



MAY 2022

ENCLOSED

Safety Topics

Heat Related Hazards and Illnesses National Emphasis Program

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

Traffic Bulletin

DOT Training, Documentation, and Frequency

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. Food Gas Training Available To GAWDA Members – Free
2. FAQs
3. Recent FDA Observations
4. May Medical Gas Roundtable (5/27/2022) – CGMP – Supplier Qualification (CGA M-7)
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 **April 13th** @ 1PM Eastern. Visit us at www.gawda.org/safety-meeting/ to learn more and 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 _____

May 2022**Heat Related Hazards and Illnesses
National Emphasis Program – 2022****WATER. REST. SHADE.**

Keeping Workers Safe in the Heat

On April 8, 2022 OSHA announced a National Emphasis program - Outdoor and Indoor Heat Related Hazards (Heat NEP). This program is an expansion of the September 2021 "Heat Initiative Memorandum." The Heat NEP is focused on high-hazard industries with vulnerable workers, identified through data from the Department of Labor Wage and Hour Division (WHD) and is part of a broader Department of Labor response to President Biden's Executive Order (EO) 14008, "Tackling the Climate Crisis at Home and Abroad."

As with the General Duty Clause, the goal of Heat NEP is to identify and eliminate/reduce exposure to a hazard; in this case - HEAT. Each state must accept the OSHA Heat-NEP or create their own, so check your State OSHA website to determine if your State has additional requirements for the Heat NEP.



Heat-Related Illness	Symptoms and Signs
Heat stroke	▪ Confusion ▪ Slurred speech ▪ Unconsciousness ▪ Seizures ▪ Heavy sweating or hot, dry skin ▪ Very high body temperature ▪ Rapid heart rate
Heat exhaustion	▪ Fatigue ▪ Irritability ▪ Thirst ▪ Nausea or vomiting ▪ Dizziness or lightheadedness ▪ Heavy sweating ▪ Elevated body temperature or fast heart rate
Heat cramps	▪ Muscle spasms or pain ▪ Usually in legs, arms, or trunk
Heat syncope	▪ Fainting ▪ Dizziness
Heat rash	▪ Clusters of red bumps on skin ▪ Often appears on neck, upper chest, and skin folds
Rhabdomyolysis (muscle breakdown)	▪ Muscle pain ▪ Dark urine or reduced urine output ▪ Weakness

High Hazard industries include...

Most Gas and Welding Supply distributors

NAICS 325120

424690

424720

A complete list of affected NAICS codes may be found in Appendix A of the attached OSHA Heat NEP.

How does this Heat NEP affect your business:

According to the NEP instructions, high-hazard companies must have a Heat illness Prevention Plan that includes:

1. Identify employee(s) responsible for:
 - a. Administering the program,
 - b. Monitoring employees
 - c. Training employees
2. Training for new and returning employees on heat related illnesses
3. Acclimatization plan for workers: new, returning to work and temporary employees
4. Provide cool water or cool/shaded areas for full sun areas
5. Daily monitor employees for signs of heat illness
6. Monitor National Weather Service for heat conditions, heat waves and implement corresponding responses

Enforcement Methods:

1. Planned/programmed inspections for high-hazard industries
2. Programmed inspections shall occur on any day that the NWS has announced a heat warning or advisory for the local area
3. On-site heat complaint investigations (employee and anonymous complaints)
4. On-site investigations for all employer-reported hospitalizations related to heat injuries/illnesses

NOTE: Inspection procedures state:

*A review of any potential heat-related hazards should be included in any programmed or unprogrammed inspection."

*OSHA Area Offices shall instruct CSHOs to be vigilant, during their travels to job sites, to conduct compliance assistance or self-referral inspections of outdoor work environments in plain view. This means as they are driving around if they see someone working outside, they can "self-refer" an inspection.



Resources:

[OSHA National Emphasis Program - Outdoor and Indoor Heat-Related Hazards \(Heat NEP\)](#)

[OSHA Heat Illness Prevention Training Guide: A Lesson Plan for Employers](#)

[NIOSH criteria for a recommended standard: occupational exposure to heat and hot environments.](#)

[National Integrated Heat Health Information System](#)

If you have any questions on this or any other OSHA, EPA, or DHS issues, please contact me.

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Traffic Bulletin

May 2022

DOT Training, Documentation, and Frequency

Here is a compiled list of all required DOT training, documentation, and frequencies.

Hazmat Training (172.700-.704)

A **hazmat employer must train, test and certify** (sign the training documentation form) **every hazmat employee** who, in the course of employment, has any function that directly affects hazardous materials transportation safety. The hazmat employee must be trained in General Awareness, Safety, Function Specific, and Driver issues as applicable to the employee's duties.

Function Specific items for our industry would include:

- Cylinder filling of high pressure, cryogenic liquids, liquefied gases such as carbon dioxide, LPG products, and acetylene
- Cylinder requalification such as high pressure (hydrotest), low pressure gases (visual inspection), and acetylene

Driver Training (177.816)

177.816 says that the driver must receive training on the safe operation of the motor vehicle that will be transporting hazardous materials. This section goes on to describe in detail the issues the driver must be trained on. Please note: 177.816 (c) states: The driver training requirements may be satisfied by compliance with the current requirements for a Commercial Driver's License (CDL) with a tank vehicle or hazardous materials endorsement.

GAWDA has an excellent Driver Training Manual available. This would be an excellent source of driver safety meetings. It is setup into 6 short training modules with each module having its own test. Then there is a final overall test covering all the topics in the manual. Each of these modules would make an excellent driver safety meeting training session of a few minutes each. If a company did one module every 2 months, they would cover the complete manual in the year and could start back over again the following year with refresher training.



Traffic Bulletin

Security

- **In-depth training on the written plan**

Hazmat employees of employers that are required to have a security plan must receive in-depth security training on the security plan and its implementation. In-depth security training must include company security objectives, specific security procedures, employee responsibilities, actions to take in the event of a security breach, and the organizational security structure.

- **Security Awareness training**

Each hazmat employee must receive security awareness training. This training must include an awareness of security risks associated with hazardous materials transportation and methods designed to enhance transportation security. A component covering how to recognize and respond to possible security threats must be included.

I have a hazmat general awareness, safety, and security awareness test and certification if you wish to use it. Just ask and I will email it to you. If you need to do only the security awareness portion with certain employees, then you just scratch through the other portion of the answer page and just do the security part of the test questions and answers.

Documentation of Training (172.704(d))

A record of current training, inclusive of the preceding three years, must be created and retained by each hazmat employer for each hazmat employee for as long as that employee is employed by the employer as a hazmat employee and for 90 days thereafter.

The record must include:

- Hazmat employee's name;
- Most recent training completion date of the hazmat employee's training;
- Description, copy, or the location of the training materials used to meet the training requirements;
- Name and address of the person providing the training; and
- Certification that the hazmat employee has been trained and tested. (This is where someone within the company **signs** the training documentation.)



Traffic Bulletin

Drug and Alcohol

- 382.601 covers two important points: a written policy and distributing that policy to your drivers. Drivers are not required to undergo formal training. However, the employer must provide a copy of the company written drug and alcohol policy to each driver. Written notice of the availability of these materials must be provided to union representatives. These materials must be distributed prior to the start of alcohol and drug testing. Each driver must sign a receipt that he/she has received a copy of the materials. The JJ Keller pamphlet, product code **38797**, does a great job of this.
- 382.603 covers training for driver supervisors. Each employer shall ensure that all persons designated to supervise drivers receive at least 60 minutes of training on alcohol misuse and receive at least an additional 60 minutes of training on controlled substances use. The training will be used by the supervisors to determine whether reasonable suspicion exists to require a driver to undergo testing under §382.307 (reasonable suspicion testing). The training shall include the physical, behavioral, speech, and performance indicators of probable alcohol misuse and use of controlled substances. Recurrent training for supervisory personnel is not required.
- This training is available on the GAWDA University website.

Training Frequency

The hazmat (general awareness, safety, function specific (which includes driver training), and security awareness) must be done at least every 3 years.

The security in-depth training is required every 3 years unless you update your security plan and then you must train on the changes to the plan.

The supervisor drug and alcohol awareness training is only one time training, but I suggest that you that conduct this training every few years to keep the supervisors aware of the requirements.

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

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Medical, Food/Beverage and Specialty Gases Bulletin

05/01/2022

Food Gas Training Available To GAWDA Members - Free

Food Gas – CGMP Training for Pumpers

[Click here for Food Gas CGMP Training for pumpers.](#)

- 28 minute video presentation
- The FDA regulations (21 CFR 117)
- Allergen training
- Sanitation training
- Quiz
- Certificate of participation.

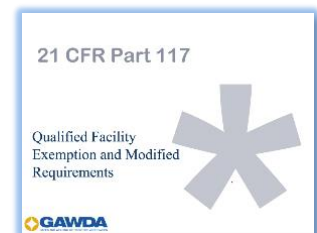


Food Gas – Qualified Facilities and submitting the FDA Attestation

[Click here for the recorded discussion of Qualified Facilities and Attestations.](#)

This is the link to the Food Gas Roundtable recording discussing the FDA Qualified Facility exemption and how to submit the Attestation.

- 15 minute video presentation
- The FDA regulations (21 CFR 117.5(a) and 21 CFR 117.201)
- Qualified Facility exemptions
- Two sales criteria for a Qualified Facility
- Alternate Qualified Facility requirements and meaning of the Attestation
- The Attestation
- How to fill out the form



Food Gas – For Owners and Managers

This video for food/beverage gas company owners and managers discusses how to set up a compliant food/beverage gas program.

Here is the link to the 62 minute video and other food gas resources...

[Click here for Food Gas Resources and owners' video.](#)



Medical, Food/Beverage and Specialty Gases Bulletin

Frequently Asked Questions

Q – Do beverage or food gas labels have any special requirements?

A – No. Unlike drug or device gases, the appropriate regulations for food gases do not include labeling instructions. Follow CGA C-7, Guide to Classification and Labeling of Compressed Gases for food gas and all gas labeling.

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 necessarily to be helpful to you.



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.

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.

May Medical Gas Roundtable - CGMP – Supplier Qualification (CGA M-7)

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, May 27, we will cover **CGMP – Supplier Qualification (CGA M-7)**. 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 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

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