GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SEPTEMBER 2020

ENCLOSED

Safety Topic

Frequently Asked Questions – COVID-19

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

Traffic Bulletin

Hours of Service Update

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. Emerging Issue
2. FAQs
3. Recent FDA Observations
4. GAWDA Professional Compliance Webinar: Fall -- October 27th-29th Webinar;
   September Medical Gas Roundtable (09/24/2020): Subpart G – Packaging and Labeling Control
5. 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/ ****

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

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 _____

This month's article reviews Frequently Asked Questions about COVID-19 and the mandated COVID-19 Safety Plan, required by some states. This plan, "COVID-19 Exposure Prevention, Preparation and Response Plan (Rev. 22May2020)", is attached to this article and posted on the member's only page of the GAWDA website. States that require a COVID-19 safety plan are listed on the OSHA website, State Plans.

Frequently Asked Questions – COVID-19

1. General Questions about COVID-19:

What is the corona virus and how does it make someone sick?
A coronavirus is a type of common virus that can infect your nose, sinuses, or upper throat. They can spread much like cold viruses. Almost everyone gets a coronavirus infection at least once in their life, most likely as a young child.

COVID-19 is the abbreviation for the Coronavirus disease 2019 which is an infectious disease caused by severe acute respiratory syndrome coronavirus 2. It was first identified in December 2019 in Wuhan, Hubei, China, and has resulted in an ongoing pandemic.

It spreads the same way other coronaviruses do, mainly through person-to-person contact. The main form of transmission is respiratory admission; however, fomites (transmission through inanimate objects) is also possible.

How long does COVID-19 live on solid surfaces?
Researchers found that those coronaviruses could remain infectious between two hours and nine days, which is in line with what the World Health Organization and CDC estimate for COVID-19.

Surfaces:
- Metal - 5 days
  - Examples: doorknobs, jewelry, silverware
- Wood - 4 days
  - Examples: furniture, decking
- Plastics - 2 to 3 days
  - Examples: milk containers and detergent bottles, subway and bus seats, backpacks, elevator buttons
- Stainless steel - 2 to 3 days
  - Examples: refrigerators, pots and pans, sinks, some water bottles
- Cardboard - 24 hours
  - Examples: shipping boxes
- Copper - 4 hours
  - Examples: pennies, teakettles, cookware
- Aluminum - 2 to 8 hours
  - Examples: soda cans, tinfoil, water bottles
- Glass - Up to 5 days
  - Examples: drinking glasses, measuring cups, mirrors, windows
- Ceramics - 5 days
  - Examples: dishes, pottery, mugs
- Paper - up to 5 days
  - Examples: mail, newspaper, paper money

2. Cleaning and Disinfection Questions:

What are the cleaning recommendations for COVID-19?
The CDC recommends individuals wash their hands frequently with soap and water (washing for 20 seconds) and the use of hand sanitizer. Cleaning the workplace should be on a regular schedule. Surfaces should be routinely cleaned using soap and water, followed with a disinfectant. Cleaning with soap and water reduces the number of germs, dirt and impurities on the surface. Disinfecting kills germs on surfaces.

Can a disinfectant wipe be used more than once?
Disinfectant wipes are designed for single use. Repeated use of the wipe results in decreased efficacy of the disinfectant.

How can we safely clean cylinders suspected to be contaminated with COVID-19?
Gas distributors are not normally equipped to clean and disinfect cylinders that is why OSHA places the burden of cleaning and disinfecting cylinders and other equipment, like cylinder carts on the end user (29CFR 2910.1030(d)(2) (xiv)). With that said, concerns for the health of employees may be reason to take additional steps. GAWDA published a safety alert concerning cleaning procedures (13March2020) that follows CGA's SA-35, "Safety Alert: Cleaning of Cylinders Returned from Health Care Facilities During a Pandemic." CGA's Safety alert states, "During the COVID-19 crisis, consideration may be given to the use of soap/water solutions to clean, or a dilute bleach/water solution followed by a clean water rinse to disinfect returned containers that may not have been properly cleaned and decontaminated. Such consideration should carefully weigh immediate cleaning concerns against possible longer-term effects on the container and the valve.

When isopropyl alcohol (IPA) or other flammable disinfectants are used as a spray application to disinfect containers, great care must be taken to ensure that there is no residual left in the valve outlet prior to the cylinder being refilled. "

Is Simple Green a good cleaning agent for cylinders?
Simple Green is a very good detergent and quite effective at removing dirt/ debris but Simple Green is not a disinfectant. During the pandemic disinfection procedures should follow CGA SA-35 which states consideration should be given to the use of a dilute chlorine solution followed by a clean water rinse to disinfect cylinders. Caution should be taken to minimize the application of the solution around the cylinder valves because chlorine is corrosive. SA-35 states that the risks of disinfection should be carefully weighed against possible longer-term effects on the container and the valve.

Following the pandemic CGA P-83 (2019 ed.) "Guidelines for Cleaning Externally Contaminated Medical Gas Containers." Section 5.3 covers Disinfection
"After the contamination has been removed, the medical gas container shall be disinfected by using, for example, isopropyl alcohol (IPA) or equivalent disinfectant wipes. Disinfection agents shall be approved by the gas supplier and used in accordance with the manufacturer's recommendations.

The application of alcohol-based disinfectants shall be limited to prevent excessive amounts on the valve and/or cylinder that could cause a potential fire risk.

Ensure that all residual disinfection agents are removed from the medical gas container."

Can we use other disinfectants?
Only two methods are recommended by the CGA because we have to be considerate that we reuse our cylinders for decades and many chemicals will have negative effects on the cylinders and may also damage the valve assembly.

Can you, the consultants, approve/recommend other disinfectants?
There are many chemicals listed and approved as disinfectants on the CDC website, but we can only recommend the practice listed in CGA SA-35.

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Is it OK to have cylinders sit at customers for 4+ days if Covid-19 suspected at the customer site?
Yes, if the cylinders can be stored where they will not be further contaminated. Or you could have a quarantine/waiting period at your site.

3. Employee Health:

What can we do to protect our employees from contracting COVID-19?

1. Limit exposure between employees and customers
2. Consider equipping the driver with work gloves and a box of disposable gloves. The driver would don a pair of disposable gloves prior to using the work gloves. The double set of gloves would be used for moving cylinders and other equipment. Once the delivery / return of cylinders or equipment was completed, the driver would place the work gloves into a container, either secured in the cab or the bed of the truck, then continue to operate the vehicle with the disposable gloves or dispose of them. Keep disinfectant wipes and hand gel in the truck.
3. Practice touchless delivery: pick-up boxes, no signature for deliveries
4. Wear face masks when working with others
5. Social distance (>6 feet) and/or install barriers
6. Limit common contact items (time clocks, common computers)
7. Increase cleaning and sanitation of the work area

What does exposed to COVID-19 mean?

The CDC defines an individual as being exposed to COVID-19 as "an individual who has had close contact (< 6 feet) for ≥15 minutes."

What if an employee has been exposed to COVID-19?

The CDC states that Critical Infrastructure workers who have been exposed to COVID-19 but remain asymptomatic should adhere to the following practices prior to and during their work shift:

1.Pre-Screen: Employers should measure the employee's temperature and assess symptoms prior to them starting work. Ideally, temperature checks should happen before the individual enters the facility.

2.Regular Monitoring: As long as the employee doesn't have a temperature or symptoms, they should self-monitor under the supervision of their employer's occupational health program.

3.Disinfect and Clean workspaces: Clean and disinfect all areas such as offices, bathrooms, common areas, shared electronic equipment routinely.

4. Wear a Mask: The employee should wear a face mask at all times while in the workplace for 14 days after last exposure. Employers can issue facemasks or can approve employees' supplied cloth face coverings in the event of shortages.

5. The employee should practice social distancing for 14 days after the last exposure.

6. Information on persons who had contact with the ill employee during the time the employee had symptoms and 2 days prior to symptoms should be compiled.
7. Others at the facility with close contact within 6 feet of the employee during this time would be considered exposed, should be treated as an "Exposed Employee" and should follow these guidelines for 14 days after the last exposure.

If the employee becomes sick during the day, they should be sent home immediately.

https://www.cdc.gov/coronavirus/2019-ncov/community/critical-workers/implementing-safety-practices.html

When can an employee that tested positive return to work?
The CDC on July 20, 2020 reported that employees with COVID-19 who have stayed home (home isolated) can stop home isolation under the following conditions:

1. 24 hours must have passed since the last fever without the use of fever-reducing medications.
2. There should be a marked improvement in symptoms (for example, when your cough or shortness of breath have improved).

3. For persons who never develop symptoms, isolation and other precautions can be discontinued 10 days *after the date of their first positive RT-PCR test for SARS-CoV-2 RNA.*

On August 15, 2020, the CDC reported, "Data to date show that a person who has had and recovered from COVID-19 may have low levels of virus in their bodies for up to 3 months after diagnosis. This means that if the person who has recovered from COVID-19 is retested within 3 months of initial infection, they may continue to have a positive test result, even though they are not spreading COVID-19."
(https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html)

Can an employee return to work if they have been sick but NOT diagnosed with COVID-19?
If they have tested negative for COVID-19 otherwise they should be treated as if they did have COVID-19 and follow the re-entry guidelines.

The CDC on July 20, 2020 reported that employees with COVID-19 who have stayed home (home isolated) can stop home isolation under the following conditions:

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As we get ready to reopen our showroom, how do we handle the employees that have a concern about coming to work?
This is when you have to coach your employees; reassure them that you are taking as many precautions as humanly possible. Some possible talking points:

1. Providing PPE: face coverings, gloves and counter shields
2. Limiting customer access to the facility, creating a pick-up area and marking 6' segregation from the counter
3. Cleaning is on an accelerated schedule and disinfectant is placed on the counter, bathrooms and breakroom
4. Personnel are encouraged to practice social distancing and the number of employees stationed at the counter was decreased to create 6' of distance/or shields placed between workspaces. Shifts or break times may have been staggered
5. Install Signage and conduct training

4. PPE:

What type of PPE will help protect our employees?
Gloves, face coverings and physical barriers are the recommended PPE for COVID-19.

A. Gloves

One of the best practices we can reinforce during COVID-19 is the use of gloves while handling materials. If the gloves are suspected to be contaminated, the employee should shake them off into a garbage can and obtain a new pair from his/her supervisor before resuming work duties. Employees should be reminded to NOT touch their face with their hands or gloves.

Drivers may adopt the practice of using a second pair of gloves under their work gloves to put another barrier between their hands and possible contamination.

Pumpers should practice good odor check form (wave the gas toward their face rather than placing their face in front of the valve). Pumpers may consider the use of disposable gloves when performing pre-fill inspections

B. Face Covering

In light of new data about how COVID-19 spreads, along with evidence of widespread COVID-19 illness in communities across the country, the CDC recommends that people wear a cloth face covering to cover their nose and mouth when in the community setting. This is to protect people around you, especially if you are infected but do not have symptoms.

If you are issuing N-95 face masks or other face covering, you need to train employees on when and how to use them and document the training.

When do you need to wear a cloth face covering?
A cloth face covering should be worn whenever people are in a community setting, especially in situations where you may within 6 feet of people. These settings include stores, gas stations and customer sites.

Can you clean or sterilize an N95 mask?
Yes, short answer.
There are four documented methods to decontaminate masks: time, heat, hydrogen peroxide, UV.
CDC - Implementing Filtering Facepiece Respirator (FFR) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators

This document also points out that the COVID-19 virus can survive on plastic, stainless steel, and cardboard surfaces for up to 72-hours and suggested that a rotation allowing at least 5 days between use of each respirator, with storage of the unused masks in individual paper bags.

C. Physical separation

Physical barriers use methods to physically separate employees in all areas of the building, including work areas and other areas such as meeting rooms, break rooms, parking lots, entrance and exit areas, and locker rooms.

- Shields between workstations or sales counters
- Signs, tape marks, or other visual cues such as decals or colored tape on the floor, placed 6 feet apart, to show where to stand when physical barriers are not possible.
- Physically removing high-touch communal items (e.g. coffee pots and bulk snacks) with alternatives such as pre-packaged, single-serving items. Encourage employees to bring their own water to minimize use and touching of water fountains or consider installing no-touch activation methods for water fountains.

5. Legal Action

Can I be sued for an employee who dies from COVID-19?

Rick Schweitzer agrees that wrongful death lawsuits from COVID-19 should generally not occur. A work-related death would be processed through a worker's compensation claim and therefore not a civil suit.

When is a COVID-19 illness considered recordable?

COVID-19 can be a recordable illness if a worker is infected as a result of performing their work-related duties. However, employers are only responsible for recording cases of COVID-19 if all of the following are met:

1. The case is a confirmed case of COVID-19 (see CDC information on persons under investigation and presumptive positive and laboratory-confirmed cases of COVID-19).
2. The case is work-related, as defined by 29 CFR 1904.5.
3. The case involves one or more of the general recording criteria set forth in 29 CFR 1904.7 (e.g., medical treatment beyond first-aid, days away from work).

Some states have more strict guidance for determining work-relatedness of COVID-19, please refer to your state requirements.

This document lists the questions submitted during the pandemic and the answers posted are current as of August 26, 2020. Information changes rapidly during this plague, please verify information at the date of inquiry.

Please contact me if you would like to discuss this plan or any other DHS, EPA or OSHA issue.

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Traffic Bulletin

September 2020

Hours of Service Update

On June 1, 2020, FMCSA revised the hours of service (HOS) regulations to provide greater flexibility for drivers without adversely affecting safety. Motor carriers are required to comply with the new HOS regulations starting on September 29, 2020, not before.

What is Changing?

1. **Short-haul Exception**
   Expands the short-haul exception to 150 air-miles and allows a 14-hour work shift to take place as part of the exception.

2. **Adverse Driving Conditions Exception**
   Expands the driving window during adverse driving conditions by up to an additional 2 hours.

3. **30-Minute Break Requirement**
   Requires a 30-minute break after 8 hours of driving time (instead of on-duty time) and allows an on-duty/not driving period to qualify as the required break.

4. **Sleeper Berth Provision**
   Modifies the sleeper berth exception to allow a driver to meet the 10-hour minimum off-duty requirement by spending at least 7, rather than at least 8 hours of that period in the berth and a minimum off-duty period of at least 2 hours spent inside or outside the berth, provided the two periods total at least 10 hours, and that neither qualify period counts against the 14-hour driving window.

Here is a link to a great presentation and summary about the new changes. This is provided by DOT. https://csa.fmcsa.dot.gov/Documents/Jun9_HOS_Presentation_508.pdf

This DOT link is a presentation done after their Q&A session. It provides more details on the common questions. https://csa.fmcsa.dot.gov/Documents/HOS_QA_Webinar_July2020.pdf

Handouts for the Drivers

Here is a link that has several handouts that you can print. Again, a great job by DOT to help get the word out and to explain how the changes work and affect our operations.
https://csa.fmcsa.dot.gov/Documents/All_HOS_Fact_Sheets_508.pdf

If there are any questions, please contact me. I always enjoy helping people.

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin
09/01/2020

Emerging Issue

The FDA issued a notice about the implementation of “Manufacturing Volume Data Reporting Requirements under CARES Act Section 3112(e)”. The CARES Act enhances FDA’s ability to identify, prevent, and mitigate possible drug shortages. Specifically, section 3112(e) amends the Federal Food, Drug, and Cosmetic Act to require that each registered drug establishment annually report the “amount of each drug . . . that was manufactured, prepared, propagated, compounded, or processed” by the registrant for commercial distribution.

We are working with the FDA to minimize the impact of this on medical gas firms. The FDA has not yet established the reporting portal. As we know more about this emerging issue, we will keep you informed.

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 handing 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.

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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;
  - 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

Medical, Food/Beverage and Specialty Gases Bulletin

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 without a license, you may 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.

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 Webinar – Audit Survival

DOT, OSHA and FDA (Food/Beverage and Medical Gases) – Audit Survival Seminar
October 27 to 29, 2020 - Webinar hosted by Weldcoa
Click here for information or to register

September Medical Gas Roundtable (09/24/2020) – 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 G - Supply-Chain Program (CGA F-3).

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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