

SAFETY & TECHNOLOGY ORGANIZER

MAY 2012

ENCLOSED

Safety Topic: "Medical Product Mix-up"

Please contact GAWDA's OSHA and EPA Consultant, Mike Dodd for more information.

Traffic Bulletin: "Marketing and Identification"

Please contact GAWDA's DOT and Security Consultant, Mike Dodd for more information.

Medical Gas Bulletin: FAQs, Medical Gas Roundtables, and Micro-audit

Please contact GAWDA Medical Gas Consultant, Tom Badstubner 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



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 _____

Incident: Medical Product Mix-up

| | |
|-------------------------------|--|
| What happened | <ul style="list-style-type: none"> • Dentist called to say that the regulator doesn't fit on the E size cylinder • Distributor owner overheard the conversation and stepped in to investigate |
| Investigation Revealed | <ul style="list-style-type: none"> • Sold them a nitrous oxide E • Distributor supervisor did not open the locked storage cage. He gave the key to the salesman to retrieve the cylinder from the storage cage and he pulled a nitrogen versus a nitrous oxide cylinder. • The cylinders were painted per CGA guidelines. • Driver did not read the cylinder decal or recognize a problem with the color. • Delivered the nitrogen E • Dentist did not read the label but had a problem getting the regulator to hook up to the post valve and called the distributor for advice |
| Actions Taken | <ul style="list-style-type: none"> • Immediately held a safety meeting to emphasize reading product decals to verify product loaded versus sold • Emphasized the company procedure of a supervisor obtaining nitrous oxide from the locked storage cage • What saved the day? <ul style="list-style-type: none"> ○ Pin indexed valves ○ Customer did not remove the pins on their regulator and called without trying to make their own fix to the problem |
| Suggestions | <ul style="list-style-type: none"> • There are excellent downloadable posters and items that can be printed to remind people about not forcing or bypassing CGA connections. • http://www.cganet.com/FDA_materials/Medgasmixup.htm |



This is an example of an incident that was shared with the Safety Committee in order to get the word out to the GAWDA membership. If you have any incidents that you would share with the members, just let me know. We do not mention and company names as you can see above.

Feel free to contact me if you have any questions.

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TRAFFIC BULLETIN

May 2012

Marking and Identification

“What information do I need to put on the side of my vehicle?” is a common question I receive. The follow-up questions are “What size and color should the markings be and where on the vehicle am I allowed to put the information?”

What are the regulations?

390.21 Marking of CMVs

All vehicles defined as commercial motor vehicles according to §390.5 and operating in interstate commerce must display prescribed identification information.

- The legal name or a single trade name of the motor carrier operating the self-propelled CMV, as listed on the motor carrier identification report (Form MCS-150) and submitted in accordance with §390.19.
- The motor carrier identification number issued by the FMCSA, preceded by the letters "USDOT".

If the name of any person other than the operating carrier appears on the CMV, the name of the operating carrier must be preceded by the words "operated by." Other identifying information may be displayed on the vehicle if it is not inconsistent with the required information.

How do I display the Information?

The markings must:

- Appear on both sides of the self-propelled CMV;
- Be in letters that contrast sharply in color with the background on which the letters are placed;
- Be readily legible, during daylight hours, from a distance of 50 feet (15.24 meters) while the CMV is stationary; and
- Be kept and maintained in a manner that retains the required legibility.

The marking may be painted on the CMV or may consist of a removable device.





TRAFFIC BULLETIN

Rented Vehicles

If you use a rented vehicle, please read 390.21 for the specific requirements of marking the vehicle and the paperwork requirements of what should appear on the contractual agreement.

Interstate versus Intrastate

The above information applies if your vehicle is in interstate commerce. If your vehicle is only involved in intrastate commerce, then slightly different sets of rules apply depending on your state.

The major differences are that some states require a city and state added to the name and DOT number markings. There are also some states that issue and require state DOT numbers to be displayed on the vehicle. Some states even require the VIN number to be displayed on the sides of the vehicles. Please see your respective state regulations for the specifics or ask me and I can look them up for you.

Motor Carrier Identification Number

A motor carrier identification number is obtained by filing Form MCS-150, available without charge from any FMCSA motor carrier safety service center or division office.

If you are applying for a USDOT number for the first time, then be aware that it will generate a visit / audit from DOT to make sure that you have all the required records and programs in place as a motor carrier.

If there are any questions regarding this Bulletin, please ask.

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MEDICAL GAS BULLETIN

5/01/2012

Frequently Asked Questions

Q – Is Beverage CO₂ regulated as a food gas?

A - Yes. Beverage CO₂, Beer Gas, Nitrogen for food packaging are all examples of food gases.

Q – What incoming raw material testing is required for companies filling Beverage CO₂?

A - You must have proof that the bulk product you buy meets food grade specifications. You can do this by:

- Testing it yourself; or,
- Getting a Certificate of Conformance from your supplier; or,
- Getting a Certificate of Analysis from your supplier.

The certificate should specify conformance with the Food Chemical Codex (FCC) or CGA Food Grade.

Q – What full cylinder testing is required for companies filling Beverage CO₂?

A – The regulations actually do not specify any finished product testing for food grade gases.

May Medical Gas Roundtable (05/07/2012) – Subpart E – Control of Components Training

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In April we covered Internal Auditor Training.

In May, we will cover 21 CFR 211, Subpart E – Control of Components Training. This training covers the qualification of your raw materials (including bulk products) used in making medical gases.

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

- **Medical Device Gas** - QSR Subparts G, H, I & J - Production and Process Controls, Acceptance Activities, CAPA, Non-Conforming Product
- **Specialty Gas** - Making Your Own Working Standards

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 juliet@asteriskllc.com.





MEDICAL GAS BULLETIN

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. **Dead Ring Test** – Verify that the dead ring test is actually being performed on high pressure steel oxygen cylinders. Of course, the dead ring test should not be performed on aluminum cylinders. This simple item has appeared in recent FDA audits.
2. **Certificate of Analysis (CoA)** – Be sure that the CoAs you receive for your bulk medical product and for your Servomex span/zero gas cylinders have the following mandatory items:
 - Name and address of the calibration standard supplier
 - Name of the product
 - Lot number or unique identification number specific for each cylinder
 - Analytical methodology used to assay the calibration standard
 - Actual analytical results (for example, 99.9 percent nitrogen)
 - The responsible person's signature and the date signed

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