



SEPTEMBER 2019

ENCLOSED

Safety Topic: GAWDA Sample Safety Policy: Active Shooter Emergency Preparedness

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

Traffic Bulletin: Special Permits

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQs: Medical Oxygen for Emergency Use
2. Recent FDA Observations: Employee Training
3. GAWDA Professional Compliance Seminar – DOT and FDA (Food/Beverage and Medical Gases) – Train the Trainer Training (10/29-31/2019); September Medical Gas Roundtable: (09/27/2019) – Subpart G – Packaging and Labeling Control
4. Micro-audit Suggestions

Please contact Tom Badstubner, GAWDA FDA Food, Medical & 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 _____

The GAWDA Safety Committee has put together sample safety policies. Here is an example of one of the many available off the member resources portion of the GAWDA website.

**Active Shooter Emergency Preparedness**
(Insert Company Name Here)

Purpose	To provide a set of proposed guidelines for emergency preparedness of welding distributors and fill plants in the event of an active shooter
Responsibility	All facility personnel
Authority	Facility manager and fill plant manager

An active shooter is defined as an individual actively engaged in killing or attempting to kill people in a populated area. While the majority of incidents involve the use of firearms, the term “active shooter” may also apply to an individual armed with any other type of weapon (e.g., firearm, knife, explosives, etc.) or describe any incident with a perpetrator who poses an active threat.

Personnel Safety

Develop an active shooter preparedness plan. At a minimum, the plan should address security assessments, preparedness, communication, actions, and training. Below lists some recommended topics for each area.

Security assessments

- Identify critical assets
- Analyze potential threats
- Evaluate existing security measures – Identify potential weaknesses and areas for improvement

Preparedness

- Train on how to recognize potential workplace violence and suspicious behavior which may include, but not limited, to the following:
 - Anti-social behavior
 - Vindictiveness which could include a recently terminated employee



- Victim mentality including hostility
- Extreme paranoia
- Persistent anger
- Violent thoughts which include threats whether overt or implied
- Controlling personality traits
- Difficulty holding jobs
- Strange behavior
- Unhealthy habits
- Become familiar with exits, emergency call boxes, potential safe harbors, and emergency response kits
- Identify an escape route in the event you are directed to evacuate
- Identify who to call to report an incident and what information to provide quickly about the situation
- Have a plan for accounting for all personnel in such an event
- Build relationships with law enforcement and neighboring emergency response agencies
- Develop a plan to get medical aid to victims quickly

Communication

- Identify a signal to notify others of an active shooter event in order to implement action plan.
- Contact 911 operations and provide following information if available
 - Location of the active shooter
 - Number of shooters
 - Physical description of shooters
 - Number and type of weapons shooter has
 - Number of potential victims at location
- Consider installing a silent/remote alarm monitoring system with multiple activation stations.

Actions taken during an incident

When an active shooter is present, one must be prepared both mentally and physically to deal with the situation. There options available are Run, Hide, and Fight

- Run
 - Have an escape route and plan in mind
 - Leave your belongings behind
 - Evacuate regardless of whether others agree to follow
 - Help others escape, if possible
 - Do not attempt to move the wounded
 - Prevent others from entering an area where the active shooter may be
 - Keep your hands visible
 - Call 911 when you are safe



- **Hide**
 - Hide in an area out of the shooter's view
 - Lock the doors and/or barricade them with heavy furniture, if possible.
 - Close and lock windows and close blinds or cover windows.
 - Turn off lights.
 - Silence all electronic devices (including vibrate mode).
 - Remain silent.
 - Look for other avenues of escape.
 - Identify ad-hoc weapons.
 - When safe to do so, use strategies to silently communicate with first responders, if possible (e.g., in rooms with exterior windows, make signs to silently signal law enforcement and emergency responders to indicate the status of the room's occupants).
 - Hide along the wall closest to the exit but out of view from the hallway (which would allow the best option for ambushing the shooter and for possible escape if the shooter enters or passes by the room).
 - Remain in place until given an all clear by identifiable law enforcement
- **Fight**
 - Fight as a last resort and only when your life is in imminent danger
 - Attempt to incapacitate the shooter
 - Act with as much physical aggression as possible
 - Improvise weapons or throw items at the active shooter
 - Commit to your actions . . . your life depends on it

Training and exercises

- Schedule regular drills incorporating the ALICE protocol -- Alert, Lockdown, Inform, Counter, and Evacuate
- Understand where to shelter if necessary, going to the nearest room or office and locking the door
- Practice closing blinds, turning off lights, covering windows and remaining quiet

Additional resources to consider when developing an active shooter preparedness plan include:

www.dhs.gov

www.ready.gov



Again, the purpose of this sample policy is to reduce accidents in the workplace and to provide our members with a template that they can use to write their own safety policy.

Feel free to contact me if you have any questions.

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Traffic Bulletin

September 2019

Special Permits

There are basically two kinds of DOT special permits for our cylinders. There are permits for manufacturing packages that are different from approved specifications. There are also permits that let you do things differently than what is found in the published regulations. A special permit is an alternative method of complying with the Hazardous Materials Regulations. It will cover a new process, product or materials that are not specifically referenced in the regulations. You need to apply and obtain authority from DOT to hold a special permit. This is known as party to status.

On file at each location

If you have a package that has a special permit on it, you must have a current copy of the special permit on file at the location that ships or requalifies the package. You must follow the requirements outlined in the special permit. Some special permits require a copy to be kept on the motor vehicle and if it does this will be stated in the special permit.

Transporting a Special Permit package

If you receive a cylinder that is being operated under a special permit then provided you don't modify the package (for us, that means you don't fill it) then you can reoffer it for transportation without being a party to the special permit. Example – if Company XYZ fills a cylinder under a special permit and you order it from Company XYZ you can then take it to your customer. You must have a copy of the special permit on file, trained and documented all employees that touch the package, and then note the special permit on the shipping paper in association with the product description. The key is that you did not fill the cylinder or modify the package when you shipped or transported it.

If you have to offer a special permit container to a common or contract carrier then you must provide them with a current copy of the special permit at or before the time of shipment. There are a few exceptions to this requirement but almost all the time this requirement will apply.

Again, you must enter the special permit number onto the hazardous material shipping paper in association with the proper shipping name of the product in the special permit cylinder. There are a very few exceptions to this rule but 99% or more of the special permits require this.



Traffic Bulletin

Training

All employees that handle a special permit package must be trained on the requirements of the special permit and the training is required every 3 years. You will need to document this training per 172.704 (d) and here is a summary of what you need to document:

- d)(1) The hazmat employee's name;
- (d)(2) the most recent training completion date of the hazmat employee's training;
- (d)(3) a description, copy, or the location of the training materials used to meet the requirements;
- (d)(4) the name and address of the person providing the training; and
- (d)(5) certification that the hazmat employee has been trained and tested.

Do I need to be a “party to” the Special Permit?

If you read item “1. Grantee” on the special permit and see the words “See individual authorization letter”, then you need to have your company authorized by DOT to be a party to the special permit to be able to fill the cylinders used under the special permit.

How do I become a “party to” a Special Permit?

Here is the PHMSA website for special permit applications and renewals:

<https://www.phmsa.dot.gov/hazmat/special-permits/special-permits-applications>

There is a link “Access Online Applications Portal” to the online procedure:

https://portal.phmsa.dot.gov/phmsapub/faces/PHMSAHome?attempt=0&_afLoop=2426175410275889&req=6550977117077761351&_afWindowMode=0&_adf.ctrl-state=1619ntbahf_22

but unfortunately, it is difficult to use.

Your special permit will be the authorization letter you received stapled to the top of the actual special permit that you will print off. You keep the two items together as your permit.

Please note that just because you apply doesn't mean that you are automatically granted. Your current DOT safety score and performance can keep you from getting party to special permits. You also must have been audited in the past and have a Satisfactory Rating. If you apply for a special permit and have never been audited, then you will generate an audit. They will come visit so be prepared. This has happened to several of our members in the past year.



Traffic Bulletin

Special Permit Renewals

When it comes time to renew your special permit, you can use the same email process as above. I can supply you with a sample special permit renewal letter. You can also use the online PHMSA portal discussed above.

It is extremely important that the renewal takes place at least 60 days or more before the special permit expires. If you renew more than 60 days before expiration and DOT drags their feet, then you get to keep using the special permit. If you renew less than 60 days before the expiration date, and they drag their feet and the special permit expires, then you must cease using the special permit until they send you approval letter. The first permit is issued for 2 years and the renewals are issued for 4 years after that.

Yes, the special permits can be very confusing and applying for and renewing special permits can be confusing as well so if you have any questions, please contact me and I will be glad to work you through the process.

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

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Medical, Food/Beverage and Specialty Gases Bulletin

09/01/2019

Frequently Asked Questions - Medical Oxygen for Emergency Use

The FDA allows medical oxygen to be dispensed without a prescription to properly trained individuals for oxygen deficiency and resuscitation, as long as the following conditions are met:

1. A high-pressure cylinder filled with medical oxygen and used for oxygen deficiency and resuscitation must have the “emergency use” statement present on the drug label.
2. The equipment intended for such use must deliver a minimum flow rate of 6 liters of oxygen per minute for a minimum of 15 minutes, and include a content gauge and an appropriate mask or administration device.
3. Proper training is documentation that an individual has received training within the past twenty-four months or other appropriate interval, in the use of emergency oxygen including providing oxygen to both breathing and non-breathing patients, and safe use and handling of emergency oxygen equipment. Training may be obtained from any nationally recognized professional organization, such as the National Safety Council, the American Heart Association, the American Red Cross, etc.
4. Under no circumstances can emergency oxygen be used to fill high-pressure cylinders or be used in a mixture or blend.

Once all of these conditions are met, an individual or firm may have access to medical oxygen without a prescription. Keep in mind that some states may have additional requirements.

What training courses/certifications would qualify a person to buy medical oxygen for emergency use?

Here are some examples of emergency oxygen administration training:

- American Safety and Training Institute (ASTI)
 - Emergency Oxygen Administration/Bloodborne Pathogens
- American Red Cross
 - Emergency Oxygen Administration
- American Safety and Health Institute (ASHI)
 - Emergency Oxygen
- S.C.U.B.A. divers who hold a valid certificate in the following nationally recognized S.C.U.B.A. diving certifying organization programs may purchase, possess, and use medical oxygen for the purpose of emergency care or treatment at the scene of a diving emergency:
 - Diver alert network (DAN):
 - Oxygen first aid for scuba diving injuries;



Medical, Food/Beverage and Specialty Gases Bulletin

- International association of nitrox and technical divers:
 - Oxygen provider course;
- Professional association of diving instructors (PADI):
 - Emergency first response;
 - Oxygen first aid;
 - Rescue diver course;
 - Tec deep diver;
- Scuba schools international:
 - Medic first aid emergency oxygen administration;
- Technical diving international-S.C.U.B.A. diving international:
 - Diver advanced development program as a CPROX administrator;
- National association of underwater instructors (NAUI)
 - First aid;
 - Rescue scuba diver;
 - Advanced rescue scuba diver;
 - First aid instructor;
 - Oxygen administration; and
 - Instructor
- YMCA:
 - Slam rescue

Can a physician buy medical oxygen for emergency use?

In most states, a physician would need a medical license in order to buy drugs... the exception to this rule is for medical Oxygen. If physicians are using the oxygen for routine medical treatment, they would only be able to buy the medical Oxygen under their medical license. However, if physicians need oxygen only for emergencies in the office, they would not need to show their license to buy the medical oxygen. Of course, if a physician is buying many oxygen cylinders in a month, you would want to challenge the “emergency” use of the purchases.

Even in Florida, the practice of selling occasional medical oxygen cylinders to a physician, without using the medical license, is permitted. We recommend that you have a “For Emergency Use” statement on the delivery ticket to document that the sale of medical oxygen is for emergency use.



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.

Employee Training

Form 483 Observation-02-04 - Employees engaged in the manufacture, processing and packing of a drug product lack the training required to perform their assigned functions. Specifically, GMP training records for ____, a Cylinder Filler Operator at the firm, do not exist for the following items as required per SOP ____, revision ____, active ____, titled "Personnel Qualification and Training": FD&C Act; Drug & Device cGMP; FDA Compressed Medical Gas Guidelines and other Guidance; State and Local Requirements; Control of Components; Production and Process Controls; Holding and Distribution Laboratory Controls; Records & Reports/Returned and Salvaged Drug Products; Medical Gas Complaint Procedures.

How to prevent this from showing up in your inspection?

Assure all employees (including pumpers and QCU) are current on their CGMP training.



Medical, Food/Beverage and Specialty Gases Bulletin

GAWDA Professional Compliance Seminar – Certified Training



DOT and FDA (Food/Beverage and Medical Gases) – Train the Trainer Training
October 29 to 31, 2019 at Weldcoa in Aurora, IL.

Click here for more information: [GAWDA Professional Compliance Seminar - Fall](#)

September Medical Gas Roundtable (09/27/2019) – 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, CGA P-36 and CGA P-58 prior to attending the seminar.
- **Food Gas Roundtable** – Part 117 Subpart C - Reanalysis, Requirements for preventive controls qualified individual and a qualified auditor

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.



Medical, Food/Beverage and Specialty Gases Bulletin

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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