

SAFETY & TECHNOLOGY ORGANIZER

MARCH 2017

ENCLOSED

Safety Topic: Injury and Illness Recordkeeping and Reporting

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

Traffic Bulletin: Qualifying a new driver

Please contact Mike Dodd for more information.

Medical Gas Bulletin:

- 1. Registration Questions:
 - Must a medical gas "distribution-only" (warehouse) location be registered with the FDA? What is the difference between a "Manufacturer" and a "Repacker" under federal FDA regs?
- 2. GAWDA Professional Compliance Seminars 2017; March 21 23, 2017 Ball Ground, GA (at Chart); October 17 19, 2017 Aurora, IL (at Weldcoa)
- 3. Medical Gas Roundtable: March 31, we will cover Subparts D Equipment and:

 Specialty Gas: Measuring and Controlling Uncertainty in Gravimetric Fill Systems (ISO 6142).

 Food Gas Roundtable CGMP Training Part 117 Subpart A Qualified Individuals, Distributor

 The latest information about food gas regulations is reviewed the sample Food Gas SOPs are available for downloading during the seminar.
- 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.







SAFETY TOPIC

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

Injury and Illness Recordkeeping and Reporting

Who must comply

Employers with more than ten employees and whose establishments are not classified as a partially exempt industry must record work-related injuries and illnesses using OSHA Forms 300, 300A and 301.

You must keep a separate OSHA 300 Log for each establishment (location) that is expected to be in operation for one year or longer. You may keep one OSHA 300 Log covering all of your short-term establishments.

- Use the correct forms. Injuries and illnesses are recorded on the OSHA 300
 Log of Work-Related Injuries and Illnesses. For each injury or illnesses listed on
 the Log, you must complete an OSHA 301 Injury and Illness Incident Report (or
 equivalent form). Many employers choose to use their state's First Report of
 Injury (FROI) form for this purpose. At the end of the year, you must complete the
 300-A Summary and have it certified by a company executive. Get the forms
 here: https://www.osha.gov/recordkeeping/RKforms.html
- Post the OSHA 300-A Summary no later than February 1 of the year following the year covered by the records and keep the posting in place until April 30. You must post a copy of the annual summary in each establishment in a conspicuous place or places where notices to employees are customarily posted. In addition, you must ensure that the summary is not altered, defaced, or covered by other material.
- Maintain the injury and illness records for the five-year retention and update period. You must keep the OSHA injury and illness recordkeeping forms on file for five years. During that time, if the classification of a case changes (e.g. An employee who was on restricted work status needed surgery related to the original injury, resulting in days away from work), then you will need to update the OSHA 300-Log to reflect those changes. You do not need to update the annual summary or the incident reports, but you may do so if you wish.





New Item

Electronically submitting your data to OSHA.

Here is the OSHA website where you can read all the details on the new electronic submission of your OSHA reports:

https://www.osha.gov/recordkeeping/finalrule/index.html

The following is a brief summary of the new rule and how it applies to our members.

Compliance schedule

The new reporting requirements will be phased in over two years:

Establishments with 250 or more employees in industries covered by the recordkeeping regulation must submit information from their 2016 Form 300A by July 1, 2017. These same employers will be required to submit information from all 2017 forms (300A, 300, and 301) by July 1, 2018. Beginning in 2019 and every year thereafter, the information must be submitted by March 2.

Establishments with 20-249 employees in <u>certain high-risk industries</u> must submit information from their 2016 Form 300A by July 1, 2017, and their 2017 Form 300A by July 1, 2018. Beginning in 2019 and every year thereafter, the information must be submitted by March 2.

OSHA State Plan states must adopt requirements that are substantially identical to the requirements in this final rule within 6 months after publication of this final rule.

Unfortunately, our most of our industry falls under the **certain industries with historically high rates of occupational injuries and illnesses** category. https://www.osha.gov/recordkeeping/NAICScodesforelectronicsubmission.html

Most of our distributor members fall under the NAICS code 42XXXX categories, wholesale trade, which means you must submit information from your 2016 Form 300A by July 1, 2017.

Feel free to contact me if you have any questions.

Michael Dodd

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March 2017

Qualifying a new driver

What are the things that I need to do to hire a driver? How fast can I put a new driver on the road? What items do I need to have in my hands before letting a driver go out on the road? What should I look for on the motor violation records when deciding to hire a driver? What minimums should I have for hiring a driver? These are some of the questions that I get when someone is trying to put on a new driver. The following guidance assumes that you want a **driver for loads requiring placards**.

Must have items before letting a person drive

- 1. DOT employment application
- 2. CDL with hazmat endorsement (if you have a tank(s) bolted to the vehicle with more than 119 gals of capacity, then you need a cargo tank endorsement)
- 3. Current medical card
- 4. A negative pre-employment drug test
- 5. Road test form and certificate (391.31(g)), or CDL license or certificate accepted in lieu of road test (391.33),
 - a. A CDL is acceptable.
 - b. Doubles / triples or cargo tankers must have a road test certification for the specific vehicle within the previous 3 years.

Items that you must have within 30 days

- 1. Motor vehicle record from states (391.23),
 - a. Must be obtained within 30 days of employment
 - b. Must be for the prior 3 years
 - c. **Please note** that the regulations require this within 30 days, but I suggest that you have this and review it prior to letting the driver drive your vehicles.
- 2. Previous employer information (391.23), (if the applicant was a CDL driver in the past 3 years)
 - a. Must be obtained within 30 days of employment
 - b. Must be for the prior 3 years





c. The information must be verification of employment, any DOT accidents (or any other accidents that the previous employer may want to provide), and the drug and alcohol test results/violations.

Items needed later down the road

- 1. 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
- 2. List of violations (391.27) (part of the above annual review),
 - 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.
- 3. Medical Examiner's Certificate
 - a. Motor carriers using interstate CDL drivers whose driving record includes their medical certification status must use the driving record (MVR) as proof of physical qualification and keep that driving record in the driver's qualification file. The MVR must be updated every time the driver's medical certification status changes.
 - b. Employers will also have to continue maintaining medical cards for any drivers that are only intrastate drivers. Please note that some states require intrastate drivers to submit their medical card information so it can be placed into the MVR system.





4. Documentation that you have verified that the doctor was on the National Registry of Certified Medical Examiners at the time of the examination. You can do this verification at this website:

https://nationalregistry.fmcsa.dot.gov/NRPublicUI/home.seam

Suggested items for the DQ file

1. Not required, but highly suggested is to have a copy of their current driver's license in the file.

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 have to 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 that 3-year time period. Be sure to do the pre-employment drug screen.

Driver Eligibility Requirements

Next month, I will have some suggestions to consider for driver eligibility requirements. The suggestions will have some minimum requirements and some items that would possibly disqualify a driver from being considered for a driver position.

Feel free to contact me on any of these items if you have questions.

Michael Dodd

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Medical Gas Bulletin 03/01/2017

Registration Questions

Q – Must a medical gas "distribution-only" (warehouse) location be registered with the FDA?

A – No. The FDA only requires registration for those locations that fill/produce medical gases. Distribution/warehousing does not require federal FDA registration. However, most states require "licensure" of wholesale drug distributors under their Board of Pharmacy/Drug Manufacturing regulations.

Q – What is the difference between a "Manufacturer" and a "Repacker" under federal FDA registration regulations (21 CFR Part 207)?

A – These two terms used to have the same meaning and were used interchangeably for locations that fill medical gas cylinders. In the future, the term "manufacturer" will be used on the FDA registration to denote the location that:

- Initially produces the medical gas (e.g. ASU's)
- Fills medical air, by compression
- Blends two medical gases to form a drug gas mixture (e.g. helium and oxygen mixtures)

The term "repacker" is used on the FDA registration to denote the location that fills a medical gas that was initially produced by another firm (e.g. filling oxygen high-pressure cylinders at most GAWDA members).

You should assure your manufacturer/repacker classification is updated during your next FDA registration (October through December, 2017). There is no need to make any changes until then.

This change causes NO CHANGE to any other CGMP compliance requirements for medical gas firms.

CGA and GAWDA have responded to the Federal Register notice on these new rules. If our conversations with the agency causes any changes to these interpretations, we will keep you informed.



GAWDA Professional Compliance Seminars - 2017

- March 21 23, 2017 Ball Ground, GA (at Chart)
- October 17 19, 2017 Aurora, IL (at Weldcoa)

 <u>Click here for information or to register</u>

March Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, March 31, we will cover **Subparts D - Equipment**. Sample equipment maintenance records will be available for downloading during the training.

In addition we will be conducting the following additional training that day:

- **Specialty Gas** Measuring and Controlling Uncertainty in Gravimetric Fill Systems (ISO 6142).
- Food Gas Roundtable
 - CGMP Training Part 117 Subpart A Qualified Individuals, Distributors
 - The latest information about food gas regulations is reviewed –
 - The sample Food Gas SOPs are available for downloading during the seminar.

If you would like to receive invitations to the training webinars, just send an email to jodie@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 Check** Verify that the filter inspection record is current for your Servomex oxygen analyzer. The frequency of inspection is listed in the operator's manual for your instrument.
- 2. **Calibrations** Be sure that your thermometers, vacuum gauges and high pressure gauges are calibrated according to your SOPs.



3. **Daily Vacuum Gauge Verification –** Be sure you have a record that your vacuum gauge needles read zero at atmospheric pressure. This record should be made each day the vacuum gauge is used.

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