



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

### **JANUARY 2012**

#### ***ENCLOSED***

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##### ***Safety Topic: Cell Phone Ban***

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

##### ***Traffic Bulletin: "Road Test"***

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

##### ***Medical Gas Bulletin: GAWDA Medical Gas SOP Program Modernization***

*Please contact GAWDA Medical Gas Consultant, Tom Badstubner 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 \_\_\_\_\_

## New Rule Banning Cell Phone Use by CMV Drivers

The U.S. Department of Transportation has announced a new final rule that specifically prohibits interstate truck drivers from using hand-held cell phones while operating their vehicles. The joint rule from the Federal Motor Carrier Safety Administration and the Pipeline and Hazardous Materials Safety Administration is the latest action by DOT to discourage distracted driving by all operators of commercial motor vehicles.

The text of the final rule was published in the December 2 Federal Register (76 Federal Register 75470), and the rule will take effect on January 3, 2012.

September 2010, FMCSA issued a regulation banning text messaging while operating a commercial truck or bus and PHMSA followed with a companion regulation in February 2011, banning texting by intrastate hazardous materials drivers. The use of hands-free technology is still allowed under the new rule, however.

The final rule prohibits both **drivers of CMVs in interstate commerce and intrastate drivers who operate CMVs transporting a quantity of hazardous materials requiring placarding** under 49 CFR Part 172 from using a hand-held mobile telephone while operating a commercial truck. Drivers who violate the restriction will face federal civil penalties of up to \$2,750 for each offense and disqualification from operating a commercial motor vehicle for multiple offenses. Additionally, for drivers in interstate or intrastate commerce, states will suspend a driver's commercial driver's license after two or more serious traffic violations.

The rule does not specifically prohibit the use of CB or two-way radios, unless they have a push-to-talk function, in which case they are considered mobile phone devices and are subject to the rule. FMCSA says that drivers must transition to using using compliant (i.e., hands-free) mobile phone devices that do not require pushing a button to talk.

Other elements of the rule include the following:

- FMCSA agreed that drivers should be allowed to “reach for” a hands-free mobile phone device “provided the device is within the driver’s reach while he or she is in the normal seated position, with the seat belt fastened...a mobile device may be used if the driver can “initiate, answer, or terminate a call by touching a single button...”
- The final rule does not restrict mobile phone use “when the driver has moved the vehicle to the side of, or off, a highway and has halted in a location where the vehicle can safely remain stationary.”
- The rule requires employers to “ensure” compliance. FMCSA did not accept the argument of several commenters that employer sanctions are inappropriate where an employer has a policy banning hand-held phone use already in place. Employers may be subject to civil penalties up to \$11,000.



- The rule provides for disqualification of interstate commercial drivers convicted of using a handheld mobile telephone, and inter- or intrastate CDL holders convicted of two or more serious traffic violations of state or local laws or ordinances that restrict the use of handheld mobile devices. States will have three years to impose these new disqualifications under state law.
- The final rule provides an exception allowing drivers to use their handheld mobile telephones if necessary to communicate with law enforcement officials or other emergency services.

## Why did DOT enact the new rules?

Data from studies indicate that both reaching for and dialing a mobile telephone increase the odds of a CMV driver's involvement in a safety-critical event, such as a crash, near crash, or unintended lane departure.

The odds of being involved in a safety-critical event are three times greater when the driver is reaching for an object than when the driver is not reaching for an object. The odds of being involved in a safety-critical event are six times greater while the driver is dialing a cell phone than when the driver is not dialing a cell phone. These increases in risk are primarily attributable to the driver's eyes being off the forward roadway.

## Frequently Asked Questions

FMCSA has put together some helpful questions and answers on this topic. You can find them at this website:

<http://www.fmcsa.dot.gov/about/other/faq/cellphone-ban-faqs.aspx>

(I want to thank Rick Schweitzer for providing most of the material for this topic.)

**Feel free to contact me if you have questions. This is a very complicated rule and I fully expect lots of questions.**

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# TRAFFIC BULLETIN

**January 2012**

## **Road Test**

### **The “Road Test”, do I have to give it or not to a new driver?**

The regulations start out in 391.31 by saying that a person shall not drive a commercial motor vehicle unless he/she has first successfully completed a road test and has been issued a certificate of driver's road test.

Then in 391.33 the regulations give you a few exceptions. Please note, if the driver operates doubles, triples, or a vehicle requiring a tank endorsement, then you must always give the new driver a road test. However, if the driver operates any other type of vehicle, the motor carrier may accept in place of a road test the following:

A valid CDL from a state that requires a road test as part of obtaining the CDL; or

A copy of a valid certificate of road test issued within the previous 3 years.

Even though you may accept a current CDL or certificate of road test from another motor carrier, I highly recommend that you always give each new driver a road test. This is the only way you know that the driver really can drive your vehicle and do it in a safe and proper manner. I continue to receive thanks from our members for reminding them to always do road tests. You would be amazed by the number of drivers that have a CDL but don't know up from down in driving a truck.

## **The Road Test**

The road test must be done in a vehicle of the type the driver will be assigned. There are minimum items and things you are required to do when administering a road test. These are:

A pre-trip inspection;

Coupling and uncoupling a combination, if the driver may drive such equipment;

Placing the vehicle in operation;

Using the vehicle's controls and emergency equipment;

Driving in traffic and passing other vehicles;

Turning;

Braking, and slowing by means other than braking; and

Backing and parking.

The person that gives the test must rate the performance of the driver and this rating shall be on the form used to give the test and the person giving the test must sign the form. If the road test is completed successfully, the person giving the test must complete a certificate of road test that contains substantially the following:

- Driver's name
- Social Security No.
- Driver's license number
- State
- Type of power unit
- Type of trailers (if applicable)
- If a passenger carrier, the type of bus
- This certification:





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- This is to certify that the above-named driver was given a road test under my supervision on \_\_\_\_, 20\_\_, consisting of approximately \_\_ miles of driving.
- It is considered my opinion that this driver possesses sufficient driving skills to operate safely the type of commercial motor vehicle listed above.
- Signature of the tester
- Title of the tester
- Organization and address of the tester
- Date of the certification

JJ Keller includes a good road test form and certification in their driver qualification files.

## Who can give the test?

A person who is competent to evaluate and determine whether the person who takes the test has demonstrated that he/she is capable of operating the commercial motor vehicle shall give the test. The road test must be of sufficient duration to enable the person who gives it to evaluate the skill of the driver in the above minimum items.

## Recordkeeping

A copy of the certificate shall be given to the driver who was examined.

The motor carrier shall retain in the driver qualification file of the person who was examined:

- The original of the signed road test form; and
- The original or a copy of the certificate of the road test
- If an employer accepts a previous road test certificate or operator's license in lieu of a road test, the employing carrier must retain a legible copy of the certificate or license in the driver's qualification file.

Feel free to contact me if you have questions.

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# MEDICAL GAS BULLETIN

1/01/2012

## GAWDA Medical Gas SOP Program Modernization

The GAWDA Medical Gas SOP Program is THE industry standard compliance program. It is based on a solid set of procedures and is well implemented among program members.

We have received valuable feedback about the ease of use and compliance preparedness features of the SOPs. Together we have implemented over a hundred changes in the last three years. We may be able to further improve the procedures AND improve the compliance of program members at the same time. One such opportunity is to place the vacuum gauge verification record right on the fill log. This would be easier for the operator. It would also be much easier for the reviewer since there would be fewer pages to consider when deciding if the medical product should be released. Similar suggestions are for recording the expiration dates of detector tubes, etc.

We are holding a complete program modernization review on January 4<sup>th</sup>, 2012. This will be an opportunity to make comments and suggestions about your SOPs. We expect to modernize the procedures and make continuous improvement where needed. Since there are about 250 individual procedures and forms to consider, we will schedule the SOP review throughout the day. Contact [tom@asteriskllc.com](mailto:tom@asteriskllc.com) if you would like to see the review schedule.

What needs to be done now?

1. Block the entire day (1/4/2012) for attendance at the webinar. It will be a brutally difficult undertaking, but it is important.
2. In the meantime, look over the SOPs and make suggestions about potential changes. Use the form in the manual (INDEX 160 a1) to document your feedback and send it to [tom@asteriskllc.com](mailto:tom@asteriskllc.com) or fax it to 508-883-3558. Let me know if you want a Word version of the revision request form.

Shortly after the complete review of the SOPs, we will refresh your copies of the SOPs. This is a chance to have your good ideas implemented in the procedures.

A side benefit of the complete review is that you will receive a FDA CGMP Training Certificate for your participation in this project.

If you are not currently a GAWDA Medical Gas SOP Program member, but would like to contribute to this modernization project, please contact Tom Badstubner, [tom@asteriskllc.com](mailto:tom@asteriskllc.com)

## January Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On January 6, we will cover **Subparts A & B - Organization and Personnel**.

## Training Schedule - 2012

### GAWDA Professional Compliance Seminars

*The latest, documented training you need for DOT and FDA compliance...*

- March 27-29 Ball Ground, GA
- October 2-4 Aurora, IL

### FDA Drug CGMP - Current Good Manufacturing Practices

- 1/6/12 Subpart A & B - Personnel Qualifications
- 2/3/12 Subpart C - Buildings and Facilities
- 3/2/12 Subpart D - Equipment
- 4/6/12 CGMP - Internal Auditor Training





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- 5/4/12 Subpart E – Control of Components
- 6/1/12 CGMP - How to Survive an FDA Audit
- 7/13/12 Subpart F – Production and Process Controls
- 8/3/12 CGMP - Process Validation for Cylinder Plants
- 9/7/12 Subpart G – Packaging and Labeling Control
- 10/5/12 CGMP - High Pressure Prefill Inspection and Filling High Pressure Cylinders
- 11/2/12 Subparts H & I – Holding and Distribution, Laboratory Controls
- 12/7/12 Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products

## Specialty Gas Seminars

- 1/6/12 Gas Chromatograph Method Development
- 2/3/12 Analytical Math (Precision, Accuracy, Linearity, Chromatography Performance)
- 3/2/12 Measuring and Controlling Uncertainty in Gravimetric Fill Systems (ISO 6142)
- 4/6/12 Analytical Method Validation for Medical Gases
- 5/4/12 Making Your Own Working Standards
- 6/1/12 Robust and Efficient Gas Sampling Techniques
- 7/13/12 Making Highly Reliable Gravimetric Mixtures
- 8/3/12 Fuel/Oxidizer Safe Practices
- 9/7/12 High Pressure Prefill Inspection and Filling High Pressure Cylinders
- 10/5/12 Measuring and Controlling Uncertainty in Gas Chromatographs (ISO 6143)
- 11/2/12 Gas Chromatography Fundamentals
- 12/7/12 Gas Chromatography Column & Detector Selection / Troubleshooting

## FDA Device QSR - Quality System Regulations and ISO 17025

- 1/6/12 QSR Subparts A & B – Quality Systems Requirements
- 2/3/12 ISO 17025 - Measurement Uncertainty
- 3/2/12 QSR Subparts C D E & F- Design Controls, Document Controls, Purchasing Controls, Identification and Traceability
- 4/6/12 ISO 17025 - Proficiency Testing
- 5/4/12 QSR Subparts G, H, I & J - Production and Process Controls, Acceptance Activities, CAPA, Non-Conforming Product
- 6/1/12 ISO 17025 - Establishing Calibration Schedules
- 7/13/12 QSR Subparts K, L & M - Handling, Storage, Distribution, Installation, Packaging and Labeling Control, Records
- 8/3/12 ISO 17025 - Measurement Traceability
- 9/7/12 QSR Subpart N, O and Part 803 – Servicing, Medical Device Reporting, Statistical Techniques
- 10/5/12 ISO 17025/QSR - Complaints, Non-Conformances, Corrective Action/Preventive Action (CAPA)
- 11/2/12 ISO 17025 - Internal Audits and Management Reviews
- 12/7/12 ISO 17025 - Propagation of Errors

These live and other webinars are also available as a streaming recording. 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 are not already receiving invitations to the training webinars, just send an email to [tom@asteriskllc.com](mailto:tom@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. **Quality Control Unit Training** – Verify that your QCU has received CGMP training within the last year. This training should be documented. The GAWDA Medical Gas Roundtables are examples of CGMP training.
2. **Personnel Training** – Verify that your operations personnel and drivers have received documented CGMP and function specific training.

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