

SAFETY & TECHNOLOGY ORGANIZER

JULY 2015

ENCLOSED

Safety Topic: OSHA Injury Recordkeeping 3XX froms

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

Traffic Bulletin: Load Securement

Please contact Mike Dodd for more information.

Medical Gas Bulletin:

- 1. FAQ: What should we do if the FDA wants us to launch a full investigation for each neck leaker we find during the leak test while we fill cylinders?**
- 2. FDA Drug Listing- Am I required to periodically review my drug listing?**
- 3. July Medical Gas Roundtable – (7/31/15)CGMP –Subpart F – Production and Process Controls**
- 4. Micro Audit Suggestions**

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 _____

JULY 2015 Safety Topic

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.

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-osh300form1-1-04.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 publishes a handbook on recordkeeping and reporting accidents. This is a link to it:

http://www.osha.gov/Publications/recordkeeping/OSHA_3245_REVISED.pdf

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. 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

July 2015

Load Securement

Protection against shifting and falling cargo, better known as load securement, is covered in the Code of Federal Regulations sections 393.100-136. The following sections have been selected because they relate to our industry.

393.100 Which types of commercial motor vehicles are subject to the cargo securement standards of this subpart, and what general requirements apply?

- (a) Applicability. The rules in this subpart are applicable to trucks, truck tractors, semitrailers, full trailers, and pole trailers.
- (b) Prevention against loss of load. Each commercial motor vehicle must, when transporting cargo on public roads, be loaded and equipped, and the cargo secured, in accordance with this subpart to prevent the cargo from leaking, spilling, blowing or falling from the motor vehicle.
- (c) Prevention against shifting of load. Cargo must be contained, immobilized or secured in accordance with this subpart to prevent shifting upon or within the vehicle to such an extent that the vehicle's stability or maneuverability is adversely affected.

393.102 What are the minimum performance criteria for cargo securement devices and systems?

- (a) Performance criteria. Cargo securement devices and systems must be capable of withstanding the following three forces, applied separately:
 - (a)(1) 0.8 g deceleration in the forward direction;
 - (a)(2) 0.5 g acceleration in the rearward direction; and
 - (a)(3) 0.5 g acceleration in a lateral direction.
- (b) Performance criteria for devices to prevent vertical movement of loads that are not contained within the structure of the vehicle. Securement systems must provide a downward force equivalent to at least 20 percent of the weight of the article of cargo if the article is not fully contained within the structure of the vehicle. If the article is fully contained within the structure of the vehicle, it may be secured in accordance with § 393.106(b).
- (c) Prohibition on exceeding working load limits. Cargo securement devices and systems must be designed, installed, and maintained to ensure that the maximum forces acting on the devices or systems do not exceed the working load limit for the devices under the conditions listed in paragraphs (a) and (b) of this section.

393.106 What are the general requirements for securing articles of cargo?

- (a) Applicability. The rules in this section are applicable to the transportation of all types of articles of cargo, except commodities in bulk that lack structure or fixed shape (e.g., liquids, gases, grain, liquid concrete, sand, gravel, aggregates) and are transported in a tank, hopper, box or similar device that forms part of the structure of a commercial motor vehicle.
- (b) General. Cargo must be firmly immobilized or secured on or within a vehicle by structures of adequate strength, dunnage or dunnage bags, shoring bars, tiedowns or a combination of these.
- (c) Cargo placement and restraint. (1) Articles of cargo that are likely to roll must be restrained by chocks, wedges, a cradle or other equivalent means to prevent rolling. The means of preventing rolling must not be capable of becoming unintentionally unfastened or loose while the vehicle is in transit.
 - (c)(2) Articles or cargo placed beside each other and secured by transverse tiedowns must either:
 - (c)(2)(i) Be placed in direct contact with each other, or
 - (c)(2)(ii) Be prevented from shifting towards each other while in transit.
- (d) Minimum strength of cargo securement devices and systems. The aggregate working load limit of any securement system used to secure an article or group of articles against movement





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must be at least one-half times the weight of the article or group of articles. The aggregate working load limit is the sum of:

- (d)(1) One-half of the working load limit of each associated connector or attachment mechanism used to secure a part of the article of cargo to the vehicle; and
- (d)(2) One-half of the working load limit for each end section of a tiedown that is attached to an anchor point.

The hazardous materials regulations also address load securement for our cylinders.

177.834 General requirements.

- (a) Packages secured in a motor vehicle. Any package containing any hazardous material, not permanently attached to a motor vehicle, must be secured against shifting, including relative motion between packages, within the vehicle on which it is being transported, under conditions normally incident to transportation. Packages having valves or other fittings must be loaded in a manner to minimize the likelihood of damage during transportation.

177.840 Class 2 (gases) materials.

- (a) Floors or platforms essentially flat. Cylinders containing Class 2 (gases) materials shall not be loaded onto any part of the floor or platform of any motor vehicle which is not essentially flat; cylinders containing Class 2 (gases) materials may be loaded onto any motor vehicle not having a floor or platform only if such motor vehicle be equipped with suitable racks having adequate means for securing such cylinders in place therein. Nothing contained in this section shall be so construed as to prohibit the loading of such cylinders on any motor vehicle having a floor or platform and racks as herein before described.

- (a)(1) Cylinders. Cylinders containing Class 2 gases must be securely restrained in an upright or horizontal position, loaded in racks, or packed in boxes or crates to prevent the cylinders from being shifted, overturned or ejected from the motor vehicle under normal transportation conditions. However, after December 31, 2003, a pressure relief device, when installed, must be in communication with the vapor space of a cylinder containing a Division 2.1 (flammable gas) material.

There is a section above that needs particular emphasis or clarification for our members.

- (b) Performance criteria for devices to prevent vertical movement of loads that are not contained within the structure of the vehicle. Securement systems must provide a downward force equivalent to at least 20 percent of the weight of the article of cargo if the article is not fully contained within the structure of the vehicle. If the article is fully contained within the structure of the vehicle, it may be secured in accordance with § 393.106(b).

If you are using pallets that only use gravity to hold them onto the vehicle then you would not be meeting the 20% downforce requirement. So several methods have been devised to accomplish this. I have seen hooks and strapping, clevis pins, and swinging bars used to secure the pallet to the vehicle.

If you are using carts to hold small cylinders or medical cylinders, then you need something to keep the cylinders in the carts besides just gravity. You can use rotating bars on the top of the carts, covers, or straps to secure the cylinders into the carts.





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Most of our members use web straps to secure the cylinders to the vehicle. These should be continually inspected for wear and tear. The rejection criteria require web straps to be removed from service when there is damage of more than 25% of the width of the strap. The strap attachment devices (hooks, chains, clips, etc.) should also be checked.

For more details and suggestions please see the Load Securement sample safety practice that we have posted on the members only portion of the GAWDA website. If you have trouble accessing this just ask me and I will forward you a copy.

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

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MEDICAL GAS BULLETIN

Medical Gas Bulletin
07/01/2015

Frequently Asked Questions

Q – FDA Inspection Enforcement - What should we do if the FDA wants us to launch a full investigation for each neck leaker we find during the leak test while we fill cylinders?

A – During a few routine inspections, the FDA has begun to issue Form 483's indicating that we need to be conducting formal investigations when we find neck leaks during the filling process. This is contrary to long-standing industry practice and agency enforcement. We are having ongoing discussions with the agency over this and other issues. If the FDA claims that you have this type of unusual violation during an inspection, please contact your GAWDA Medical Gas Consultant, tom@asteriskllc.com. We can then share with you the very latest industry position and suggested response to the agency.

Q – FDA Drug Listing – Am I required to periodically review my drug listing?

A – Yes. Though the FDA regulations (21 CFR 207.30) have been replaced by guidance, we are still required to review the correctness of the drug listings and make any corrections, if needed. The guidance specifies the month of June and December for these reviews, though the agency accepts changes to listings at any time.

The OSHA GHS label changes would trigger a relisting of the drug label. In addition, we should update the drug listing with the NDA/NADA (New Drug Application/New Animal Drug Application) numbers in order to remove the “Unapproved Medical Gas” statement from the online listing.

We are pleased to conduct a free review of your drug listing and send you quick report with suggestions. If you would like us to conduct this review, just send a message to tom@asteriskllc.com.

July Medical Gas Roundtable (07/31/2015) – CGMP - Subpart F – Production and Process Controls

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In June we covered how to survive an FDA audit.

In July, we will cover Subpart F – Production and Process Controls --- SOPs, filling cylinders, equipment identification, reprocessing, etc.

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

- **Medical Device Gases** - QSR Subparts K, L & M - Handling, Storage, Distribution, Installation, Packaging and Labeling Control, Records
- **Specialty Gas** - Making Highly Reliable Gravimetric Mixtures
- **Food Gas Roundtable** – CGMP Training – 21 CFR 110, Subpart G - Defect Action Levels
 - The latest information about food gas regulations is reviewed –
 - The sample Food Gas SOPs are available for downloading during the seminar.

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.

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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. **Authorized Procedures** – Verify that your Quality Control Unit has authorized your SOPs in writing.
2. **Following SOPs** – Be sure that your cylinder filling personnel are strictly following the authorized procedures. This is easily accomplished by taking a copy of the cylinder fill procedure to the manifold and watching the operator fill the cylinders.

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