GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

MAY 2020

ENCLOSED

Safety Topic

Personal Protective Equipment (PPE)

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

Traffic Bulletin

Medical Certificates

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. Frequently Asked Questions – Odor Tests; Fill; Affidavits
2. Recent FDA Observations
3. Training Webinars: Onsite AND via Teleconference - October 27-29, November 3-5
4. May Medical Gas Roundtable: Subpart E – Control of Components Training
5. Micro-Audit Suggestions

Please contact Tom Badstubner, GAWDA FDA Food, Medical & Specialty Gases Consultant, for more information.

**** GAWDA's Covid-19 Resource Center may be found 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.

GASES AND WELDING DISTRIBUTORS ASSOCIATION
One Oakwood Blvd., Suite 195, Hollywood, Fl 33020 P(954)367-7728 F(954)367-7790

GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY TOPIC

May 2020

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 _____

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GASES AND WELDING DISTRIBUTORS ASSOCIATION

Personal Protective Equipment (PPE)

Hazards exist everywhere: Viruses, noise, chemicals, falling objects, slippery surfaces/uneven surfaces and sharp objects. Employers are required by regulation to protect employees from known and potential hazards in the workplace. The General Duty Clause, Section 5(a)(1) of the Occupational Safety and Health (OSH) Act of 1970, 29 USC 654(a)(1), requires employers to furnish to each worker "employment and a place of employment, which are free from recognized hazards that are causing or are likely to cause death or serious physical harm."
Employers can be cited for violation of the General Duty Clause if a recognized serious hazard exists in their workplace and the employer does not take reasonable steps to prevent or abate the hazard. The General Duty Clause is used only where there is no standard that applies to the particular hazard. The following elements are necessary to prove a violation of the General Duty Clause:

1. *The employer failed to keep the workplace free of a hazard to which employees of that employer were exposed;*
2. *The hazard was recognized;*
3. *The hazard was causing or was likely to cause death or serious physical harm; and*
4. *There was a feasible and useful method to correct the hazard.*

There is a Hierarchy of Controls to “Correct the hazard.”
1st - Eliminate the Hazard: a cylinder cart has a flat tire. Eliminate the hazard, change the tire.
2nd - Substitute the Hazard: change a cleaning agent from a caustic solution that requires dilution to a pre-diluted non-caustic cleaning solution
3rd - Administrative Control: SOPs, training employees or hanging instructive posters
4th - PPE; protection for the employee’s body: leather palmed work gloves to decrease the severity of a hand hit between two cylinders colliding.

This guide will help both employers and employees do the following:

- Understand the types of PPE.
- Know the basics of conducting a "hazard assessment" of the workplace.
- Select appropriate PPE for a variety of circumstances.
- Understand what kind of training is needed in the proper use and care of PPE.

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Establishing a written PPE Program detailing what PPE employees use, in which work areas, makes it easier to ensure that employees use PPE properly in the workplace.

The Requirement for PPE

To ensure the greatest possible protection for employees in the workplace, the cooperative efforts of both employers and employees will help in establishing and maintaining a safe and healthful work environment.

In general, employers are responsible for:

- Performing a "hazard assessment" of the workplace to identify and control physical and health hazards.
- Identifying and providing appropriate PPE for employees.
- Training employees in the use and care of the PPE.
- Maintaining PPE, including replacing worn or damaged PPE.
- Periodically reviewing, updating and evaluating the effectiveness of the PPE program.

In general, employees should:

- Properly wear PPE,
- Attend training sessions on PPE,
- Care for, clean and maintain PPE, and

Inform a supervisor of the need to repair or replace PPE.

Types of PPE

All PPE must meet ANSI (American National Standards Institute) standard in effect at the time of its manufacture or provide protection equivalent to PPE manufactured to the ANSI criteria. Employers should inform employees who provide their own PPE of the employer's selection decisions and ensure that any employee-owned PPE used in the workplace conforms to the employer's criteria, based on the hazard assessment, OSHA requirements and ANSI standards. NOTE: If an employee uses a respirator, the employer must then maintain a Respirator Program.

OSHA requires PPE to meet the following ANSI standards:

Eye and Face Protection: ANSI Z87.1-1989
Head Protection: ANSI Z89.1-1986.
Foot Protection: ANSI Z41.1-1991.
For hand protection, there is no ANSI standard for gloves but OSHA recommends that selection be based upon the tasks to be performed and the performance and construction characteristics of the glove material. In our industry, leather palmed cotton backed gloves are the industry standard.

Selecting PPE

All PPE clothing and equipment should be of safe design and construction, and should be maintained in a clean and reliable fashion. Employers should take the fit and comfort of PPE into consideration when selecting appropriate items for their workplace. PPE that fits well and is comfortable to wear will encourage employee use of PPE. Most protective devices are available in multiple sizes and care should be taken to select the proper size for each employee. If several different types of PPE are worn together, make sure they are compatible. If PPE does not fit properly, it can make the difference between being safely covered or dangerously exposed. It may not provide the level of protection desired and may discourage employee use.

Hazard Assessment

In order to assess the need for PPE a Hazard assessment should be performed for each activity in the facility.
Engagement of an employee(s) who performs the job will greatly increase the accuracy of the assessment.

The basic steps of a **Hazard Assessment** are:

1. Identify the jobs where exposures exist or are possible, then rank their exposure (likelihood and severity).
Review of the Injury and first aid logs will help identify those jobs.

2. Walk through the SOPs (Standard Operating Procedures), beginning with the job that has the greatest likelihood of hazard exposure and severity.

Consider the hazard categories that may be present:

- Motion or impact
- Extreme temperatures
- Chemical or biological
- Harmful dust
- Light (optical) radiation
- Employee falls and falling/dropped objects
- Sharp objects
- Compressing, rolling, or pinching objects
- Electrical, including static electricity discharge

3. Observe and record if any of the following hazards are present and if/what PPE are used:

- Sources of motion or impact (e.g., machinery or processes where any movement of tools, machine elements, or particles could exist, or movement of personnel that could result in collision with stationary objects).
- Sources of extreme temperatures that could result in burns, eye injury, ignition of protective equipment, frostbite, etc.
- Types of chemical and biological exposures.
- Sources of harmful dust.
- Sources of light (optical) radiation, e.g., welding, brazing, cutting, furnaces, heat treating, high-intensity lights, etc.
- Sources of employee fall hazards or the potential for falling or dropping objects.
- Sources of sharp objects that might pierce the feet or cut the hands.
- Sources of compressing, rolling, or pinching objects that could crush the feet.
- Sources of electrical hazards such as electric shock or burns (from electric arcs, blasts, or heat), as well as static electricity discharge.
- Layout of workplace and location of co-workers.

4. Following the walk through, organize and categorize the information to analyze the hazards and choose the proper PPE. The Safety Manager should sign and date the form. Periodic review of the Hazard Assessment, Injury and First aid logs will ensure the approved PPE is still appropriate. Job Hazard Analysis form on last page.

Training

Employers are required to train each employee who must use PPE. Employees must be trained to know at least the following:

- When PPE is necessary.
- What PPE is necessary.
- How to properly put on, take off, adjust and wear the PPE.
- The limitations of the PPE.
- Proper care, maintenance, useful life and disposal of PPE.

Employers should make sure that each employee demonstrates an understanding of the PPE training as well as the ability to properly wear and use PPE before they are allowed to perform work requiring the use of the PPE. If an employer believes that a previously trained employee is not demonstrating the proper understanding and skill level in the use of PPE, that employee should receive retraining. Other situations that require additional or retraining of employees include the following circumstances; changes in the workplace or in the type of required PPE that make prior training obsolete.

The employer must document the training of each employee required to wear or use PPE by preparing a certification containing the name of each employee trained, the date of training and a clear identification of the subject of the certification.

OSHA has a very good booklet on Personal Protective Equipment and CGA P-44, *Selection of Personal Protective Equipment* is also a very good resource, it too is free if you are enrolled in the CGA & GAWDA Publication Subscription Program & Distributor Safety Award

If there are questions or items that I can help you with, please contact me.

Marilyn R. Dempsey
Safety Dragons Workplace Consultants, LLC
940-999-8466
marilyn@safetydragons.com

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SAFETY TOPIC

May 2020

	Jobs Hazard Analysis. (JHA)	Date :
JOB/ACTIVITY NAME:		JSA #:
DEPARTMENT:	BLDG/AREA LOCATION(s):	OTHER INFORMATION:

REQUIRED PERSONAL PROTECTIVE EQUIPMENT FOR ENTIRE JOB

safety glasses safety shoes chemical resistant gloves other _____

other_____

chemical goggles hard hat welding gloves

face shield harness lanyard leather gloves other _____

other_____ welding goggles hearing protection

Basic Steps	Potential Hazards	Controls

I understand & will adhere to the steps, hazards & controls as described in this JSA. I understand that performing steps out of sequence may pose hazards that have not been evaluated, nor authorized. I will contact my supervisor prior to continuing work, if the scope of work changes or new hazards are introduced. I understand I have the authority and responsibility to stop work I believe to be unsafe.

Worker Name (please print) Signature Date

I have reviewed the steps, hazards & controls described in this JSA with the worker listed above and authorize them to perform the work. Workers are qualified (i.e. licensed or certified, as appropriate, & in full compliance with SLAC training requirements) to perform this activity._____

Supervisor Signature Date

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Traffic Bulletin

May 2020

Medical Certificates

MOTOR CARRIERS:

- Motor carriers using interstate CDL/CLP drivers whose driving record currently includes their most recent medical certification status must use the driving record (MVR) as proof of physical qualification and keep that driving record in the driver's qualification file. The MVR must be updated every time the driver's medical certification status changes, i.e., after every new DOT medical exam. This requirement has been in place since January 30, 2012, for any interstate CDL driver whose MVR includes medical certification status.
- If a CDL/CLP driver obtains a new medical certificate then the motor carrier can retain a copy of that certificate for up to 15 days, giving the state time (up to 10 days) to add the new information to the driver's record. By the end of those 15 days, the carrier must have a new MVR showing the updated medical information.
- Motor carriers must verify that their CDL/CLP drivers self-certified under the appropriate operational category for their jobs. For example, a driver who self-certified as an intrastate driver is not authorized to operate in interstate commerce.

Medical examiners and state licensing agencies are required to keep a copy of each driver's medical card for three years. Employers also have to continue maintaining medical cards for any drivers not subject to the rule, including non-CDL drivers.

The requirements only apply to interstate CDL/CLP holders and their motor carrier employers, but states are expected to adopt similar rules for most in-state CDL/CLP drivers.

Changes coming June 22, 2021

For interstate CDL and CLP drivers, the steps in recordkeeping will be revised for all driver medical examinations on or after **June 22, 2021**.

The medical examiner is instructed to submit the medical exam results directly to the FMCSA via the National Registry of Certified Medical Examiners web portal by midnight (local time) of the next calendar day after the completed exam. In turn, FMCSA will transmit the results to CDLIS within a day or two of the exams.

As of the result of these new processes for exams performed as of June 22, 2021:

- The CDL and CLP drivers will not be issued a medical examiner's certificate by the examiner. As a result, he/she will no longer have to carry the certificate, even temporarily, since enforcement will have access at roadside.
- The motor carrier will not use a medical examiner's certificate as temporary proof of the medical certification. The motor carrier must request an MVR within a couple of days of the exam and is not given 15 days as previously allowed since the information should be accessible to the state as soon as FMCSA enters it into CDLIS.
- The motor carrier no longer needs to verify the examiner appears on the National Registry of Certified Medical Examiners website since the examiner must be certified in order to submit the results of the exam via the secured web portal. This does not apply to non-CDL drivers.

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

Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin
05/01/2020

Frequently Asked Questions

Q – Why do we need to perform the Odor Test?

A – The odor is a quick test to help assure no potentially harmful ingredients are backed-up into the cylinder before filling with:

- Oxygen – medical, industrial, food grade
- Medical gases (except those containing Carbon Dioxide, Nitrous Oxide, Flammable Gases, etc.)

The odor test is designed to protect the patient who will eventually breathe the gas AND the operator who is filling the cylinders. In the past, both medical and industrial cylinders have been contaminated with dangerous ingredients when combined with oxygen.

Q – I do not fill my own food/beverage gases. Do I need to register with the FDA to warehouse food/beverage gases? What about medical gases?

A – If you fill **AND/OR** warehouse food gases, you need to register your food facilities with the FDA. To restate, even a food gas warehouse must register with the FDA.

However, for medical gases, you usually only need to register with the FDA for manufacturing operations (production, repacking, transfilling). Locations that do not manufacture medical gases, but only distribute gases filled by another company, usually must be licensed by the states in which they distribute… but not the federal FDA. Please contact jodie@asteriskllc.com if you would like more information.

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.

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

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

GAWDA Professional Compliance Training – HOLD THE DATES

This year, the Fall Professional Compliance Training will be held onsite AND via Teleconference

October 27 to 29, 2020 - Onsite at Weldcoa in Aurora, IL

November 3 to 5 – Teleconference hosted by Weldcoa

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 29, 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 at different times that day:

- ***Specialty Gas*** - Making Your Own Working Calibration Gas Standards
- **Food Gas Roundtable** –
    - CGMP Training – Part 117 – Preventive Controls
    - 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.

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. **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

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