



MARCH 2022

ENCLOSED

Safety Topics

Substance Abuse Policy

Canine Bites, Awareness and Mitigation

Please contact Marilyn Dempsey, GAWDA DHS, EPA, & OSHA Consultant for more information.

Traffic Bulletin

Filing Updated MCS-150

Please contact Mike Dodd, GAWDA DOT Consultant for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. Free Training Available: Medical Gas Liquid Container Valve Outlet and Labeling Regulations
2. FAQs: Detector Tubes
3. Recent FDA Observations
4. March Medical Gas Roundtable (3/25/2022) -- Subpart C – Buildings and Facilities
5. 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 **March 9th** @ 1PM Eastern. Visit us at www.gawda.org/safety-meeting/ to learn more and sign up today.

**** GAWDA’s SMC is April 3-5. Visit us at <http://bit.ly/GAWDASMC22> to 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.

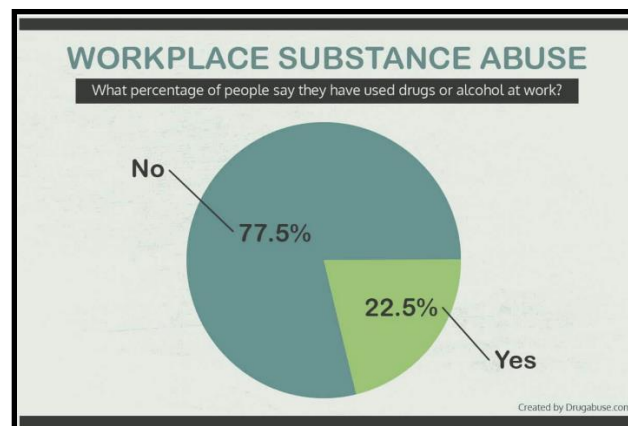
ROUTE TO:

- ☐ General Manager
- ☐ Safety Coordinator
- ☐ Supervisor Dept. _____
- ☐ Other _____
- ☐ Date of Meeting _____

March 2022

- Substance Abuse Policy
- Canine Bites, Awareness and Mitigation

Substance Abuse Policy



As we move past the regulatory submission season, it's a good time to take a look at your current policies - including the Substance Abuse Policy. The American Addiction Center conducted a survey, December 2020, and found 22.5% of employees use drugs or alcohol while at work. And The CDC reinforced the truth we all know, "on the job substance abuse can lead to increased accidents and injuries". For those two arguments, alone, a policy should be in place and below are more:

5 Reasons to have a Substance Abuse Policy

1. Reduce workplace Injuries
2. Improve productivity
3. Establish a safe working environment
4. Decrease worker's compensation claims and decrease absenteeism
5. Demonstrate the company's commitment to a safe and healthy workplace.



The policy should be reviewed by an HR lawyer or consultant and it may read as simply as:

“Employees are prohibited from unlawfully consuming, distributing, possessing, selling, or using controlled substances while on duty. In addition, employees may not be under the influence of any controlled substance, such as drugs or alcohol, while at work, on company premises, or engaged in company business. Prescription or over-the-counter medications, taken as prescribed, are an exception to this policy. Anyone violating this policy may be subject to disciplinary action, up to and including termination.”

Other policies you may consider reviewing/ creating:

Cylinder Handling	Company Vehicle Use
Accident	Cell Phone Use
Injury	Tobacco and Vaping
Incident	Safe Driving - CDL drivers
Near Miss	Safe Driving - non CDL

Canine Bites, Awareness and Mitigation

Drivers encounter many different types of delivery locations, from laboratory to junk yard and CBD extraction; some of those locations keep dogs for security reasons. The GAWDA safety committee developed an excellent guideline to help train your drivers how to know when a dog is being aggressive and how to AVOID being bit by a dog. This training was developed by your GAWDA constituents, including a former UPS driver - this is a very good training resource.



Find the document in the GAWDA.org [Members Only Documents](#) section.

If you have questions regarding policy legality, please contact your HR person or [Rick Schweitzer](#) - GAWDA Legal and HR Consultant.

If you have any questions or concerns regarding these topics, or any other DHS,EPA or OSHA topic, please contact me at:

Marilyn Dempsey
GAWDA Consultant: DHS, EPA, OSHA
Safety Dragon Workplace Consultants, LLC
E: Marilyn@safetydragons.com
M: 940-999-8466



Traffic Bulletin

March 2022

Carriers Must File Updated MCS-150 Every 2 Years

To gather more accurate and timely information about the carriers it regulates, the Federal Motor Carrier Safety Administration (FMCSA) requires interstate motor carriers to file an updated Motor Carrier Identification Report (MCS-150) every two years. Some states require motor carriers to obtain a USDOT number even if they are only in intrastate commerce.

The Form MCS-150 is a single-page report that all motor carriers subject to the Federal Motor Carrier Safety Regulations (FMCSR) must complete and submit to the FMCSA before they begin to operate in interstate commerce. Motor carriers must provide basic information, such as name, address, telephone number, cargo classifications, any types of hazardous materials carried, numbers and types of equipment (trucks, tractors, trailers, passenger vehicles) used, number of drivers, and types of operations.

FMCSA enters the MCS-150 information into the Motor Carrier Safety Information System (MCMIS) and assigns the carrier a U.S. DOT identification number. FMCSA uses the information contained in MCMIS to track motor carrier safety performance, to assess nationwide motor carrier safety trends, and to evaluate effectiveness of federal motor carrier programs.

Certain carriers of hazardous materials must obtain an FMCSA Hazardous Materials Safety Permit. Carriers qualifying for this permit file the MCS-150B "Combined Motor Carrier Identification Report and HM Permit Application" in lieu of the MCS-150. **Do not complete a MCS-150B unless you are required to do so.** Please contact me before choosing this option. I can give you more details.

The regulations for the Motor Carrier Identification Report are found in 390.19 of the Federal Motor Carrier Safety Regulations.

You can do your every 2-year update at this website:

http://li-public.fmcsa.dot.gov/LIVIEW/PKG_REGISTRATION.prc_option

Just check the entry **"I need to update my USDOT number registration information or file my biennial update(MCS-150)."**

You will need a USDOT number PIN to do the online update. You can get one here:

https://li-public.fmcsa.dot.gov/LIVIEW/PKG_PIN_START.PRC_INTRO



Traffic Bulletin

There is no charge for doing the update and you may update anytime you wish so long as it is at least every 2 years.

If you need to obtain a USDOT number then you can do it at the same website above for doing the updates and you would check the first entry **“I think I need to register with the FMCSA to get a NEW USDOT number, Operating Authority (MC/FF/MX number)”**.

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

Michael Dodd
GAWDA DOT Consultant
MLD Safety Associates, LLC
P.O. Box 93
Poplar Bluff, MO 63902
(573) 718-2887
Email: MLDSafety@hotmail.com

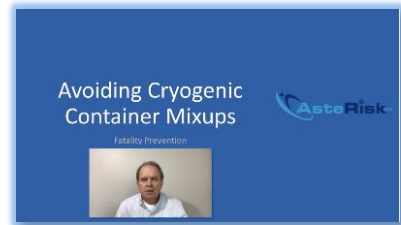


Medical, Food/Beverage and Specialty Gases Bulletin

03/01/2022

Medical Gas Liquid Container Valve Outlet and Labeling Regulations

[Click here for Medical Gas Liquid Container Valve Outlet and Labeling Regulations](#)



- 15 minute video presentation
- Tragic product mix-up case studies when connections were changed
- CGA Guidance V-23 (formerly SB-26)
- The FDA regulations (21 CFR 211.94) pertaining to medical gas cryogenic container connections
- Recognizing appropriate and inappropriate connections
- Quiz
- Certificate of participation.



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/or 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 – In the past, USP specified 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 O2, USP/N2, NF produced by Air Liquifaction * - NO and NO2 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 - H2O, NH3, NO, CO, NO2, Halogens, CO2	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://nextteq.com/products/gas-detection/detector-tubes/ and other vendors	Available from: https://afciintl.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 - 2022

February 28 - March 4

October 17 – 21

March Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, March 25, we will cover **Subpart C – Buildings and Facilities**. *A sample facility maintenance and cleaning record will be available for downloading during the training.*



Medical, Food/Beverage and Specialty Gases Bulletin

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.

Tom Badstubner
GAWDA Medical Gas Consultant
Telephone: 508-883-0927
Email: tom@asteriskllc.com

