



SAFETY & TECHNOLOGY ORGANIZER

MAY 2014

ENCLOSED

Safety Topic: *Safety Posters Now Available!*

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

Traffic Bulletin: *"Medical Examiner Certification"*

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

Medical Gas Bulletin: *FAQ, Medical Gas Roundtable 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 _____

SAFETY POSTERS NOW AVAILABLE

The GAWDA safety committee has recently updated the safety posters we are very used to seeing in our locations. These posters are extremely helpful in explaining our position on properly transporting cylinders in vehicles and the requirements for placards when transporting certain quantities of hazardous materials.

These are available by contacting Cecilia Barbier at cbarbier@gawda.org. They will be priced at \$15 each. You will find these very suitable for framing or attaching to bulletin boards.

PLACARDING REQUIREMENTS FOR CYLINDER GASES AND RELATED PRODUCTS

PLACARDS REQUIRED UNDER SECTION 172.504, TABLE 1

USE OF TEXT ON PLACARDS (FOR EXAMPLE "FLAMMABLE GAS") IS OPTIONAL.

A TRUCK CARRYING ANY QUANTITY OF THE PRODUCTS LISTED TO THE RIGHT MUST BE PLACARDED FOR THE PRODUCTS AS SHOWN. THERE IS NO MINIMUM WEIGHT EXEMPTION.

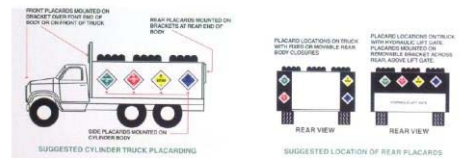


PLACARDS REQUIRED UNDER SECTION 172.504, TABLE 2

YOU WILL NEVER BE WRONG TO PLACARD A TRUCK FOR WHATEVER QUANTITY OF PRODUCTS LISTED IN TABLE 2 THAT IT IS CARRYING. HOWEVER - CERTAIN EXEMPTIONS AND CONSIDERATIONS ARE PERMITTED:

1. FOR THIS TABLE USE (WHETHER OR CONTAINER AND CONTENTS) OF ANY ONE OR COMBINATION OF PRODUCTS LISTED IN TABLE 2 NO PLACARD IS REQUIRED.
2. 1,001 LB. OR MORE OF NON-FLAMMABLE AND FLAMMABLE GASES, ONLY THE FLAMMABLE GAS PLACARD MUST BE DISPLAYED.
3. 1,001 LB. OR MORE OF NON-FLAMMABLE GASES AND OXYGEN CYLCS. YOU MAY SHOW EITHER THE NON-FLAMMABLE GAS OR OXYGEN PLACARD.
4. 1,001 LB. OR MORE OF FLAMMABLE GAS, NON-FLAMMABLE GAS, AND OXYGEN; THE FLAMMABLE GAS PLACARD MUST BE DISPLAYED AND OTHER THE NON-FLAMMABLE GAS OR OXYGEN PLACARD MAY BE DISPLAYED.

THESE ILLUSTRATIONS SHOWN BELOW INDICATE ACCEPTABLE LOCATIONS FOR PLACARDS ON ALL 4 SIDES OF THE TRUCK. THE ACTUAL NUMBER OF PLACARDS REQUIRED FOR ANY GIVEN LOAD WILL BE DETERMINED BY THE PRODUCTS CARRIED AND NOTATIONS SHOWN ABOVE.



THIS CHART COMPILED BY **GAWDA** REVISION 12/2013

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TRAFFIC BULLETIN

Medical Examiner Certification

MEDICAL EXAMINER CERTIFICATION BECOMES EFFECTIVE MAY 21, 2014

As of May 21, 2014, commercial motor vehicle drivers will only be able to use medical examiners who are registered on a federal certification database to perform their medical qualification exams. The [National Registry of Certified Medical Examiners](#) is a new Federal Motor Carrier Safety Administration program that requires all medical examiners who wish to perform physical examinations for interstate commercial motor vehicle drivers to be trained and certified in FMCSA physical qualification standards. Medical examiners who have completed the training and successfully passed the test are included in an online directory on the National Registry website. As of May 2014, CMV drivers will be required to be examined and qualified only by an ME who is listed on the National Register.

The core curriculum for the ME training and certification process focuses on those areas of 49 CFR Part 391 applicable to driver physical qualifications. In addition, the curriculum asks the examiners to inquire about a CMV driver's history of any sleeping or respiratory disorders, including obstructive sleep apnea. Companies using certified MEs for their driver exams are already reporting an increase in drivers sent for sleep apnea screening.

There are concerns that not enough medical examiners will be certified by May 21 to meet industry needs. The FMCSA is monitoring the situation and has said that there will be enough certified examiners nationwide, but perhaps not in some remote areas. Thus, GAWDA members are encouraged to have their drivers whose medical cards will expire in the next few months seek medical exams before the May 21 deadline with currently qualified medical examiners in order to avoid a driver having to travel long distances to find a certified ME after May 21.

I wish to thank Rick Schweitzer for providing the above information.

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

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MEDICAL GAS BULLETIN

05/01/2014

Frequently Asked Questions

Q – What is the latest information regarding New Animal Drug Application (NADA) submissions for drug listings?

A – The Center for Veterinary Medicine (CVM) has implemented additional validation procedures on medical gas drug listings for animal drugs. The agency believes that listings with NADA numbers should be classified as an Active Pharmaceutical Ingredient (API). We disagree with the Agency's position and have formally notified the agency of our objections.

The API requirements cause significant disruptions in the listing process for animal drug gases. After resolving this issue with the FDA, we will let you know how to proceed.

Interestingly, this does not seem to affect the human drug listings. We recommend that you continue to re-list your medical gases with the NDA (for humans) number in order to remove the “unapproved medical gas” statement from your drug listings.**Drug Storage**

The 2003, Draft Guidance for Industry - Current Good Manufacturing Practice for Medical Gases summarizes the FDA thinking and regulations about medical gas security:

May Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On **Friday, May 30**, we will cover **Subpart E – Control of Components Training**. This training covers the qualification of your raw materials (including bulk products) used in making medical gases

In addition we will be conducting the following additional training on **May 30**:

- 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
- Food Gas Roundtable** – 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 amy@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)
3. The responsible person's signature and the date signed

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