GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

JANUARY 2017

ENCLOSED

Safety Topic: OSHA Injury Recordkeeping 3XX forms

Please contact Mike Dodd, GAWDA DOT, Security, OSHA & EPA Consultant for more information.

Traffic Bulletin: Service Trucks

Please contact Mike Dodd for more information.

Medical Gas Bulletin:

1. FDA Compliance: Food Supplier Qualification and Medical Gas Supplier Qualification
2. Frequently Asked Questions – Is the FDA now regulating industrial cryogenic containers by requiring tamper-proof or tamper-evident connections?
3. GAWDA Professional Compliance Seminars
4. Medical Gas Roundtable: 1/27/2017 21 CFR 211 Subparts A & B - Organization and Personnel.
3. Medical Device Gases (QSR) - Subparts A & B – Quality Systems Requirements
Specialty Gas - Gas Chromatography Method Development
Food Gas Roundtable – FSMA: introducing Part 117 & Registration
4. Micro Audit Suggestions

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.

GASES AND WELDING DISTRIBUTORS ASSOCIATION
One Oakwood Blvd. Suite 195, Hollywood, Fl 33020 P(954)367-7728 F(954)367-7790

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 _____

OSHA Injury Recordkeeping 3XX forms

Highlights of OSHA's Recordkeeping Rule

OSHA's rule addressing the recording and reporting of occupational injuries and illnesses affects approximately 1.4 million establishments. A number of specific industries in the retail, service, finance, insurance, and real estate sectors that are classified as low hazard are exempt from most requirements of the rule as are small businesses with 10 or fewer employees. Please remember that if you have 11 or more employees in your company (that is the whole company and not just a location) then you are under the recordkeeping rules.

OSHA revised the rule in 2002 and 2003. The new rule improves employee involvement, calls for greater employee privacy protection, creates simpler forms, provides clearer regulatory requirements, and allows employers more flexibility to use computers to meet OSHA regulatory requirements. Following is a brief summary of key provisions of the rule.

- Updates three recordkeeping forms:
  - OSHA Form 300 (Log of Work-Related Injuries and Illnesses); simplified and printed on smaller, legal size paper.
  - OSHA Form 301 (Injury and Illness Incident Report); includes more data about how the injury or illness occurred.
  - OSHA Form 300A (Summary of Work-Related Injuries and Illnesses); a new form created to make it easier to post and calculate incidence rates.
- Provides a single set of recording criteria for both work-related injuries and work-related illnesses. (The former rule required employers to record all illnesses, regardless of severity.)
- Requires records to include a work-related injury or illness resulting in one of the following: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, loss of consciousness, or diagnosis of a significant injury or illness by a physician or other licensed health care professional.
- Includes new definitions of medical treatment, first aid, and restricted work to simplify recording decisions.
- Requires a significant degree of aggravation before a preexisting injury or illness is considered work related.
- Adds further exceptions to the definition of work-relatedness to limit recording of cases involving eating and drinking of food and beverages, common colds and flu, blood donations, exercise programs, mental illnesses, etc.

- Clarifies the recording of "light duty" or restricted work cases. Requires employers to record cases when the injured or ill employee is restricted from "routine job functions," which are defined as work activities the employee regularly performs at least once weekly.
- Requires employers to record all needlestick and sharps injuries involving contamination by another person's blood or other potentially infectious materials.
- Includes separate provisions describing the recording criteria for cases involving the work-related transmission of tuberculosis.
- Eliminates the term "lost workdays" and requires recording of days away from work or days restricted or days transferred to another job. Calls for employers to count calendar days rather than workdays.
- Requires employers to establish a procedure for employees to report injuries and illnesses and tell their employees how to report. (Employers are prohibited from discriminating against employees who do report by Section 11(c) of the Occupational Safety and Health Act of 1970.)
- For the first time, employees and former employees will be guaranteed access to their individual OSHA 301 forms. Employee representatives will be provided access to the "information about the case" section of the OSHA 301 form in establishments where they represent employees.
- Protects employee privacy by (1) prohibiting employers from entering an individual's name on Form 300 for certain types of injuries or illnesses (e.g., sexual assaults, HIV infections, mental illnesses); (2) allowing employers not to describe the nature of sensitive injuries where the employee's identity would be known; (3) giving employee representatives access only to the portion of Form 301 that contains no personal information; and (4) requiring employers to remove employees' names before providing the data to persons not provided access rights under the rule.
- Requires the annual summary to be posted for 3 months instead of 1. Requires certification of the summary by a company executive.
- Excludes some public transportation and motor vehicle accidents from the reporting of fatalities and catastrophes.
- States that operate their own job safety and health programs will be adopting comparable recordkeeping rules. States must have the same requirements for which injuries and illnesses are recordable and how they are recorded. However, other provisions, such as industry exemptions, may be different as long as they are as stringent as the federal requirements.

OSHA has the forms and instructions available at this link:
http://www.osha.gov/recordkeeping/new-osha300form1-1-04.pdf

Here is a great link to a PowerPoint training program on the recordkeeping program:
http://www.osha.gov/recordkeeping/RKpresentations.html

Be sure to look at the comprehensive versions. There is a PowerPoint program for doing the presentation / training. There is a version with the speaker's notes and there is an instructor's guide.

OSHA has detailed guidance on the recordkeeping rule. This is a link to it: https://www.osha.gov/recordkeeping/entryfaq.html

Please remember that you must post your OSHA Form 300A for the 3 month period of Feb. 1st through April 30th. You must keep your OSHA recordkeeping forms for 5 years.

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. *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 went 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.

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

Traffic Bulletin

January 2017

Service Trucks

From time to time I get calls asking if service vehicle operators need to have all the items that their regular drivers need. To answer that question, one needs to refer to the two definitions of commercial motor vehicle found in the regulations.

The definition of "commercial motor vehicle" differs, depending on the part of the regulations being referenced. The general definition is found in §390.5. This definition refers to a vehicle used on highways, in **interstate** commerce (vehicle crosses state lines or transports commodities that are in interstate commerce), that meets one of the following criteria (I have left out the transporting of passengers statements):

- has a gross vehicle weight rating (GVWR) or gross combination weight rating (GCWR), or gross vehicle weight or gross combination weight of 10,001 pounds or more, whichever is greater; or

- is transporting hazardous materials in quantities requiring the vehicle to be placarded.

The regulations in Parts 390 through 397 apply to drivers of vehicles meeting the above definition. These parts include driver qualification, hours of service, and inspection and maintenance requirements.

A different definition of "commercial motor vehicle" is used for Parts 382 and 383. These parts regulate the commercial driver's license (CDL) and alcohol and drug testing. This definition refers to a vehicle used in commerce, **whether interstate *or* intrastate** (stays inside state lines), that meets one of the following criteria (again leaving out the transporting of passengers):

- has a gross combination weight rating of 26,001 or more pounds inclusive of a towed unit with a gross vehicle weight rating of more than 10,000 pounds;

- has a gross vehicle weight rating of 26,001 or more pounds;

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- is of any size and is used in the transportation of hazardous materials in quantities requiring the vehicle to be placarded.

As you can see, it can be a little confusing. Start first with the GVWR of the service vehicle to see if you are over 10,000 pounds (typically a 1 ton vehicle). Then ask yourself if you are crossing state lines with that vehicle. If yes, then follow the guidelines for the first definition. If no, then follow the guidelines for the second definition. If you are towing a trailer with a GVWR greater than 10,000, then be sure to add the trailer GVWR to that of the vehicle doing the towing to see if you exceed the 26,001 threshold.

Remember, if the vehicle is required to be placarded then all the rules apply regardless of GVWR weights.

Most states have adopted the above definitions, but some states have slight modifications or exceptions to the above. Be sure to check if your state has modified the definitions.

If there are any questions regarding this Bulletin or you want to check your state requirements, 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

Medical Gas Bulletin
01/01/2017

FDA Compliance ToDo List

1. **Food Supplier Qualification –** Obtain a certificate of Conformance from your bulk food gas suppliers. Assure that your bulk product meets one of the following grades:
    a. For Carbon Dioxide –
        i. FCC (Food Chemical Codex)
        ii. CGA G-6.2 Commodity Specification for Carbon Dioxide QVL H or I
        iii. ISBT (International Society of Beverage Technologists)
    b. For Nitrogen –
        i. FCC
        ii. NF (National Formulary)
        iii. ISBT
        iv. CGA G-10.1 Commodity Specification for Nitrogen QVL B

2. **Medical Gas Supplier Qualification** – assure that your
    a. Contract actually specifies USP/NF (Medical Gas)
    b. Suppler is registered with the FDA and licensed in your state
    c. Supplier has a valid NDA (New Drug Application) and NADA (New Animal Drug Application)

Contact tom@asteriskllc.com for checklists to accomplish these qualifications.

Frequently Asked Questions – CGA SB-26, industrial cryogenic containers and the FDA

Q – Is the FDA now regulating ***industrial*** cryogenic containers by requiring tamper-proof or tamper-evident connections?

A – The relevant portion of the new FDA regulations specify:

> *Portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (e.g., those that have been silver-brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the containers' use) except by the manufacturer.*

This new regulation refers only to portable cryogenic medical containers and not to industrial containers. However, the underlying (and referenced) standard is CGA SB-26, *Cylinder Connections on Portable Liquid Cryogenic Cylinders*.

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CGA SB-26 was developed in 2000 following several tragic incidents where cryogenic container outlet connections had been switched to connect the wrong gas to a customer's distribution system. This type of incident occurred in ***both industrial and medical*** systems. Multiple fatalities resulted.

Therefore, the industry standard, CGA SB-26, applies to both medical and industrial portable cryogenic containers. The standard for industrial portable cryogenic containers is slightly different from the FDA's regulation. CGA SB-26 allows one of three different methods to secure the outlet connections from tampering. The outlet connection protection method that is easiest to accomplish at the typical GAWDA member's plant is accomplished by using a device that deters the removal of the fitting and provides indication that removal was attempted or accomplished. We used to refer to these type of protections as "tamper-evident". We strongly encourage you to get your own copy of CGA SB-26 and fully understand the options. This publication is available for free to GAWDA members who participate in the CGA safety program (www.cganet.com). If you are not a part of the CGA safety program, this would be a good time to join… it's free. Otherwise, the publication's cost is only $5.00.

To summarize – the FDA's regulation does not explicitly cover portable cryogenic ***industrial*** containers, but long-standing, standard industry practice is to protect the outlets of industrial containers as described above and in CGA SB-26. Some industrial liquid containers in service may have had these protection devices compromised by users in the past. Plant personnel who fill portable cryogenic medical ***and*** industrial containers should also be trained to inspect, and correct if needed, the outlet protection devices during the pre-fill inspection of each container.

GAWDA Professional Compliance Seminars - 2017

- March 21 - 23, 2017 - Ball Ground, GA (at Chart)

- October 17 - 19, 2017 - Aurora, IL (at Weldcoa)

Hold the date... more details later

January Medical Gas Roundtable (27 January 2017)

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In this roundtable, we will cover **21 CFR 211 Subparts A & B - Organization and Personnel**.

This presentation will include discussions about the responsibilities, authorities and procedures of the Quality Control Unit. We will also review the types of training required for operators, drivers and counter personnel.

Medical Gas Bulletin

For your information, we are also conducting the following webinars that day:

- ***Medical Device Gases (QSR) -*** Subparts A & B – Quality Systems Requirements
- ***Specialty Gas*** - Gas Chromatography Method Development
- **Food Gas Roundtable** – FSMA: introducing Part 117 & Registration - Free resources, procedures and training for your food gas compliance including the latest Food Safety Modernization Act regulations and how to comply with 21 CFR 117.

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 tom@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. **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.

Tom Badstubner
GAWDA Medical Gas Consultant
Telephone: 508-883-0927
Fax: 508-883-3558
Email: tom@asteriskllc.com