

SAFETY & TECHNOLOGY ORGANIZER

APRIL 2018

ENCLOSED

Safety Topic: Personal Protective Equipment (PPE) in Fill Plants

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

Traffic Bulletin: DOT Filing System

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

- 1. Recent Recent FDA Observations (inspections at medical gas companies).**
- 2. Cryogenic Fill Hose, *Procedures*.**
- 3. FAQ: What is the latest activity regarding more writing appropriate regulations for medical gas manufacturers?**
- 4. Dates for Medical & Food Gas Roundtable; CGMP & Specialty Gas Training.**
- 5. 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 _____

Personal Protective Equipment (PPE) in Fill Plants

The GAWDA Safety Committee just completed another sample safety policy and I wanted to pass it along to the membership. This will be posted along with all the other sample safety policies on the membership side of the GAWDA website.

Personal Protective Equipment (PPE) in Fill Plants

(Insert Company Name Here)

Purpose	To provide guidance in the selection, use, maintenance and replacement of PPE commonly used in high pressure compressed gas and liquid fill operations
Responsibility	All cylinder fillers, loaders, handlers, maintenance personnel, contractors and visitors working in compressed gas and cryogenic liquid fill plants
Authority	Plant Manager and/or Fill Plant Lead

Key Considerations

1. This document is meant to provide guidance in the selection and use of Personal Protective Equipment commonly used in compressed gas and cryogenic fill plant operations.
2. Because hazards vary from one facility to the next, a worksite risk assessment and job hazard analysis shall be conducted to determine specific PPE needs.
3. PPE shall only be used by authorized personnel who have received training in hazard recognition and proper PPE use, maintenance, storage and replacement. It is the employee's responsibility to report any damaged or lost PPE. It is the employer's responsibility to promptly repair or replace defective PPE.
4. For more in-depth industry guidance on PPE selection and use, refer to [CGA Publication P-44 Selection of Personal Protective Equipment.](#)



Recommended PPE for Specific Job Tasks

Job Task	Recommended PPE
High Pressure Cylinder Fillers	<ul style="list-style-type: none"> • Steel or composite safety toe cap boots/shoes with metatarsal protection • Safety glasses • Oil-free gloves * • Long pants ** • Hearing protection • Hard hat
Cryogenic Liquid Cylinder Fillers	<ul style="list-style-type: none"> • Steel or composite safety toe cap boots/shoes with metatarsal protection • Safety glasses • Full face shield • Oil-free insulated gauntlet gloves * • Long pants & long-sleeved shirt ** • Hearing protection • Hard hat
High Pressure and Liquid Cylinder Loaders and Handlers	<ul style="list-style-type: none"> • Steel or composite safety toe cap boots/shoes with metatarsal protection • Safety glasses • Oil-free gloves* • Long pants • Hearing protection

Recommended PPE for Specific Job Tasks (cont.)

Job Task	Recommended PPE
Maintenance Personnel & Contractors	<ul style="list-style-type: none"> • Steel or composite safety toe cap boots/shoes with metatarsal protection • Safety glasses • Oil-free gloves • Long pants • Hearing protection • Hard hat



Visitors	PPE selection will depend on the types of hazards visitors are exposed to. Refer to your Worksite Risk Assessment to determine specific PPE needs.
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*** To avoid potential flash or fire issues with oxygen, gloves shall be constructed of leather, cotton, or both. No synthetic material.**

**** 100% cotton or fire-resistant clothing shall be worn when filling flammable gases and is highly recommended for oxygen filling.**

Many thanks to the members of the Safety Committee for their work on the new sample program.

Michael Dodd

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Traffic Bulletin

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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 years 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.)
- Leased Vehicles (maintenance lease only) (copies of the agreement; Schedule A) (current)



Traffic Bulletin

- 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) (current)
- Security Awareness Training (training required every 3 years) (current)
- 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) (current)
- Post Trip Month 1 (only required when some 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 (2 years)

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:

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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.

Cryogenic Fill Hose

Form 483 Observation-03-02 - Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not followed. Specifically,

- A. One of the hoses used to fill the Liquid Oxygen USP PLC (portable liquid cryogenic) containers were observed to be located on the floor with the opening of the hose in direct contact to the floor.
- B. You do not use protective end caps on the hoses after they are cleaned which are used during filling operations for the Liquid Oxygen USP product which are located in the ___ Fill Manifold area.

How to prevent this from showing up in your inspection?

Assure cryogenic fill hoses are capped and the ends are not lying on the floor. An effective method to accomplish this is to solder/bolt a hose cap to a post near the cryogenic fill scale. Require operators to fasten the open hose end to the cap after each fill. Be certain that your fill hoses are protected by a relief valve, vent or weep hole to prevent liquid traps. See sample below.

Medical, Food/Beverage and Specialty Gases Bulletin



Frequently Asked Questions

Q – What is the latest activity regarding more writing appropriate regulations for medical gas manufacturers?

A – The FDA has held two public workshops (12/2017 and 02/2018). A third workshop is scheduled for May 11, 2018. The first workshop introduced the possibility of moving the medical gas regulations from 21 CFR Part 211 to a completely new “Part”. This is a good solution since medical gases are fundamentally different from traditional pharmaceuticals in many important respects (closed pressurized containers, reusable containers and closures, reusable labels, etc.). We (GAWDA/CGA) have completely rewritten the FDA regulations as a draft for the agency to consider. We expect to discuss our draft regulations in May. Even if the FDA accepts all our positions, it could take several/many years for the proposed regulations to work through the agencies processes and reviews.

Medical, Food/Beverage and Specialty Gases Bulletin

April Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, April 27, we will cover **CGMP – Supplier Qualification**. This will cover the recent FDA expectations for verifying that your bulk products have been produced by a properly “certified” original manufacturer. We also will have new procedures and forms to assist in your supplier qualification effort.

In addition, we will be conducting the following additional training on April 28:

- **Specialty Gas** - Analytical Method Validation for Medical Gases
- **Food Gas Roundtable** –
 - CGMP Training – 21 CFR 117, Subpart B Current Good Manufacturing Practice
 - §117.10-117.110
 - 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. **Annual Record Review** – Verify that you have conducted and documented an annual records review for your medical gas production facility. Contact tom@asteriskllc.com for a sample form to easily document this requirement.
2. **Food Receipts** – Be sure that your food gas bulk receipt paperwork documents that you are receiving food or beverage grade product into your bulk tanks which are used to produce food gases (especially CO₂ and N₂)
3. **Food Lot Numbers** – Be sure you are using lot numbers on food grade gases. You must also have a lot number record of food gas shipments. This lot number record may be kept electronically.

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