injury and property damage.

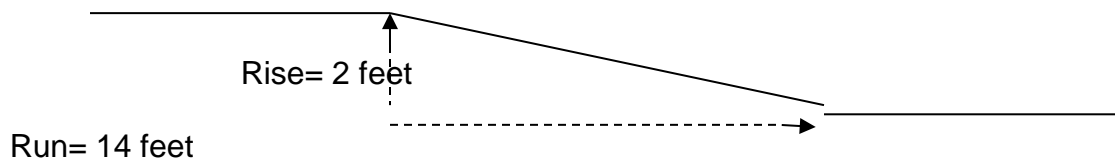
### Grades greater than 10%

It is recommended that a forklift or electric pallet jack be used when traveling on ramps with grades greater than 10%. Cylinders shall be secured/ strapped to prevent load from shifting while being transported. Examples of 10% grade are no more than 6" rise in 5', no more than 1' rise in 10', no more than 2' rise in 20', etc.

### Figuring Grade

**Grade= Rise/Run x 100**

Example:



$$2 / 14 \times 100 = \underline{14\% \text{ Grade}}$$

Here is a sample survey form that you can use for this program. Your drivers can use this form to inform you of any locations that might be a concern.



# Stairs & Ramps Delivery Survey

**Date:** \_\_\_\_\_

**Driver:** \_\_\_\_\_

**Customer  
Name:** \_\_\_\_\_

**Delivery  
Address:** \_\_\_\_\_

**City:** \_\_\_\_\_

**State:** \_\_\_\_\_

- Does delivery require more than a step-up or curb? \_\_\_\_\_
- How many steps are involved? \_\_\_\_\_
- Does the delivery require the use of a ramp with more than a 10% incline either up or down? \_\_\_\_\_
- Can other solutions be offered to customer? \_\_\_\_\_

• **Comments or Suggestions:**

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**Signature of Surveyor:** \_\_\_\_\_



**Please see the “Safe Cylinder Handling” sample policy for details on handling cylinders in general.**

Again, the purpose of this sample policy is to reduce accidents in the workplace and to provide our members with a template that they can use to write their own safety policy.

Feel free to contact me if you have any questions.

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# Traffic Bulletin Traffic Bulletin

**March 2019**

## **Medical Marijuana and CDL Drivers**

Recently some members have asked some questions regarding the DOT's position on the use of medical marijuana by drivers of commercial motor vehicles. The following is DOT's official policy. The basic answer is No it will not be allowed.

### **DOT OFFICE OF DRUG AND ALCOHOL POLICY AND COMPLIANCE NOTICE**

Recently, the Department of Justice (DOJ) issued guidelines for Federal prosecutors in states that have enacted laws authorizing the use of "medical marijuana."

<http://www.justice.gov/opa/documents/medical-marijuana.pdf>.

We have had several inquiries about whether the DOJ advice to Federal prosecutors regarding pursuing criminal cases will have an impact upon the Department of Transportation's longstanding regulation about the use of marijuana by safety-sensitive transportation employees – pilots, school bus drivers, truck drivers, train engineers, subway operators, aircraft maintenance personnel, transit fire-armed security personnel, ship captains, and pipeline emergency response personnel, among others.

We want to make it perfectly clear that the DOJ guidelines will have no bearing on the Department of Transportation's regulated drug testing program. We will not change our regulated drug testing program based upon these guidelines to Federal prosecutors.

The Department of Transportation's Drug and Alcohol Testing Regulation – 49 CFR Part 40, at 40.151(e) – does not authorize "medical marijuana" under a state law to be a valid medical explanation for a transportation employee's positive drug test result.

That section states:

#### **§ 40.151 What are MROs prohibited from doing as part of the verification process?**

As an MRO, you are prohibited from doing the following as part of the verification process:

(e) You must not verify a test negative based on information that a physician recommended that the employee use a drug listed in Schedule I of the Controlled Substances Act. (e.g., under a state law that purports to authorize such recommendations, such as the "medical marijuana" laws that some states have adopted.)

Therefore, Medical Review Officers will not verify a drug test as negative based upon information that a physician recommended that the employee use "medical marijuana."



# Traffic Bulletin

Please note that marijuana remains a drug listed in Schedule I of the Controlled Substances Act.

It remains unacceptable for any safety-sensitive employee subject to drug testing under the Department of Transportation's drug testing regulations to use marijuana.

We want to assure the traveling public that our transportation system is the safest it can possibly be.

Jim L. Swart

Director

Office of the Secretary of Transportation

Office of Drug and Alcohol

Policy and Compliance

Department of Transportation

October 22, 2009

If you have any questions on the above policy, please contact me at:

Michael Dodd

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# Medical, Food/Beverage and Specialty Gases Bulletin

**Medical Gas Bulletin**  
**03/01/2019**

## Frequently Asked Questions – Color Coding Medical Gases

**Q** – Does the FDA regulate the color of a medical gas cylinder sidewall or collar?

**A – No.** Here is the reference: 21 CFR §201.328 Labeling of medical gas containers (paragraphs b and c). See <https://www.govinfo.gov/content/pkg/CFR-2018-title21-vol4/pdf/CFR-2018-title21-vol4-sec201-328.pdf>

*(b) High-pressure medical gas cylinders. Each high-pressure medical gas cylinder must be colored on the shoulder portion of the cylinder in the color or colors designated in paragraph (c) of this section.*

*The color or colors must be visible when viewed from the top of cylinder.*

*(c) Medical gas colors. The colors required to identify medical gases under paragraph (a) and (b) of this section are:*

Medical gas	Color
Medical Air .....	Yellow.
Carbon Dioxide .....	Gray.
Helium .....	Brown.
Nitrogen .....	Black.
Nitrous Oxide .....	Blue.
Oxygen .....	Green.
Mixture or Blend .....	Colors corresponding to each component gas.

The collar and cap are not the “shoulder”. There are no FDA regulations about the collar or cap colors. This is completely consistent with the industry standard on this subject CGA C-9.

## 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.



# Medical, Food/Beverage and Specialty Gases Bulletin

## 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 – 2019 Spring - FDA/DOT Audit Survival**



- March 19 - 21, 2019 - Ball Ground, GA (at Chart)
- October 29 - 31, 2018 - Aurora, IL (at Weldcoa)

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

# Medical, Food/Beverage and Specialty Gases Bulletin

## March Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, March 29, 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.

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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