



NOVEMBER 2021

ENCLOSED

Safety Topics

Fall Protection

Walking/Working Surfaces

Please contact [Marilyn Dempsey](#), GAWDA DHS, EPA, & OSHA Consultant for more information.

Traffic Bulletin

DOT Records Retention

Please contact [Mike Dodd](#), GAWDA DOT Consultant for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQs: FDA Drug Listings
2. Recent FDA Observations
3. November Medical Gas Roundtable (11/19/2021) – Instrument Qualification & Analytical Method Validation for Medical Gases
4. Micro-Audit Suggestions

Please contact [Tom Badstubner](#), GAWDA FDA Food, Medical & Specialty Gases Consultant for more information.

**** Join us for our Monthly LIVE “Safety Managers’ Safety Meeting” ****

Our next meeting is [November 10th](#) @ 1PM Eastern. Visit us at www.gawda.org/safety-meeting/ to learn more and sign up today.

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 _____

November 2021**Fall Protection****Walking/Working Surfaces**

The National Safety Council published the Top 10 OSHA violations for 2021.

1. Fall Protection – General Requirements (1926.501): 5,295 violations
2. Respiratory Protection (1910.134): 2,527
3. Ladders (1926.1053): 2,026
4. Scaffolding (1926.451): 1,948
5. Hazard Communication (1910.1200): 1,947
6. Lockout/Tagout (1910.147): 1,698
7. Fall Protection – Training Requirements (1926.503): 1,666
8. Personal Protective and Lifesaving Equipment – Eye and Face Protection (1926.102): 1,452
9. Powered Industrial Trucks (1910.178): 1,420
10. Machine Guarding (1910.212): 1,113

A more in-depth analysis of the Top 10 violations for 2021 will be published in the December edition of Safety+Health magazine, a National Safety Council publication.





Fall Protection was the *Number 1* cited OSHA safety violation for the 11th year in a row. Fall protection is defined as any means used to protect workers from falls during work in areas where fall hazards exist. Fall protection is essentially a system that protects workers who could lose their balance at any given height (four feet in General Industry; e.g. docks) from falling, usually resulting in injuries. One way to help train employees on Fall Protection is to implement the recently published safety practice from the GAWDA Safety Committee. This document covers where falls are likely to occur and how to protect against falls in those areas, including:

- *Guardrails
- *Stairs
- *Skylights
- *Safety Nets
- *Ramps
- *Mezzanines/Elevated Storage Areas
- *Loading Docks

Walking Working surfaces, although not specifically listed on the OSHA Top 10, are included in Fall Protection, Ladders, Scaffolding and the Fall Protection Training requirements. The main parts of the Walking-Working Surfaces rule are hazard assessment, inspections, training, and equipment. All general industry employers must:

- **Conduct hazard assessments** to determine their workplace fall and falling object hazards.
- **Inspect all walking and working surfaces** for fall or falling object hazards on a regular basis and as necessary.
- **Train and retrain** when necessary their employees on fall protection systems and equipment.
 - Fall protection systems include:
 - Personal fall protection,
 - Safety nets,
 - Ladder safety systems,
 - Portable guardrail systems,
 - Dockboard systems, and
 - Designated areas.
 - Equipment that requires training includes:
 - All ladder types, and
 - Personal fall protection equipment.



The GAWDA Safety Committee published a safety practice to aid compliance and training on Walking Working Surfaces. Some areas that can be particularly dangerous include: production areas, entryways, height transition areas and liquid fill areas. Also the type of footwear and weather conditions can present their own type of hazards (for more information on weather related walking/working issues please review the October GAWDA Safety Organizer).

Both the Fall Protection and Walking Working Surface Safety Practices may be found on the Member's Only page under the Sample Safety Practices tab.

If you have any questions about these topics, or any other DHS, EPA or OSHA topic, please contact:

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Traffic Bulletin

Traffic Bulletin

November 2021

DOT Records Retention

What to Keep and How Long

You are required to maintain certain records on your drivers and vehicles for specified periods of time. Look for the drug and alcohol program recordkeeping requirements in next month's Traffic Bulletin.

Accident Records (390.15)

Motor carriers shall maintain for a period of three years after an accident occurs, an accident register (a list of accidents) containing at least the following information:

- Date of accident,
- City or town in which or most near where the accident occurred and the State in which the accident occurred,
- Driver name,
- Number of injuries,
- Number of fatalities, and
- Whether hazardous materials, other than fuel spilled from the fuel tanks of motor vehicles involved in the accident, were released.
- Copies of all accident reports required by State or other governmental entities or insurers.

If you need any sample forms for the **Accident Register** and **Accident Report**, then please contact me.

Driver Qualification File (391.51)

You must retain the driver qualification file for 3 years after you no longer employ the person as a driver. There are several items required in the DQ file.

Hours of Service (395.1 & 395.8)

You are required to keep driver hours of service records for 6 months. This is kept via driver logs unless you meet the exceptions in 395.1 where you are allowed to keep other records of driver hours which must contain at least; the start time, the stop time and the total hours worked for each day, and the total time for the preceding 7 days in accordance with 395.8(j)(2) for drivers used for the first time or intermittently.

Insurance (387)

You are required to show proof of financial responsibility. Our members need a current copy of the DOT MCS-90 form, which is supplied by your insurance company. If you ship hazard zone A poisons or have cargo tanks exceeding 3500 gals. of water capacity, then you will need to show \$5,000,000 in coverage. Everyone else will need \$1,000,000 in coverage.



Traffic Bulletin

Post-trip Vehicles Inspections (396.11)

The driver is required to perform a post-trip inspection on their vehicle at the end of each day. If you driver fills out a report because something was found defective, then report must note any defects found and the certification of the repairs if any defects were noted. The following day, the next driver must review the report and certify the repairs were made. These must be kept for 3 months.

Periodic Inspection (396.21)

Each vehicle must be inspected at least once per year and a copy of the inspection must be kept for 14 months. A copy of the report or a decal containing minimal information (see 396.17(c)(2)) must be on the vehicle.

Roadside Inspection (396.9)

You must keep for one year any roadside inspections that were done on your vehicles. You have 15 days to fix any noted defects, sign the report and return it to the authorities. I suggest you keep the reports for 2 years because the Safety Management System shows roadside inspections for 2 years.

Vehicle Maintenance Files (396.3)

You are required to keep maintenance records for one year on any vehicle you have controlled for one month or longer. These records must be maintained where the vehicle is housed or they may be kept by the servicing location. The file must contain the vehicle information (company number, make, serial number, year, and tire size) and the inspection, repair and maintenance records. You must keep these records for 6 months after the vehicle is sold, traded or scrapped.

Hazardous Materials

If you handle hazardous materials, then you must keep a copy of the following items:

1. Federal Hazardous Materials Registration (107.608) (3 years)
2. State Hazardous Materials Registration (if your State has a program)
3. If you cross state lines, then you must do the annual Unified Carrier Registration and I suggest you keep these for 3 years.
4. Training records for all affected hazardous materials employees. The training must be done at least every 3 years. (172.704)
 - a. Hazmat training
 - b. Security In-depth training (Only if you are required to have a written security plan.)
 - c. Security Awareness training
5. Shipping papers (Hazardous Materials Manifest) must be kept for 2 years.

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

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Medical, Food/Beverage and Specialty Gases Bulletin

11/01/2021

Frequently Asked Questions – FDA Drug Listings

Q – What is the difference between “Food Grade” Carbon Dioxide and “Beverage Grade” Carbon Dioxide?

A – First... some background on the use of the term “Beverage” vs “Food Grade”.

1. **To the FDA**, “Beverage Grade” simply means “Food Grade”. There are not separate beverage specifications in the FDA regulations.
 - The **manufacturing process** is regulated by 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*
 - The **testing specifications** are contained in the Food Chemical Codex (FCC). E.g., the purity is not less than 99.5% and several other impurity specifications
 - The **test plan** is determined by your Hazard Assessment (HARPC) – usually no testing is required for cylinders. Most companies would do some testing on bulk trailers, though it is not required by the FDA (unless your HARPC indicates that testing is needed).
2. To the International Society of Beverage Technologists (**ISBT**), “Beverage Grade” means “ISBT Beverage Grade”
 - **The manufacturing process** is regulated by 21 CFR 117, and supplemented with specific instructions in ISBT’s “Bulk Carbon Dioxide Quality & Food Safety Guidelines And Analytical Methods And Techniques Reference” and “Fountain Carbon Dioxide Quality & Food Safety Guideline” (for cylinders).
 - The **testing specifications** are contained in ISBT’s “Bulk Carbon Dioxide Quality & Food Safety Guidelines And Analytical Methods And Techniques Reference”. E.g., the purity is not less than 99.9% and several other impurity specifications.
 - The **test plan**,
 - For **bulk production** - is determined by ISBT’s “Bulk Carbon Dioxide Quality & Food Safety Guidelines And Analytical Methods And Techniques Reference”
 - For filling **trailers** or “mini-bulk transports”- is determined by agreement between the supplier and the customer
 - For filling **cylinders** - is determined by your Hazard Assessment – usually no testing is required for filling cylinders

If you are selling “ISBT Beverage Grade” CO₂, you should follow the FDA regulations and ISBT guidelines (2, above). If you are selling “Food Grade” or “Beverage Grade”, you can use the FDA requirements (1, above).

We have sample SOPs, specifications and training available. Please contact tom@asteriskllc.com if you need access to the sample Food/Beverage Gas procedures or training.



Medical, Food/Beverage and Specialty Gases Bulletin

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.

Annual Record Review

Form 483 Observation-03-02 - Written procedures are not followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected. Specifically, your firm does not perform an annual product review of each medical gas by reviewing the batch records, complaints, returned products, investigations and or recalls to determine the need for changes in the process or control procedures for the following medical gases: _____

How to prevent this from showing up in your inspection?

Document your Annual Records Review. Contact tom@asteriskllc.com for a sample SOP and Annual Records Review form.

November Medical Gas Roundtable (11/19/2021) – Instrument Qualification & Analytical Method Validation for Medical Gases

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** - Fuel/Oxidizer Safe Practices (2000 BTU model & CGA P-36)
- **Food Gas Roundtable** – Part 117 Subpart D & E - Modified Requirements and Qualified Facility Exemption

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. Keep in mind that Servomex allows a longer inspection period for analyzing clean, dry gases (medical gases). Read the manual or your SOP carefully.
2. **Segregation** – Be sure your full medical gas cylinders are segregated from your industrial gas cylinders.

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