GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

NOVEMBER 2017

ENCLOSED

Safety Topic: Accident and Incident Sharing

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

Traffic Bulletin: DRIVER QUALIFICATION FILE §391.51 DOT MANDATED ITEMS

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQ: FDA Drug Listings
2. November Medical Gas Roundtable (11/17/2017) – Subparts H & I – Holding and Distribution, Laboratory Controls
3. Webinars:
   ***1*. Specialty Gas - Measuring and Controlling Uncertainty in Gas Chromatographs**
   ***2*. Food Gas Roundtable - Part 117 Subpart F – Records Policy**
4. Micro Audit

Please contact Tom Badstubner, GAWDA FDA Food, Medical and Specialty Gases Consultant, 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
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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 _____

Accident and Incident Sharing

The GAWDA Safety Committee would like to receive any accidents or incidents that you would like to share with the membership. We will make sure that there are no company names or employee names mentioned. We want the submitter to remain anonymous. The hope and goal is that by sharing these accidents and incidents we might avoid or prevent this same item at your business.

These should make great safety meeting topics for the future. We also intend to post these on the GAWDA website making it easier for the membership to retrieve them for future use.

I have had four fatality potential incidents brought to my attention in the past two months and I just want to let you know what they were but I can't and I wouldn't give you the company names involved.

Three of the incidents were employees venting acetylene cylinders prior to requalification but not using a proper drain manifold. Two of the incidents resulted in the employee being severely burned and the third almost resulted in the loss of the large fill plant. The fourth incident was a cylinder found leaking through the side wall near the bottom while being filled. The cylinder was not hammer tested prior to filling.

Here is an example of what we have in mind. This was sent to the Safety Committee by one of our members.

- **What happened?**
  - While tightening a web strap on a group of cylinders on a truck, the strap broke
  - The driver lost his balance, fell, and broke a femur resulting in 90 lost workdays and over $100,000 in worker's compensation costs
  - The driver had over 30 years in the industry

- **Investigation revealed**
  - New straps were available in the facility
  - Drivers had never been trained in the proper inspection of web straps
  - Management had solely relied on drivers to determine the serviceability of straps
  - Management had no accountability for straps other to purchase as requested
- **Actions taken**
  - Drivers trained on strap inspection
  - Management will periodically inspect the straps to ensure that straps are replaced or repaired as needed
  - Training on straps to be done periodically to maintain the awareness level

If you have any accidents or incidents that you would like to share, then send them to me or any of the Safety Committee members.

The Safety Committee is working on a project to concentrate on workplace injuries and lost workday cases and whatever we can do to help lower the number of cases in the future. So we would love to hear about any lost workday cases or incidents or near misses that your company may have had and willing to share so others in our industry might avoid these in the future. Again, we will keep your company name extremely confidential.

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

Michael Dodd

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Traffic Bulletin

November 2017

DRIVER QUALIFICATION FILE
§391.51
DOT MANDATED ITEMS

A motor carrier is required to maintain a driver's qualification (DQ) file for each driver it employs. The DQ file need not be physically one recordkeeping medium such as a file folder, but must be a filing system that is identifiable to a specific individual.

Examples would include:

- A single driver qualification file folder where everything is kept inside one file; or
- In addition to a file folder, an electronic file such as a record on a database program where you keep some or all of the required items on the computer and some in the file as a hard copy; or
- A filing system, which may contain several physical files each, labeled to a specific individual. Some employers keep a separate driver qualification file, drug and alcohol file, and a personnel file. **(This is the system that I recommend. It is the easiest and most organized.)**

The DQ file may be combined with the driver's personnel file. (I don't recommend this option because the file can get very cluttered with all the HR items.)

DQ File Contents – mandated items. (All other records are company optional.)

The following documents are to be included in a DQ file for each regularly employed driver:

1. Application for employment (391.21),
2. Motor vehicle record from states (391.23),
    a. Must be obtained within 30 days of employment (I recommend having this before the driver drives your truck.)
    b. Must be for the prior 3 years
3. Previous employer information (391.23),
    a. Must be obtained within 30 days of employment
    b. Must be for the prior 3 years
4. Road test form and certificate (391.31(g)), or license or certificate accepted in lieu of road test (391.33),
    a. A CDL is acceptable.

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   b. Doubles / Triples or tankers must have a road test or a road test certification within the previous 3 years.
5. Medical exam certificate, original or a copy (391.43(g)),
   a. Beginning January 30, 2014, a medical exam certificate is not required for CDL drivers whose motor vehicle record contains medical certification status information. The motor carrier must instead retain a copy of the driver's motor vehicle record showing certification.
6. Motor carrier certification that the driver used an approved medical examiner. (391.51 (b)(9))
7. Any letter granting a waiver of a physical disqualification (391.49),
8. Annual review of driving record (391.25),
   a. Must be done at least annually
   b. Must keep a copy of the state inquiry results in the file.
   c. The motor carrier must consider the driver's accident record and any evidence that the driver has violated laws governing the operation of motor vehicles, and must give great weight to violations, such as speeding, reckless driving, and operating while under the influence of alcohol or drugs, that indicate that the driver has exhibited a disregard for the safety of the public.
9. List of violations (391.27),
   a. The driver shall provide a list of driving violations for the previous 12 months. The driver shall sign this list.
   b. If the driver has already provided this information as required by 383.31, then they don't have to repeat the information. 383.31 requires that drivers notify their carrier within 30 days of any vehicle violations, other than parking tickets, of which they have been convicted. The notification must be in writing and contain the 7 items listed in 383.31.
10. Any other matter relating to a driver's qualifications or ability to drive a motor vehicle safely.
11. Not required, but highly suggested is to have a copy of their current driver's license in the file. This is how you have proof of a current CDL, the proper vehicle class, the proper endorsements, and the expiration date.

A motor carrier is not required to have items 1 through 4 listed above in the DQ file for any current driver that was hired before January 1, 1971.

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Retention Periods

Items 1-4 are kept in the Driver qualification permanently.

Items 5-11 may be removed from the file after 3 years from when the form was executed. (391.51(d))

You must keep a driver's qualification file for 3 years after the person is no longer a driver. Records may be kept at the main office or at a regional or terminal location. The regulations require that records be available at the main office or other location within 48 hours after an official request has been made.

Common Question

"What do I do about an existing employee that I want to make a driver?" The easiest and best thing to do is to treat the employee as a brand-new hire. Make sure you have used a DOT driver application form. If not, then have them fill out a new DOT employee application. You still must do the previous employer background checks for the previous 3 years, but you do get to count the time the employee was working for you in the time period. Be sure to do the pre-employment drug screen.

The Driver Qualification File is a key component of the carrier's safety program. Whenever the DOT does a Compliance Review, you may expect DOT auditors to spend a great deal of time on Driver Qualification Files.

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin

11/01/2017

Frequently Asked Questions – FDA Drug Listings

Q – Why are we being asked to submit a review of our medical gas labels before 12/31/2017?

A – The FDA has a long-standing regulation that drug label listings should be updated whenever a change in the label or drug listing content is needed. In addition, we are required to check the label and listing during June and December of each year. In the past, if your internal label review indicated that everything was correct, you were not required to notify the agency.

However, the regulations were revised on 4/1/2017:

21 CFR 207.29(b) Annual review and update of registration information. Registrants must review and update all registration information required under 207.25 for each establishment.

(1) The first review and update must occur during the period beginning on October 1 and ending December 31 of the year of initial registration, if the initial registration occurs prior to October 1. Subsequent reviews and updates must occur annually, during the period beginning on October 1 and ending December 31 of each calendar year.

(2) The updates must reflect all changes that have occurred since the last annual review and update.

(3) If no changes have occurred since the last registration, registrants must certify that no changes have occurred. (Emphasis added.)

This “no-change” certification can be accomplished through a new submission system, “CDERDirect”. However, it is likely easier to simply use the normal Electronic Submission Gateway (ESG). If you are working with a registrar for your FDA registration and listings, the “no-change” submission can be done by them. If you submit your own registrations and listings and would like additional information about the process, please contact tom@asteriskllc.com.

If the agency does not receive confirmation that your drug product listing is correct, your listing will be deleted after 1/1/2018.

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One reason the agency is changing their process is that there are so many orphan drug product listings due to drug changes, company acquisitions, etc. They need to have a process to keep the drug product listing database current.

November Medical Gas Roundtable (11/17/2017) – 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:

- ***Specialty Gas*** - Measuring and Controlling Uncertainty in Gas Chromatographs (ISO 6143)
- **Food Gas Roundtable** – Part 117 Subpart F – Records Policy

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 jodie@asteriskllc.com.

Medical, Food/Beverage and Specialty Gases 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. **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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