

SAFETY & TECHNOLOGY ORGANIZER

September 2017

ENCLOSED

Safety Topic: Personal Protective Equipment (PPE)

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

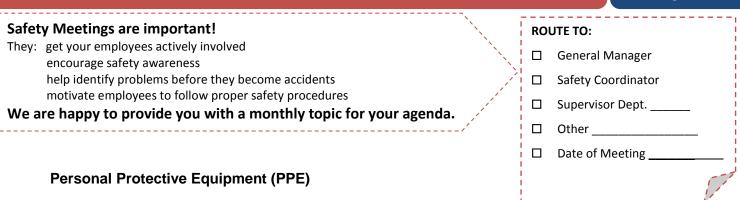
Traffic Bulletin: Driver Disqualifications and Penalties Please contact Mike Dodd for more information.

Medical, Food and Specialty Gases Bulletin

- 1. What is the status of Draft Guidance for Medical Gases?
- 2. Dates, Locations & Topics for: GAWDA Professional Compliance Seminar Medical Gas Roundtable Webinars: Specialty Gas Operations; Specialty Gas Sales; Food Gas Roundtable; Food Gas PCQI Training
- 3. Micro Audit Suggestions

Please contact Tom Badstubner, GAWDA FDA Medical, Food 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.



Hazards exist in every workplace in many different forms: sharp edges, falling objects, flying sparks, chemicals, noise and a myriad of other potentially dangerous situations. The Occupational Safety and Health Administration (OSHA) requires that employers protect their employees from workplace hazards that can cause injury.

Controlling a hazard at its source is the best way to protect employees. Depending on the hazard or workplace conditions, OSHA recommends the use of engineering or work practice controls to manage or eliminate hazards to the greatest extent possible. For example, building a barrier between the hazard and the employees is an engineering control; changing the way in which employees perform their work is a work practice control.

When engineering, work practice and administrative controls are not feasible or do not provide sufficient protection, employers must provide personal protective equipment (PPE) to their employees and ensure its use. Personal protective equipment, commonly referred to as "PPE", is equipment worn to minimize exposure to a variety of hazards. Examples of PPE include such items as gloves, foot and eye protection, protective hearing devices (earplugs, muffs) hard hats, respirators and full body suits.

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.

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.

Hazard Assessment

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A first critical step in developing a comprehensive safety and health program is to identify physical and health hazards in the workplace. This process is known as a "hazard assessment." Potential hazards may be physical or health-related and a comprehensive hazard assessment should identify hazards in both categories. Examples of physical hazards include moving objects, fluctuating temperatures, high intensity lighting, rolling or pinching objects, electrical connections and sharp edges. Examples of health hazards include overexposure to harmful dusts or chemicals.

The hazard assessment should begin with a walk-through survey of the facility to develop a list of potential hazards in the following basic hazard categories:

- Impact,
- Penetration,
- Compression (roll-over),
- Chemical,
- Heat/cold,
- Harmful dust,
- Light (optical) radiation, and
- Biologic.

In addition to noting the basic layout of the facility and reviewing any history of occupational illnesses or injuries, things to look for during the walk-through survey include:

- Sources of electricity.
- Sources of motion such as machines or processes where movement may exist that could result in an impact between personnel and equipment.
- Sources of high temperatures that could result in burns, eye injuries or fire.
- Types of chemicals used in the workplace.
- Sources of harmful dusts.
- Sources of light radiation, such as welding, brazing, cutting, furnaces, heat treating, high intensity lights, etc.
- The potential for falling or dropping objects.
- Sharp objects that could poke, cut, stab or puncture.
- Biologic hazards such as blood or other potentially infected material.

The workplace should be periodically reassessed for any changes in conditions, equipment or operating procedures that could affect occupational hazards. This periodic reassessment should also include a review of injury and illness records to spot any trends or areas of concern and

taking appropriate corrective action. The suitability of existing PPE, including an evaluation of its condition and age, should be included in the reassessment.

Documentation of the hazard assessment is required through a written certification that includes the following information:

- Identification of the workplace evaluated;
- Name of the person conducting the assessment;
- Date of the assessment; and
- Identification of the document certifying completion of the hazard assessment.

Selecting PPE

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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.

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.

There is an excellent publication on this; CGA P-44, *Selection of Personal Protective Equipment*. The current price is \$37 but if you are a CGA/GAWDA subscription member then you get to download it for free. <u>https://www.cganet.com/customer/gawda.aspx</u>

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

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Driver Disqualifications and Penalties

This bulletin outlines the penalties and/or suspensions of CDL licenses for certain infractions committed by a driver. Remember, the primary purpose of this regulation is to get drivers convicted of serious violations in either trucks or personal vehicles off the road. There are 4 categories of offenses: major, serious, railroad grade crossing, and violating out-of-service orders.

Disqualification for major offenses:

Table 1 to 383.51

If a driver operates a motor vehicle and is convicted of:	For a first conviction or refusal to be tested while operating a CMV, a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a first conviction or refusal to be tested while operating a non-CMV, a CDL holder must be disqualified from operating a CMV for	For a first conviction or refusal to be tested while operating a CMV transporting hazardous materials required to be placarded under the Hazardous Materials Regulations (49 CFR part 172, subpart F), a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a second conviction or refusal to be tested in a separate incident of any combination of offenses in this Table while operating a CMV, a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For second conviction or refusal to be tested in a separate incident of any combination of offenses in this Table while operating a non- CMV, a CDL holder must be disqualified from operating a CMV for
1) Being under the influence of alcohol as prescribed by State law.	1 year	1 year	3 years	Life	Life
2) Being under the influence of a controlled substance.	1 year	1 year	3 years	Life	Life
3) Having an alcohol concentration of .04 or greater while operating a CMV.	1 year	Not applicable	3 years	Life	Not applicable
4) Refusing to take an alcohol test as required by a State or jurisdiction under its implied	1 year	1 year	3 years	Life	Life

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consent laws or regulations as defined in 383.72 of this part.					
5) Leaving the scene of an accident.	1 year	1 year	3 years	Life	Life
6) Using the vehicle to commit a felony, other than a felony described in paragraph (b)(9) of this table	1 year	1 year	3 years	Life	Life
7) Driving a CMV when, as a result of prior violations committed operating a CMV, the driver's CDL is revoked, suspended, or cancelled, or the driver is disqualified from operating a CMV.	1 year	Not applicable	3 years	Life	Not applicable
8) Causing a fatality through the negligent operation of a CMV, including but not limited to the crimes of motor vehicle manslaughter, homicide by motor vehicle and negligent homicide.	1 year	Not applicable	3 years	Life	Not applicable
9) using the vehicle in the commission of a felony involving manufacturing, distributing, or dispensing a controlled substance.	Life-not eligible for 10 year reinstatement				

Disqualification for serious traffic offenses:

Table 2 to 383.51

If the driver operates a motor vehicle and is convicted of:	For a second conviction of any combination of offenses in this Table in a separate incident within a 3-year period while operating a CMV, a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a second conviction of any combination of offenses in this Table in a separate incident within a 3-year period while operating a non- CMV, a CDL holder must be disqualified from operating a CMV for	For a third or subsequent conviction of any combination of offenses in this Table in a separate incident within a 3-year period while operating a CMV, a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a third or subsequent conviction of any combination of offenses in this Table in a separate incident within a 3-year period while operating a non- CMV, a CDL holder must be disqualified from operating a CMV for
(1) Speeding excessively, involving any speed of 24.1 kmph (15mph) or more above the posted speed limit***	60 days	60 days	120 days	120 days
(2) Driving recklessly, as defined by State or local law or regulation, including but, not limited to, offenses of driving a motor vehicle in willful or wanton disregard for the safety of persons or property***	60 days	60 days	120 days	120 days
(3) Making improper or erratic traffic lane changes***	60 days	60 days	120 days	120 days
(4) Following the vehicle ahead too closely ***	60 days	60 days	120 days	120 days
(5) Violating State or local law relating to motor vehicle traffic control (other than a parking violation) arising in connection with a fatal accident ***	60 days	60 days	120 days	120 days
(6) Driving a CMV without obtaining a CDL	60 days	Not applicable	120 days	Not applicable
(7)Driving a CMV without a CDL in the driver's possession ¹ .	60 days	Not applicable	120 days	Not applicable

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(8) Driving a CMV without the proper class	60 days	Not applicable	120 days	Not applicable
of CDL and/or				
endorsements for the specific vehicle group				
being operated or for				
the passengers or type				
of cargo being				
transported.				

¹ Any individual who provides proof to the enforcement authority that issued the citation, by the date the individual must appear in court or pay any fine for such a violation, that the individual held a valid CDL on the date the citation was issued, shall not be guilty of this offense.

Disqualification for railroad-highway grade crossing offenses:

If the driver is convicted of operating a CMV in violation of a Federal, State or local law because	For a first conviction a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a second conviction of any combination of offenses in this Table in a separate incident within a 3-year period, a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a third or subsequent conviction of any combination of offenses in this Table in a separate incident within a 3- year period, a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for
(1) The driver is not required to always stop, but fails to slow down and check that tracks are clear of an approaching train * * *	No less than 60 days	No less than 120 days	No less than 1 year
(2) The driver is not required to always stop, but fails to stop before reaching the crossing, if the tracks are not clear * * *	No less than 60 days	No less than 120 days	No less than 1 year
(3) The driver is always required to stop, buts fails to stop before driving onto the crossing	No less than 60 days	No less than 120 days	No less than 1 year
(4) The driver fails to have sufficient space to drive completely through the crossing without stopping * * *	No less than 60 days	No less than 120 days	No less than 1 year
(5) The driver fails to obey a traffic control device or the directions of an enforcement official at the crossing * * *	No less than 60 days	No less than 120 days	No less than 1 year
(6) The driver fails to negotiate a crossing because of insufficient undercarriage clearance * * *	No less than 60 days	No less than 120 days	No less than 1 year

Table 3 to 383.51

Disqualification for violating out-of-service orders:

Table 4 to 383.51

If the driver operates a CMV and is convicted of	For a first conviction while operating a CMV, a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a second conviction in a separate incident within a 10- year period while operating a CMV, a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for	For a third or subsequent conviction in a separate incident within a 10-year period while operating a CMV, a person required to have a CDL and a CDL holder must be disqualified from operating a CMV for
(1) Violating a driver or vehicle out-of-service order while transporting nonhazardous materials	No less than 90 days or more than 1 year	No less than 1 year or more than 5 years	No less than 3 years or more than 5 years
(2) Violating a driver or vehicle out-of-service order while transporting hazardous materials required to be placarded under part 172, subpart F of this title, or while operating a vehicle designed to transport 16 or more passengers, including the driver	No less than 180 days or more than 2 years	No less than 3 years or more than 5 years	No less than 3 years or more than 5 years

If there are any questions, please contact me.

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Medical, Food and Specialty Gases Bulletin

09/01/2017

What is the status of Draft Guidance for Medical Gases?

The FDA issued the latest Draft Guidance for Medical Gases in late July, 2017. Since then, GAWDA and CGA have met many times to review the Draft Guidance and formulate an industry response by the end of August.

For now, please continue to follow long-standing guidance and industry positions. When/if the agency issues Final Guidance, we may need to adjust some of our practices. We will keep you informed of any changes.

GAWDA Professional Compliance Seminar – Audit Survival

Hold The Date (October 17-19, 2017)... GAWDA Professional Compliance Seminar at Weldcoa, Aurora, IL. This seminar focuses on surviving DOT/FDA audits and Food/Beverage Gas Compliance. <u>Click here for more information</u>.



September Medical Gas Roundtable (09/29/2017) – Subpart G – Packaging and Labeling Control

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In September we will be discussing labeling issuance, labeling operation and expiration dating regulations and exemptions.

For your information, we are also conducting the following webinars in September:

 Specialty Gas Operations - Fuel/Oxidizer Mixtures - Alternative Approaches – we recommend that you purchase ISO 10156 and CGA P-58 prior to attending the seminar.

Medical, Food and Specialty Gases Bulletin

- Specialty Gas Sales Specialty Gas Mixtures How to sell the blend range, analytical uncertainty, mixture grades, certifications and traceability (9/25/17).
- **Food Gas Roundtable** Part 117 Subpart C Reanalysis, Requirements for preventive controls qualified individual and a qualified auditor
- Food Gas PCQI Training This two-day webinar covers the Preventive Controls Qualified Individual certified training. The PCQI is responsible for writing the HARPC and Food Safety Plan. (9/21-22/17) <u>Click here for more</u> <u>information.</u>

These and other webinars may be 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.

Micro-audit

For this month, verify these items:

- 1. **Label Inventory –** Be sure the labels in stock and at your pumper's station are correctly inventoried.
- 2. **Contents Statement –** Be sure all cylinder and container labels bear the contents statement (liters, cubic feet, etc.). This is a common violation and is easily correctable.
- 3. Expiration Dates The FDA does not expect medical gas firms to use expiration dates on designated medical gases. Contact jodie@asteriskllc.com for a sample customer notification letter if needed.

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