

SAFETY & TECHNOLOGY ORGANIZER

DECEMBER 2014

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ENCLOSED

Safety Topic: GAWDA Safety Posters

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

Traffic Bulletin: Medical card/CDL merger rule

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

Medical Gas Bulletin: FAQ's; December Medical Gas Roundtable (12/19/2014) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products

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

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SAFETY TOPIC

GAWDA Safety Posters

The GAWDA safety committee has updated the two posters that many of our members use and have posted in their locations.

One of them is the poster displaying vehicle explosions from carrying flammable gases inside enclosed vehicles. Many locations have this on the wall behind the sales counter so the customer can be pointed to them when we are trying to get them to not transport flammable gas cylinders inside their vehicles.

The other poster is the placarding regulations poster and these are typically posted where the drivers can refer to them.

These posters can be ordered from the GAWDA headquarters by using the order form found on this webpage: http://www.gawda.org/Resources/GAWDA-Resource

These are great posters and have been used by our members for many years and they have been updated with new pictures and update regulations.

As always, if there are questions or items that I can help you with, please don't hesitate to contact me.

Michael Dodd

GAWDA DOT, Security, OSHA, & EPA Consultant MLD Safety Associates, LLC P.O. Box 93 Poplar Bluff, MO 63902 (573) 718-2887

Email: MLDSafety@hotmail.com





December 2014

Medical card/CDL merger rule

JJ Keller has done a great job of explaining these new rules. The rules are complex and can be confusing at first glance. Please read the information at this link:

http://www.jjkeller.com/wcsstore/CVCatalogAssetStore/whitepapers/transport/CDL-MedCard-Merger.pdf

The final rule from the Federal Motor Carrier Safety Administration (FMCSA) requires states to place each interstate CDL driver's medical qualification status into the national commercial driver's license (CDL) database.

- An interstate commercial motor vehicle (CMV) driver who is required to hold a CDL will have to provide each of his/her medical certificates (wallet cards) and any applicable variances/exemptions to the state that issued the CDL by January 30, 2015. The expiration date of the certificate, as well as other details about the driver's medical certification, is then placed in the CDL database for tracking by the state. The driver must submit each subsequent medical certificate to the state in order to maintain an active CDL for interstate commerce:
- The state will have to make sure the driver is medically qualified before issuing, renewing, or upgrading the CDL, and will have to add the driver's medical qualification status to the driver's driving record by January 30, 2015;
- No later than January 30, 2015, employers will have to obtain each applicant's driving record to verify that he/she is medically qualified; and
- Because drivers' medical qualification status will be instantly accessible to enforcement officers, effective January 30, 2015, many drivers will no longer need to carry their medical cards with them in the truck or bus (at least for no longer than 15 days, as explained below).

Recordkeeping requirements

The current recordkeeping requirements under the rule are as follows, for all interstate CDL holders and their motor carriers:

DRIVERS:

- Non-excepted interstate CDL holders must continue to carry a copy of the current medical examiner's certificate while on duty until January 30, 2015, even if they have already supplied their medical cards to the state.
- Non-excepted interstate Commercial Learner's Permit (CLP) holders must continue to carry a copy of the current medical examiner's certificate while on duty until July 8, 2015, even if they have already supplied their medical cards to the state.
- After the deadlines noted above, interstate CDL/CLP drivers will no longer have to carry their medical certificates except for the 15 days after receiving a new

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medical certificate. That is, drivers who provide a new medical certificate to the state licensing agency must carry a copy of the certificate for up to 15 days, giving the state time (up to 10 days) to add the new information to the driver's record.

MOTOR CARRIERS:

- Motor carriers using interstate CDL drivers whose driving record includes their medical certification status must use the driving record (MVR) as proof of physical qualification and keep that driving record in the driver's qualification file. The MVR must be updated every time the driver's medical certification status changes.
- Motor carriers using interstate CDL drivers whose driving record does NOT yet
 include their medical certification status must use the driver's medical certificate
 as proof of physical qualification and keep the certificate (or a copy) in the
 driver's qualification file. States have until January 30, 2015, to place such
 information in their licensees' driving records. Once the state puts the medical
 information onto a driver's driving record, then the driving record must be used as
 proof of certification instead of the certificate.
- Once a CDL driver's medical certification information appears on the MVR, if the
 driver obtains a new medical certificate then the motor carrier can retain a copy
 of that certificate for up to 15 days, giving the state time (up to 10 days) to add
 the new information to the driver's record. After those 15 days, the carrier must
 have a new MVR showing the updated medical information.

Medical examiners and state licensing agencies will be required to keep a copy of each driver's medical card for three years. Employers will also have to continue maintaining medical cards for any drivers not subject to the rule, including non-CDL drivers. The final rule only applies to interstate CDL holders and their motor carrier employers, but states are expected to adopt similar rules for most in-state CDL drivers.

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

Michael Dodd GAWDA DOT, Security, OSHA & EPA Consultant P.O. Box 93 Poplar Bluff, MO 63902 (573) 718-2887

Email: MLDSafety@hotmail.com





Medical Gas Bulletin 12/01/2014

Frequently Asked Questions

Q – I got a message from the FDA titled "AN IMPORTANT MESSAGE FROM THE U.S. FOOD AND DRUG ADMINISTRATION" about our food gas registration. I thought I was already registered. What's this message about?

A – The FDA sent these email blast messages out to all food registrants. Many people did not need these messages since they were already registered.

Just to clarify the food registration requirements:

- All food production or warehousing facilities must be registered
- A food registration must be renewed on even numbered years (e.g. 2014) between 10/1 and 12/31.
- The FDA considers all gases that contact the food as a food (beverage carbonation, nitrogen blankets on food packages, etc.)

December Medical Gas Roundtable (12/19/2014) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products.

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In December we will be discussing the various records required by the FDA. In addition, we will have an easy to use handout about how to document your Annual Records Review.

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

- ISO 17025 ISO 17025 Propagation of Errors (developing an uncertainty budget)
- Specialty Gas Gas Chromatography Column & Detector Selection / Troubleshooting

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 amy@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:

- Complaints Verify that your complaint file has any instances of customers asking for credit because they thought the cylinder was not full. (Even if the complaint was found to be without merit).
- 2. **QCU Review -** Verify that your QCU reviews all complaints.
- 3. Other Lots? Be sure your complaint investigations consider whether any other cylinders from the same or different lots should be investigated. Document your decision to not investigate other cylinders/batches on the complaint record.

Tom Badstubner GAWDA Medical Gas Consultant

Telephone: 508-883-0927 Fax: 508-883-3558

Email: tom@asteriskllc.com