

SAFETY & TECHNOLOGY ORGANIZER

MAY 2018

ENCLOSED

Safety Topic: Forklift Training

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

Traffic Bulletin: Road Test

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

- 1. Recent Recent FDA Observations (excerpts from actual FDA inspections at medical gas companies).**
- 2. FAQ: What should I do if an FDA investigator asks me to sign an affidavit?**
- 3. Dates & Topics for Medical & Food Gas Roundtable; CGMP & Specialty Gas Training.**
- 4. Micro Audit Suggestions.**

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.



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 _____

Forklift Training

Each year, tens of thousands of injuries related to powered industrial trucks (PIT), or forklifts, occur in US workplaces. Many employees are injured when lift trucks are inadvertently driven off loading docks, lifts fall between docks and an unsecured trailer, they are struck by a lift truck, or when they fall while on elevated pallets and tines. Most incidents also involve property damage, including damage to overhead sprinklers, racking, pipes, walls, and machinery. Unfortunately, most employee injuries and property damage can be attributed to lack of safe operating procedures, lack of safety-rule enforcement, and insufficient or inadequate training.

It is a violation of Federal law for anyone UNDER 18 years of age to operate a forklift or for anyone OVER 18 years of age who is not properly trained and certified to do so.

What does the OSHA 1910.178 standard require?

The standard requires employers to develop and implement a training program based on the general principles of safe truck operation, the types of vehicle(s) being used in the workplace, the hazards of the workplace created by the use of the vehicle(s), and the general safety requirements of the OSHA standard. Trained operators must know how to do the job properly and do it safely as demonstrated by workplace evaluation. Formal (lecture, video, etc.) and practical (demonstration and practical exercises) training must be provided.

- Employers must also certify that each operator has received the training and evaluate each operator at least once every three years.
- Prior to operating the truck in the workplace, the employer must evaluate the operator's performance and determine the operator to be competent to operate a powered industrial truck safely. This is known as the performance test. OSHA has a sample form that can be used to document the performance test at this link:
<http://www.osha.gov/dte/library/pit/test.html>
- Refresher training is needed whenever an operator demonstrates a deficiency in the safe operation of the truck.

Who should conduct the training?

All training and evaluation must be conducted by persons with the necessary knowledge, training, and experience to train powered industrial truck operators and evaluate their competence. An example of a qualified trainer would be a person who, by possession of a



recognized degree, certificate, or professional standing, or who by extensive knowledge, training, and experience has demonstrated the ability to train and evaluate powered industrial truck operators.

There are many resources available to the employer if he/she chooses not to perform the training himself. Truck manufacturers, local safety and health safety organizations, such as the National Safety Council local chapters, private consultants with expertise in powered industrial trucks, local trade and vocational schools are some available resources.

Various Internet sites are devoted to forklift safety. Private companies, who provide forklift safety training services, including videos and written programs, can be located on various Internet websites. Most videos can be either leased or purchased. One important thing to remember is that simply by showing employees a video or videos on some aspect of forklift safety does not meet the full requirements of the OSHA standard. Site specific information must be conveyed as well as a method to evaluate the employee's acquired knowledge subsequent to the training.

Is testing required?

No. The standard does not specifically require testing; however, some method of evaluation is necessary.

Does OSHA require the employer to issue licenses to employees who have received training?

No. The OSHA standard does not require employees to be licensed. An employer may choose to issue licenses to trained operators if they wish.

What type of records or documentation must I keep?

The OSHA standard requires that the employer certify that each operator has received the training and has been evaluated. The written certification record must include the name of the operator, the date of the training, the date of the evaluation, and the identity of the person(s) performing the training or evaluation.

How long must I keep the certification records?

Employers who evaluate the operator's performance more frequently than every three years may retain the most recent certification record; otherwise, certification records must be maintained for three years.

OSHA has a great frequently asked questions site here:

http://www.osha.gov/dte/library/pit/pit_q-a.html

Here is the OSHA website on powered industrial trucks - forklifts:

<https://www.osha.gov/SLTC/powerindustrialtrucks/index.html>



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

Traffic Bulletin

May 2018

Road Test

The “Road Test”, do I have to give it or not to a new driver?

The regulations start out in 391.31 by saying that a person shall not drive a commercial motor vehicle unless he/she has first successfully completed a road test and has been issued a certificate of driver's road test.

Then in 391.33 the regulations give you a few exceptions. Please note, if the driver operates doubles, triples, or a vehicle requiring a tank endorsement, then you must always give the new driver a road test. However, if the driver operates any other type of vehicle, the motor carrier may accept in place of a road test the following:

- A valid CDL from a state that requires a road test as part of obtaining the CDL; or
- A copy of a valid certificate of road test issued within the previous 3 years.

Even though you may accept a current CDL or certificate of road test from another motor carrier, I highly recommend that you always give each new driver a road test. This is the only way you know that the driver really can drive your vehicle and do it in a safe and proper manner. I continue to receive thanks from our members for reminding them to always do road tests. You would be amazed by the number of drivers that have a CDL but don't know up from down in driving a truck.

The Road Test

The road test must be done in a vehicle of the type the driver will be assigned. There are minimum items and things you are required to do when administering a road test. These are:

1. A pre-trip inspection;
2. Coupling and uncoupling a combination, if the driver may drive such equipment;
3. Placing the vehicle in operation;
4. Using the vehicle's controls and emergency equipment;
5. Driving in traffic and passing other vehicles;
6. Turning;
7. Braking, and slowing by means other than braking; and
8. Backing and parking.

The person that gives the test must rate the performance of the driver and this rating shall be on the form used to give the test and the person giving the test must sign the form. If the road test is completed successfully, the person giving the test must complete a certificate of road test that contains substantially the following:



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- Driver's name
- Social Security No.
- Driver's license number
- State
- Type of power unit
- Type of trailers (if applicable)
- If a passenger carrier, the type of bus
- This certification:

This is to certify that the above-named driver was given a road test under my supervision on _____, 20____, consisting of approximately ____ miles of driving.

It is considered my opinion that this driver possesses sufficient driving skills to operate safely the type of commercial motor vehicle listed above.

- Signature of the tester
- Title of the tester
- Organization and address of the tester
- Date of the certification

JJ Keller includes a good road test form and certification in their driver qualification files.

Who can give the test?

A person who is competent to evaluate and determine whether the person who takes the test has demonstrated that he/she is capable of operating the commercial motor vehicle shall give the test. The road test must be of sufficient duration to enable the person who gives it to evaluate the skill of the driver in the above minimum items.

Recordkeeping

A copy of the certificate shall be given to the driver who was examined.

The motor carrier shall retain in the driver qualification file of the person who was examined:

- The original of the signed road test form; and
- The original or a copy of the certificate of the road test



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- If an employer accepts a previous road test certificate or operator's license in lieu of a road test, the employing carrier must retain a legible copy of the certificate or license in the driver's qualification file.

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

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin
05/01/2018

Recent FDA Observations

Please see these excerpts from actual FDA inspections at medical gas companies. Consider if these observations could happen at your facility and correct the problem, if needed. For the full list of recent FDA observations and a training record, contact tom@asteriskllc.com. Please forward a scanned copy of any FDA inspections you receive. We will remove any company identification and include in the recent FDA activity report.

Buildings

Form 483 Observation-03-03 - Buildings used in the manufacturing and holding of a drug product are not maintained in a good state of repair. Specifically,

- There was dirt and debris located on the floor in the ___ Fill Manifold area where the filling operations for the Liquid Oxygen USP product occurs.
- There was a 4 to 5 inch hole at the bottom of the dock door next to the area where their Liquid Oxygen USP product filling operations occur.

How to prevent this from showing up in your inspection?

Daily sweep up the fill area and maintain the building to a reasonable standard. We are not going to be able to have a perfect pest exclusion system, however, we can repair the obvious rodent entry holes.

Medical, Food/Beverage and Specialty Gases Bulletin

Frequently Asked Questions

Q - What should I do if an FDA investigator asks me to sign an affidavit?

A – We recommend that you never sign an affidavit from an FDA investigator before your corporate counsel approves it. In most cases, your lawyer will not approve the signing of the affidavit. The investigator may ask you to make some corrections or simply acknowledge the affidavit. Once again, we recommend that you politely let the investigator know that you are not permitted to sign, correct or acknowledge the document.

The investigator has been trained to get your signature and/or acknowledgment. For example, see the following section from the FDA's *Investigations Operations Manual*:

4.4.8.2 - Refusal to Sign the Affidavit

Prepare the statement as described above even if it is apparent the affiant will refuse to sign the affidavit. Have the affiant read the affidavit. If they decline, read it to them. Request the affiant correct and initial any errors in his/her own handwriting. Ask the affiant if the statement is true and correct. Ask him/her to write at the bottom of the statement "I have read this statement and it is true, but I am not signing it because..." in his/her own handwriting.

If the affiant still does not sign the affidavit, you should write a statement noting the refusal situation. Write this near the bottom and within the body of the affidavit. Include the actual situation, such as, you recorded the above facts as the affiant revealed them, the affiant read or refused to read the statement and avowed the statement to be true, and the affiant's reason for refusing to sign (e.g., "upon advice of corporate counsel", "per corporate policy", etc.). Sign and date this statement in the body of the document; only sign in the signature block if the affiant signs the affidavit. Once the refusal is documented on the affidavit, it is not necessary to include any additional narrative under the refusals section of the EIR.

Medical, Food/Beverage and Specialty Gases Bulletin

Be polite and respectful to the inspector, but do not sign, initial or acknowledge an affidavit unless instructed by your corporate counsel. The affidavit is designed to help the FDA and not to help you.

May Medical Gas Roundtable - Subpart E – Control of Components Training

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, May 25, we will cover **Subpart E – Control of Components Training**. This training covers the qualification of your raw materials (including bulk products) used in making medical gases.

In addition, we will be conducting the following additional training on May 25:

- **Specialty Gas** - Making Your Own Working Calibration Gas Standards
- **Food Gas Roundtable** –
 - CGMP Training – Part 117 Subpart C – Hazard Analysis and Risk Prevention Controls (HARPC) – General Program
 - 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.

Medical, Food/Beverage and Specialty Gases Bulletin

For this month, simply do these items:

1. **Dead Ring Test** – Verify that the dead ring test is actually being performed on high-pressure steel oxygen cylinders. Of course, the dead ring test should not be performed on aluminum cylinders.
2. **Certificate of Analysis (CoA)** – Be sure that the CoAs you receive for your bulk medical product and for your Servomex span/zero gas cylinders have the following mandatory items:
 - Name and address of the calibration standard supplier
 - Name of the product
 - Lot number or unique identification number specific for each cylinder
 - Analytical methodology used to assay the calibration standard
 - Actual analytical results (for example, 99.9 percent nitrogen)
 - The responsible person's signature and the date signed

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