



MARCH 2021

ENCLOSED

Safety Topics

1. Machine Guarding
2. Training Reminder

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

Traffic Bulletin

DOT Filing System

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQs: Detector Tubes
2. Recent FDA Observations
3. GAWDA Professional Compliance Seminars 2021 (3/22-26 & 10/25-29);
March Medical Gas Roundtable (3/26/2021)
4. Micro-Audit Suggestions

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

**** Visit GAWDA's COVID-19 Resource Center at www.gawda.org/covid-19/ ****

Here you will find information on Live GAWDA Consultant Covid -19 Roundtables, Safety Alerts, and Members-Only links.

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 _____

**March 2021****Machine Guarding**

Machine guarding isn't confined to machine presses and rollers, within our own facilities we have equipment that must be guarded. Some examples of equipment that should be guarded include: exhaust fans, safety stops for blasting machine doors, belt drives and grinding equipment.

Guards must :

- Protect against contact
- Guards must be secured to the machine
- Ensure that no object can fall into the moving parts
- Guards should not create additional hazards or interfere with machine performance.

In addition to mechanical guarding, grounding electrical equipment is one of the most important safety measures. Grounding should be applied to the entire system and each individual piece of electrical equipment.

Responsibility:

Department Managers and Supervisors must:

- Ensure operators do not remove or operate machine without machine safeguards.
- Ensure operators implement all safety program requirements.
- Provide machine/process specific hands-on training to all operators.

Every employee who operates machinery must:

- Be trained on and apply the use of machine safeguards
- Inspect the machines and safeguards prior to each use
- Always use safeguards as required
- Alert Owner Department Management when machines and/or safeguards need repair/replacement
- Assess work to determine if machine safeguards cannot be used and work with the supervisor to provide Administrative controls for safety.

Spring is a great time to check your machine guards and equipment grounding!



Training Reminder

The GAWDA Safety committee has published a Sample Safety Practice for Cylinder Loading Dock Safety which contains loading dock inspection and operational safety measures. This document may be used as a safety training and can be located on the [GAWDA website/ Members only page/ Sample Safety Practice/ Cylinder Loading Dock Safety](#).

If you have any questions on the subjects presented here or other questions related to DHS, EPA or OSHA, please contact me.

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GAWDA Professional Compliance Webinar
Hold the dates – March 22 – 26, 2021
[Click here for information or to register](#)



Traffic Bulletin

Traffic Bulletin

March 2021

DOT Filing System

Members have asked me how they should keep their DOT files. DOT allows you to keep them in just about any fashion that you wish provided the driver qualification and the drug and alcohol files are kept secure with authorized access only. Here is a suggested method that I have put together for members in the past that seems to work well. These items do not cover every situation, but they will help 95% of our members.

Here are what the bullets stand for:

- = Hanging File Folders (retention period)
 - = Manila File Folders (retention period)

Here are the files and the suggested tab titles:

- DOT Filing System Table of Contents (place this sheet in the file)
- MCS-150 (current information)
- MCS-90 (current)
- Hazmat Registration (3 years)
- Unified Carrier Registration (only if CMVs in interstate commerce) (3 years)
- List of Drivers (current)
- List of Commercial Motor Vehicles (current)
- Accident Register
 - Accident Register (3-year retention)
 - Accident Register and Accident Report Forms (blank forms)
- DOT Accidents
 - (place actual DOT accidents into separate manila folders)
- Company Policy regarding Alcohol & Controlled Substances (current version)
- Annual Summaries of Drug & Alcohol testing (5 years of summaries)
- Driver Supervisor D&A Substance Abuse Recognition training (current)
- Documentation of Brake Inspector / Adjusting training (retained by the motor carrier for the period during which that individual is performing annual motor vehicle inspections for the motor carrier, and for one year thereafter)
- Documentation of Annual Inspector qualifications (retained by the motor carrier for the period during which that individual is performing annual motor vehicle inspections for the motor carrier, and for one year thereafter)
- Schedule of Commercial Vehicle Maintenance (current)
- Vehicle Maintenance Files (The records shall be retained where the vehicle is either housed or maintained for a period of 1 year and for 6 months after the motor vehicle leaves the motor carrier's control.)



Traffic Bulletin

- Leased Vehicles (maintenance lease only) (copies of the lease agreement; Schedule A) (current)
- Roadside Inspection Reports (copy of the inspection and any repair bill kept for 1 year) (suggest 2 yrs. because of the SMS program)
- Previous DOT audits (either State or Federal)
- Driver Qualification Files (kept for 3 years after leaving or ceasing driver functions)
 - DQ file folder
 - Driver Drug & Alcohol File folder
- Hazmat Training (training required every 3 years) (keep for 3 years)
- Security Awareness Training (training required every 3 years) (keep for 3 years)
- DOT Security Program (these three items only if you are required to have a security plan)
 - Vulnerability Assessment (used for the security plan) (current)
 - Security Plan (current)
 - In-Depth Training on Security Plan (training required every 3 years) (keep for 3 years)
- Post Trip Month 1 (only required when something is found defective) (3 months)
- Post Trip Month 2
- Post Trip Month 3
- Post Trip Month you are currently working on
- Special Permits (copies of the permits and training on the permits for anyone that handles the special permitted package) (3 years)
- Shipping Papers / Manifests (keep for 2 years)
- Cargo Tanks (U1A forms) (permanent) (Periodic testing except for 173.20 exceptions (25.3 psig and under)) (current)

Many people do not have their employees doing their own brake adjustments or annual DOT vehicle inspections, so they would not need the above 2 files documenting the training certifications (Documentation of Brake Inspector / Adjusting training, Documentation of Annual Inspector qualifications).

Many people do not have a maintenance lease set up for their vehicles, so they will not need the file titled "Leased Vehicles".

Having these files set up and together in a filing system will really help you keep organized and look very good during a DOT audit.

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

Michael Dodd

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Medical, Food/Beverage and Specialty Gases Bulletin

03/01/2021

Frequently Asked Questions – Detector Tubes

Q – Are there acceptable alternatives to the Draeger tubes?

A – Yes. There are three good ways to save significant labor and detector tube costs for your medical gas analyses. Your approach would be influenced by the volume of each medical gas you fill and test.

Alternate Tubes - USP used to specify the Draeger part numbers for certain tests – for example the Carbon Monoxide test in Nitrogen, NF. However, USP now specifies the chemistry inside the tube rather than the part number. This opens up the possibility to use competitive (and potentially less expensive) detector tubes for medical gas analyses. We have qualified the chemistry in the “Gastec” and “KwikDraw by Uniphos” tubes and prepared a cross reference guide. The cross-reference guide includes a section for your Quality Control Unit to approve the new tubes and part numbers. The Detector Tube Cross Reference Guide is on the following page.

Alternate Instruments - Also, if you perform a large quantity of detector tube analyses, you may be able to use alternate technology to eliminate using detector tubes completely (e.g., Non-dispersive Infrared). These alternate analytical methods are often faster, more accurate and less expensive to use. These alternate analytical technologies would require validation to be equivalent to the USP/NF methods. Let us know if you are considering an alternative analytical method and we may be able to make it simpler for you.

Process Validation - Lastly, if you validate your production process, you may be able to reduce the testing requirements to eliminate many detector tube analyses. For example, it is possible to perform a process validation and prove that the Carbon Monoxide test is unnecessary for high pressure Nitrogen NF analyses.



Medical, Food/Beverage and Specialty Gases Bulletin

The following Draeger, Gastec and KwikDraw detector tubes are interchangeable for USP/NF medical gas testing purposes.									As of 21 Feb 2021
Detector Tube	Air Limit (ppm)	CO2 Limit (ppm)	He Limit (ppm)	N2 Limit (ppm)	N2O Limit (ppm)	O2 Limit (ppm)	Draeger P/N	Gastec P/N	KwikDraw by Uniphos (formerly MSA) P/N
Ammonia		25 (L)			25 (V)		8101941 (2.5 to 100 ppm) or CH20501 (5 to 700 ppm)	3L (0.5 to 78 ppm) or 3LA (2.5 to 200 ppm)	D5085845 (2 to 600 ppm)
Carbon Dioxide	500	ID Positive			ID Negative and max 300 ppm	300	8101811 (100 to 3000 ppm)	2LC (100 to 4000 ppm)	D5086814 (100 - 3000 ppm)
Carbon Monoxide	10	10 (V)	10	10	10 (V)	10	6733051 (2 to 300 ppm) or CH25601 (5 to 700 ppm)	1L (2.5 to 2000 ppm) or 1LK (5 to 600 ppm)	D5085836 (5- 1000 ppm)
Halogens (Chlorine)					1 (V)		CH24301 (0.2 to 30 ppm)	8LA (0.1 to 16 ppm)	D5085801 (0.2 - 30 ppm)
Hydrogen Sulfide		1 (V)					8101461 (0.5 to 5 ppm) or 8101961 (1 to 60 ppm) or 8101831 (1 to 100 ppm)	4L (1 to 240 ppm) or 4LK (1 to 40 ppm) or 4LL (0.25 to 120 ppm)	HSH-1 (0.5 to 10 ppm) or D5085826 (1-200 ppm)
Nitric Oxide	2.5*	2.5 (V)			1 (V)		8103661 (0.2 to 30 ppm)	11L (0.04 to 16.5 ppm)	D5085818 (0.5-50 ppm)
Nitrogen Dioxide	2.5*	2.5 (L)			1 (L)		8103661 (0.2 to 30 ppm)	11L (0.04 to 16.5 ppm)	D5085818 (0.5-50 ppm)
Sulfur Dioxide	5	5 (L)					CH31701 (1 to 25 ppm) or 6728491 (0.5 to 25 ppm)	5LC (0.1 to 25 ppm)	D5085803 (0.5-30 ppm)
Water		150 mg/m ³ (V)			150 mg/m ³ (V)		6728531 (5 to 200 mg per cubic meter)	6A (20 to 80 mg per cubic meter) and 6Ag (150 to 3000 mg per cubic meter)	D7086872 (5 - 200 mg/m ³)
Notes:	Not required when using O ₂ , USP/N ₂ , NF produced by Air Liquifaction * - NO and NO ₂ total limit is 2.5 ppm	(V) or (L) indicates the test is performed on the Vapor or Liquid phase of the sample			(V) or (L) indicates the test is performed on the Vapor or Liquid phase of the sample. Testing sequence - H ₂ O, NH ₃ , NO, CO, NO ₂ , Halogens, CO ₂	Not required for oxygen produced by Air Liquifaction	Available from: https://www.shopcross.com/safety-list/gas-detection/draeger-tubes and other vendors	Available from: https://nexteq.com/products/gas-detection/detector-tubes/ and other vendors	Available from: https://aficintl.com 800-952-3293

Approved by the Quality Control Unit:

Signature/Date: _____ / _____



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.

Lot Stickers

Form 483 Observation-03-01 - Procedures designed to assure that correct labels are used for drug products are not written and/or followed. Specifically, the labels which you include in your batch records (lot stickers) for your Liquid Oxygen USP product, which contain lot number information, are not maintained and controlled as numerous labels (>25) were observed on the floor by filling manifold no. ____, where the liquid oxygen are filled and labeling operations for these "lot stickers" occur. These labels (lot stickers) were used on Liquid Oxygen USP lot ____ which was filled and distributed on ____.

Form 483 Observation-01-04 - Strict control is not exercised over labeling issued for use in drug product labeling operations. Specifically, labels are not properly reconciled by your firm. For example, during the walk-through on ____, we viewed returned product lot labels on the floor of the production area.

How to prevent this from showing up in your inspection?

Assure your pumpers clean the old lot numbers off the floor after each cylinder filling activity.

GAWDA Professional Compliance Seminars - 2021

March 22 - 26

October 25 - 29

[Click here for more information.](#)



Medical, Food/Beverage and Specialty Gases Bulletin

March Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, March 26, we will cover **Subpart C – Buildings and Facilities**. *A sample facility maintenance and cleaning record 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 B – Current Good Manufacturing Practices
 - 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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