



APRIL 2021

ENCLOSED

Safety Topics

1. Contact Tracing
2. Training Reminder: Fire Prevention/Fire Drills/Fire Extinguisher Training

Please contact [Marilyn Dempsey](#), GAWDA DHS, EPA, & OSHA Consultant for more information.

Traffic Bulletin

Driver Distractions: Personal Communication Devices

Please contact [Mike Dodd](#), GAWDA DOT Consultant for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQs: Oxygen Cylinders
2. Recent FDA Observations
3. GAWDA April Medical Gas Roundtable, Specialty Gas, and Food Gas Roundtable (4/30/2021)
4. Micro-Audit Suggestions

Please contact [Tom Badstubner](#), GAWDA FDA Food, Medical & Specialty Gases Consultant for more information.

**** Visit GAWDA's COVID-19 Resource Center 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.



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.

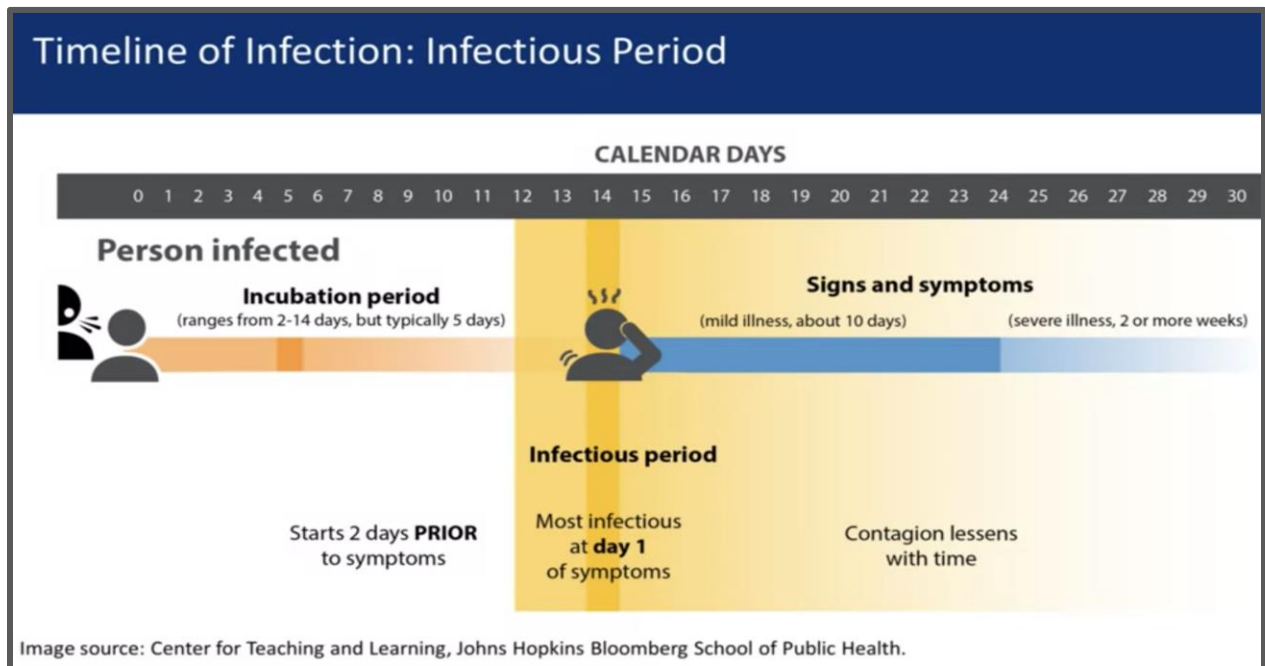
ROUTE TO:

- General Manager
- Safety Coordinator
- Supervisor Dept. _____
- Other _____
- Date of Meeting _____



April 2021

Contact Tracing



COVID-19 contact tracing is a tool used to slow the spread of COVID-19 by identifying and isolating exposed individuals, allowing them to quarantine quickly. Contact tracing is usually conducted by local health departments; however Guidance issued by the [Equal Employment Opportunity Commission](#) (EEOC) states that employers can ask employees whether they have been diagnosed with COVID-19 and whether they are experiencing coronavirus symptoms.

Exposure as defined by the Centers for Disease Control and Prevention (CDC) begins when someone is [within 6 feet of the infected person\(s\) for 15 minutes or more](#) (cumulative time). The agency also notes that infected people can spread the virus 48 hours before the onset of symptoms. Travis Vance calls that combination of factors [the "6-15-48 rule"](#).



You will need infected employees to identify others who worked within 6 feet of them, for 15 minutes or more (cumulative), within the 48 hours prior to the sick individual showing symptoms, or later. (Fisher Phillips, North Carolina)

Employers can conduct Contact Tracing and satisfy their exposure-notification obligations by following these steps:

Step 1: Be prepared. Describe the company's contact-tracing process as part of a policy for responding to a case of COVID-19 in the workplace, and make the policy available to all employees, notifying them that if they contract the coronavirus, they will be asked to provide a list of contacts at work. Set up processes to allow for quick identification of contacts. Create a list of standard questions or talking points to use in interviews to learn the movements of the exposed person and to provide guidance for seeking medical help.

Designate a Team. Choose an employee or group of employees who will work closely with public health agencies, interview employees and notify affected contacts.

NOTE: Always Check your State's laws regarding contact tracing to ensure your policy is compliant.

Step 2: Identify and Interview Symptomatic Employees

Prioritize confidentiality. Employers have the right to ask employees if they have symptoms or have been diagnosed with COVID-19 without violating the Americans with Disabilities Act, according to guidance from the Equal Employment Opportunity Commission. But they should never divulge the name of an infected employee to others at the workplace beyond those conducting the investigation.

Interview the symptomatic employee as soon as possible after they are identified. Interviewers should ask for the names of all employees, visitors or vendors they had close contact within the workplace starting from 48 hours before symptoms appeared through the time of the interview

Work with state and local health departments. They are the big guns of contact tracing and have greater legal authority to find people, especially beyond the workplace, said Dr. Clarence Lam, interim director for occupational health services at Johns Hopkins Medicine. "Right now, it's challenging to figure out where an individual got their COVID case from. The risk can be as high in a grocery store as the workplace," he said, noting that public health contact tracers can follow those lines of transmissions.

Step 3: Notify Employees Who May Have Been Exposed

Employees identified in Step 2 are informed they had contact with a person in the workplace who is suspected or confirmed to have COVID-19. To maintain confidentiality, they are not provided with the name of the employee. Contacts are also given guidelines for self-quarantine, told to contact their healthcare provider if they experience COVID-19 symptoms and given the chance to ask questions. (Laborers' Health & Safety Fund of North America, 2020).



Step 4: Follow up with quarantined employees.

Remember to stay in touch with employees who've been quarantined, and if any of them show symptoms or are diagnosed with COVID-19, begin another contact-tracing exercise to identify those they might have exposed. (Cleeland, 2020).

Forms: Forms do not have to be fancy. The form should record any contacts made two days prior to onset of symptoms (or positive test, whichever is first) through 10 days (min). The form can be created as a paper form using a word document, excel/ or create an online form using a Microsoft product or Google docs/forms then create a link or QR code. Please note that any type of completed form must be kept confidential.

References:

Fisher Phillips. (2020, May 26). 6-15-48: These 3 Numbers Offer A Simple Way. <https://www.fisherphillips.com/resources-alerts-6-15-48-these-3-numbers-offer>.

Cleeland, N. (2020, June 2). Contact Tracing for Employers. How to handle investigations and notifications if a worker has COVID-19. SHRM. <https://www.shrm.org/resourcesandtools/hr-topics/employee-relations/pages/contact-tracing-employers.aspx>.

Laborers' Health & Safety Fund of North America. (2020, October 3). COVID-19 Contact Tracing Explained: Roles for Employers and Workers. <https://www.lhsfna.org/LHSFNA/assets/File/COVID-19%20Contact%20Tracing%2010%2023%2020.pdf>.

CDC (2021, March 12). When You Can be Around Others After You Had or Likely Had COVID-19. <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/end-home-isolation.html>.



Training: Fire Safety

Fire safety is important in the home and at work. According to the Bureau of Labor Statistics every year approximately 3% of all workplace fatalities are due to fires/explosions in the workplace. Practicing evacuation of your facility will help ensure everyone is able to evacuate safely in the event of a fire emergency.

OSHA requires an Emergency Action Plan that includes procedures to report and respond to fire and other emergencies (29CFR1910.38).

OSHA requirements for Fire Emergency :

1. How to report
2. How to respond; including an emergency evacuation route
3. Procedures to be followed by employees who remain to operate critical plant operations before they evacuate;
4. Procedures to account for all employees after evacuation;
5. Procedures to be followed by employees performing rescue or medical duties; and
6. The name or job title of every employee who may be contacted by employees who need more information about the plan or an explanation of their duties under the plan.
7. Employee alarm system.
8. Training. An employer must designate and train employees to assist in a safe and orderly evacuation of other employees.
9. Review of emergency action plan. An employer must review the emergency action plan with each employee covered by the plan:
 - a. Initial job assignment
 - b. Employees responsibilities change under the plan
 - c. When the plan is changed

[OSHA's etool Fight or Flee](#) can help you decide if you want/ have to train your employees on Fire Extinguisher use.



Option 1	Option 2	Option 3	Option 4
Total evacuation of employees from the workplace immediately when alarm sounds. No one is authorized to use available portable fire extinguishers.	Designated employees are authorized to use portable fire extinguishers to fight fires. All other employees must evacuate workplace immediately when alarm sounds.	All employees are authorized to use portable fire extinguishers to fight fires.	Extinguishers are provided but not intended for employee use.
Requirement	Requirement	Requirement	Requirement
Establish an emergency action plan, fire prevention plan and train employees accordingly. Extinguishers are not existing and not required. [29 CFR 1910.157(b)(1)]	Establish an emergency action plan and train employees accordingly. Meet all general fire extinguisher requirements plus annually train designated employees to use fire extinguishers. Fire extinguishers in the workplace must be inspected, tested, and maintained. [29 CFR 1910.157(b)(2)]	If any employees will be evacuating, establish an emergency action plan and train employees accordingly. Meet all general fire extinguisher requirements plus annually train all employees to use fire extinguishers. Fire extinguishers in the workplace must be inspected, tested, and maintained. [29 CFR 1910.157(b)(2)]	Establish an emergency action plan, fire prevention plan and train employees accordingly. If fire extinguishers are left in the workplace, they must be inspected, tested, and maintained. Extinguishers are provided but not intended for employee use. [29 CFR 1910.157(a)]

The GAWDA Safety Committee created a Sample Safety Practice for Fire Emergency Preparedness to assist with your company’s Emergency Action Plan. This practice can be found on the GAWDA website/ Member’s only page/ Sample Safety Practices/ Fire Emergency Preparedness.

Consultant’s suggestion: Operationally check all alarm equipment and evacuation maps for accuracy. Practice fire evaluation drills twice annually: once, announced and the second time unannounced. Remember to have everyone sign a record of training and remind them that in a real fire emergency, they will still need to physically sign a paper acknowledging their safe evacuation, prior to leaving the site.

If you have any questions on these topics, or any other DHS, EPA or OSHA topic, please contact me.

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Traffic Bulletin

Traffic Bulletin

April 2021

Driver Distractions: Personal Communication Devices

Driving a company vehicle while distracted can significantly increase the risk of causing a collision. One of the most common distractions while driving is the use of cellular phones or other communication devices. Your company should desire to protect your employees and others on the highways by adopting the following policy on the use of communication devices.

Definitions

Company Vehicle

A “company vehicle” is a company-owned vehicle operated on or off the job, a company-rented or leased vehicle operated on or off the job, or an employee-owned or leased vehicle operated for company business.

Communications Devices

“Communication devices” include: cellular phones, pagers, Personal Digital Assistants, Citizens’ Band radios or handheld radios.

Safe Location

A safe location is a legal parking or stopping location on public or private property. It is not the side of the road or highway. Highway shoulders are for emergency stopping and are not considered a safe location. Examples of safe locations are parking lots, gas stations, etc.

Regulations

392.80 Prohibition against texting.

- (a) **Prohibition.** No driver shall engage in texting while driving.
- (b) **Motor Carriers.** No motor carrier shall allow or require its drivers to engage in texting while driving.
- (c) **Definition.** For the purpose of this section only, *driving* means operating a commercial motor vehicle, with the motor running, including while temporarily stationary because of traffic, a traffic control device, or other momentary delays. Driving does not include operating a commercial motor vehicle with or without the motor running when the driver moved the vehicle to the side of, or off, a highway, as defined in 49 CFR 390.5, and halted in a location where the vehicle can safely remain stationary.
- (d) **Emergency exception.** Texting while driving is permissible by drivers of a commercial motor vehicle when necessary to communicate with law enforcement officials or other emergency services.



Traffic Bulletin

392.82 Using a hand-held mobile telephone.

(a)(1) No driver shall use a hand-held mobile telephone while driving a CMV.

(a)(2) No motor carrier shall allow or require its drivers to use a hand-held mobile telephone while driving a CMV.

(b) **Definitions.** For the purpose of this section only, *driving* means operating a commercial motor vehicle on a highway, including while temporarily stationary because of traffic, a traffic control device, or other momentary delays. Driving does not include operating a commercial motor vehicle when the driver has moved the vehicle to the side of, or off, a highway and has halted in a location where the vehicle can safely remain stationary.

(c) **Emergency exception.** Using a hand-held mobile telephone is permissible by drivers of a CMV when necessary to communicate with law enforcement officials or other emergency services.

Suggested Company Policy

- **Handheld** communication devices may not be used while driving in a company vehicle. This includes talking on or listening to a **handheld** cellular phone, text messaging, reading, or responding to email messages or accessing voice mail.
- **Handheld** communication devices may only be used in vehicles when the vehicle is stopped in a safe location, out of the lanes of travel and off the roadway. Bluetooth or other hands-free communication devices may only be used when a company vehicle is parked in a safe location.
- Cellular phones, pagers, Bluetooth, or other hands-free communication devices may be kept on while the vehicle is in motion to alert drivers that a call or message has been received and the driver may receive, terminate, or initiate a call only if this can be done by pushing one button.
- Employees who are charged with traffic violations resulting from the use of a communication device (whether company provided or personal) while driving on company business will be solely responsible for all liabilities that result from such actions.
- Communication devices are not to be used while fueling vehicles.
- Safety must come before all other concerns. Under no circumstances are employees allowed to place themselves at risk to fulfill business needs.
- Violation of this policy may result in disciplinary action up to and including termination.

Please note: This is only a suggested policy and GAWDA member companies should adjust their company policies as their individual needs require.

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

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Medical, Food/Beverage and Specialty Gases Bulletin

04/01/2021

Frequently Asked Questions

Q – How can I convert industrial grade Oxygen cylinders to medical grade oxygen cylinders?

A - You can convert industrial to medical grade oxygen. The details are in CGA M-18, *Standard for the Change of Product and Change of Grade for High Pressure and Refrigerated Liquid Containers*. See <https://portal.cganet.com/Publication/Details.aspx?id=M-18> This publication is **free** to GAWDA members by subscribing to the free CGA/GAWDA Safety Program. It is quick and easy to subscribe: <https://www.gawda.org/resources/cga-subscription-program/>

Check out section 6.2 in CGA M-18. It lists the process steps for converting from industrial grade to medical grade oxygen service for high pressure cylinders:

- Identification
- Odor test
- Valve removal, internal inspection and revalving
- Purging/evacuation/pressurization
- Filling
- Testing for conformance

See M-18 for the important details/specifications of each step.

M-18 also has instructions for changing the grade on liquid, cryogenic containers.

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.



Medical, Food/Beverage and Specialty Gases Bulletin

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.



April Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, April 30, we will cover **Subparts D - Equipment**. *Sample equipment maintenance records will be available for downloading during the training.*

In addition, we will be conducting the following additional training on April 30:

- **Specialty Gas** - Gas Chromatograph Troubleshooting
- **Food Gas Roundtable** –
 - CGMP Training – 21 CFR 117, Subpart C – HARPC (CGA F-2)
 - 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. **Annual Record Review** – Verify that you have conducted and documented an annual records review for your medical gas production facility. See the last page 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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