



SAFETY & TECHNOLOGY ORGANIZER

NOVEMBER 2014

ENCLOSED

Safety Topic: *OSHA Recordkeeping Updated*

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

Traffic Bulletin: *Unified Carrier Registration*

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

Medical Gas Bulletin: *CGA and GAWDA Medical Gas action in Michigan*

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



November 2014

OSHA Recordkeeping Updated

On September 11, 2014, the federal Occupational Safety & Health Administration (OSHA) announced updated occupational injury and illness reporting and recordkeeping requirements.

To view the News Release issued by the U.S. Department of Labor announcing this OSHA action, please go to:

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=26673

The newly revised final rule

(<https://www.osha.gov/recordkeeping2014/NAICSReporting.pdf>) does two key things:

1. Updates the list of industries that are exempt from the requirement to routinely keep OSHA injury and illness records. (Our industry is not exempt from the rules.)

To view this list, go to:

<https://www.osha.gov/recordkeeping/ppt1/RK1exempttable.html>

Conversely, to view OSHA's list of newly-covered industries, go to:

https://www.osha.gov/recordkeeping2014/reporting_industries.html

Previously based on the Standard Industrial Classification (SIC) system and Bureau of Labor Statistics (BLS) data from the mid-to-late 1990s, the new list is based on the North American Industry Classification System (NAICS) and more recent BLS data. *Important note: the revised final rule continues to exempt from this requirement any employer with 10 or fewer employees regardless of industry classification.*

2. Expands the list of severe work-related injuries that employers must report to OSHA by requiring the reporting within 24 hours of all work-related in-patient hospitalizations, amputations and loss of an eye. Previously, employers were required to report the hospitalization of three or more workers within eight hours. There was no requirement regarding amputations or eye losses. *Important note: all employers, whether or not exempt from the requirement that it routinely keep OSHA injury and illness records, must report work-related fatalities within eight hours and hospitalizations, amputations and eye losses with 24 hours.*

The revised rule goes into effect and applies to establishments located in states under the jurisdiction of OSHA on January 1, 2015, and in State Plan States (i.e., those states that operate their own safety and health programs) on that date or as soon thereafter as possible.



For more information including links to helpful fact sheets, please go to:
www.osha.gov/recordkeeping2014

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

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TRAFFIC BULLETIN

November 2014

Unified Carrier Registration

Everyone operating Commercial Motor Vehicles (CMVs)(power units only) in **interstate** commerce must register and pay a fee based on the number of CMVs operated in interstate commerce. Vehicles used solely in intrastate commerce are exempted from the registration and fees.

The website <http://www.ucr.in.gov/> will have the instructions and forms doing the registrations for the 2013, 2014, and 2015 reporting periods. You must register for each of the years that you operated CMVs in interstate commerce.

The UCR Agreement is a base-state system, under which a UCR registrant pays UCR fees through its Base State on behalf of all the participating States. A UCR registrant shall select its Base State using the following hierarchy:

- I. If your principal place of business state as completed in Section 1 of the form is AK, AL, AR, CA, CO, CT, DE, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NM, NY, OH, OK, PA, RI, SC, SD, TN, TX, UT, VA, WA, WI, or WV, you must use that state as your base state.
- II. If your principal place of business state is not one of those listed above but you have an office or operating facility located in one of those states, you must use that state as your base state.
- III. If you cannot select a base state using (I) or (II) above, you must select your base state from (I) above that is nearest your principal place of business or select your base state as follows:
 - a. If your principal place of business state is DC, MD, NJ or VT or the Canadian Province of ON, NB, NL, NS, PE, or QC, you may select one of the following states: CT, DE, MA, ME, NH, NY, PA, RI, VA, or WV.
 - b. If your principal place of business state is FL or a state of Mexico, you may select one of the following states: AL, AR, GA, KY, LA, MS, NC, OK, SC, TN, or TX.
 - c. If your principal place of business state is the Canadian Province of ON or MB, you may select one of the following states: IA, IL, IN, KS, MI, MN, MO, NE, OH, or WI.
 - d. If your principal place of business state is AZ, HI, NV, OR or WY, or the Canadian Province of AB, BC, MB, or SK or YT or a state of Mexico, you may select one of the following states: AK, CA, CO, ID, MT, ND, NM, SD, UT, or WA.





TRAFFIC BULLETIN

What vehicles are considered commercial motor vehicles for purposes of the UCR fees?

The number of commercial motor vehicles for purposes of determining a carrier's UCR fees is the number of commercial motor vehicles that are power units and not towed vehicles such as trailers that the carrier reported in the most recent Form MCS-150 it filed with FMCSA or the total number of commercial motor vehicles that are power units it owned or operated under long-term lease for the twelve-month period ending on June 30 immediately prior to the beginning of the UCR Agreement registration year for which the fees are being determined. A commercial motor vehicle is one that is operated in commerce and has a GVW or GVWR of at least 10,001 pounds or, in the case of a passenger vehicle, is one built to carry more than 10 persons, including the driver. It also includes a vehicle that transports hazardous materials in a quantity that requires placarding. It does not include, for this purpose, a vehicle that operates wholly in intrastate commerce.

How do I count the number of commercial motor vehicles to report in columns A, B, C, and D of Section 4 on the UCR application form?

You have two options: (1) Use the number of commercial motor vehicles listed on the last MCS-150 form you submitted for your USDOT number; or (2) Use the number of commercial motor vehicles you operated for the 12-month period ending June 30 of the year immediately prior to the year for which the UCR registration is made.

The UCR Board of Directors has established a National UCR System at www.ucr.in.gov. All UCR registrants may use this online system, regardless of base state, and it is the recommended method to register.

UCR Recordkeeping

1. UCR registrants are required to preserve the UCR records upon which the annual applications and renewals are based for three (3) years from the due date or filing date, whichever is later, plus any time period included as a result of State decisions or inquiries.
The three (3) year period is the current calendar year and the prior two (2) calendar years.
2. Records may be kept on paper, microfilm, microfiche, or other computerized or condensed record storage system as required by the Base State.





TRAFFIC BULLETIN

If you have any questions about whether you are still in the program or not, please contact:

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MEDICAL GAS BULLETIN

Medical Gas Bulletin
11/01/2014

CGA and GAWDA Medical Gas action in Michigan

A recent Michigan law requires all drug manufacturers to have a “Pharmacist in Charge” (PIC). CGA President, Mike Tiller, and GAWDA Medical Gas Consultant, Tom Badstubner, visited key members of the Governor’s staff and regulatory staff to discuss this new law. The law was originally intended to apply to compounding pharmacies and to prevent types of incidents that happened in Massachusetts where adulterated drugs were compounded and fatalities resulted.

After a spirited debate of the need to require the PIC to medical gas firms, the regulators met privately. When the meeting resumed, they recognized that medical gas firms are indeed exempt from the PIC requirements. This is good news for most GAWDA members. However, the exemption does not apply to Durable Medical Equipment (DME) suppliers and this could affect some members.

Contact Tom Badstubner if you would like to discuss how this law might affect your business.

Frequently Asked Questions

Q – How can I know for sure if my drug registration is current with the FDA?

A – Before 2009, the FDA would send you a completed registration form. Since the agency has implemented the electronic registration system, they no longer send you any form at all. The only way you can be certain that you are registered is by logging onto the FDA registration search website: <http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>. Enter a portion of your firm’s name and press the “Submit Query” button. Your search results will be displayed along with the Expiration Date of your registration.

FYI – here are two other useful FDA websites:

- Check your drug listings: <http://dailymed.nlm.nih.gov/dailymed/search.cfm>
- Check your FDA inspection summary:
<http://www.accessdata.fda.gov/scripts/inspsearch/>
 - Enter all/part of your company name.
 - The far right hand column (“classification”) is an indication of the severity of the inspection:
 - NAI – No Action Indicated (This is the classification you would like to see for your inspections)
 - VAI – Voluntary Action Indicated
 - OAI – Official Action Indicated
 - Keep in mind that not all inspections are posted on the Internet. State inspections as well as federal inspections that were hand written are not included in the database.





MEDICAL GAS BULLETIN

November Medical Gas Roundtable (11/21/2014) – Subparts H & I – Holding and Distribution, Laboratory Controls

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In November we will be discussing warehousing and laboratory operations.

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

- QSR/ISO 17025** - Internal Audits and Management Reviews
- Specialty Gas** - Gas Chromatography Fundamentals

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:

1. **Servomex Filter** - Verify that you have records that the filter on the Servomex has been inspected according to the frequency in your instrument manual.
2. **Segregation** – Be sure your full medical gas cylinders are segregated from your industrial gas cylinders.

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