



SEPTEMBER 2022

ENCLOSED

Safety Topics

COVID Update

OSHA'S National Emphasis Program on Heat Illness Update

GAWDA Safety Committee & Best Safety Practices 2022

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

Traffic Bulletin

Medical Marijuana and CDL Drivers

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. New Proposed Medical Gas Regulations
2. FAQs – DSCA
3. Recent FDA Observations
4. GAWDA Professional Compliance Training (10/18-20/2022); September Medical Gas Roundtable (9/30/2022) – CGMP - High Pressure Prefill Inspection and Filling High Pressure Cylinders
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 **September 14th** @ 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 _____

September 2022**COVID Update****OSHA'S National Emphasis Program on Heat Illness Update
GAWDA's Safety Committee & Best Safety Practices 2022****COVID Update**

August 11, 2022 OSHA revised their guidance on COVID Exposure and Infection. A [Safety Alert: Coronavirus Response Protocol](#), OSHA basically removed all mention of quarantine; isolation for a minimum of 5 days is the recommended protocol for COVID positive cases, regardless of the presentation of symptoms. A person who is exposed should test 5 days after exposure. Masking is listed for anyone who has been exposed or infected with COVID.

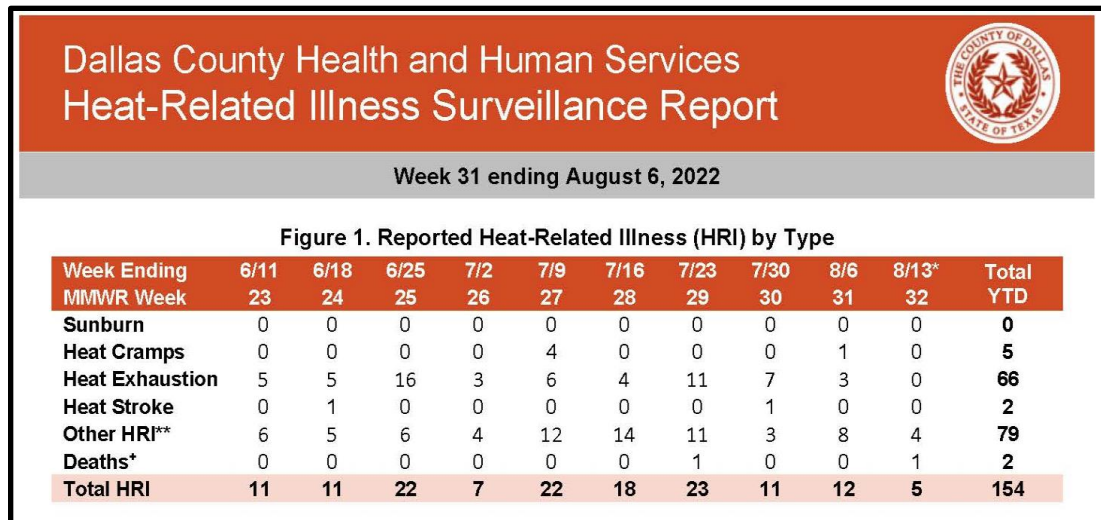
OSHA'S National Emphasis Program on Heat Illness Update

The National Emphasis Program – Outdoor and Indoor Heat-Related Hazards is an expansion of the “enforcement initiative to prevent and protect employees from serious heat-related illnesses and deaths while working in hazardous hot indoor or outdoor environments,” (A. Evans, Asst. Deputy. Secr. OSHA). The agency has specific NAICS codes they are focusing on, including:

3251 Basic Chemical Manufacturing
4246 Chemical and Allied Products Merchant Wholesalers

Recently, I was sent the chart of Heat Related Illnesses from the Dallas County Health and Human Services (see below). The hospitals are required to track the number of patients and type of heat related illnesses; this information is available to OSHA and may be used to narrow the scope of inspections, either by industry or location. If your facility has sent an employee to the hospital for treatment, even if it was for a sunburn, OSHA may have access to that information and may potentially trigger a Heat-related inspection.





GAWDA Safety Committee & Best Safety Practices 2022

If you're not familiar with the Members only page on the GAWDA website, you're missing out on many great resources. One of those resources is Best Safety Practices created by the GAWDA Safety Committee. Jim Herring and Bill Woods chair the committee of 22 members.

The best practices are meant to provide guidance, not requirements, to help you run a safe business. The committee ensures the best practices on the Members Only page are current and accurate. They also create new best practices about issues pertinent to them and other GAWDA members. This year the GAWDA Safety Committee has reviewed and created the following documents to help you in your business.

New Sample Safety Practices

- Insect Bites and Stings Prevention
- Heat Related Illness Prevention

Reviewed, Revised and Reformatted Sample Safety Practices

- Active Shooter Emergency Preparedness
- Backing and Parking
- Bloodborne Pathogen Program
- Canine Bites, Awareness and Mitigation
- Contractor Safety Requirements Agreement
- Customer Safety at Member Sites
- Cylinder Connection at Customer Sites



- Cylinder Loading Dock Safety
- Cylinder Deliveries at Customers with Stairs and Ramps
- Cylinders - Guidelines for Leaking Cylinders at Customer Locations
- Cylinders - Safe Handling of
- Delivery Survey
- Docking Ramps - Selection and Use of
- Driver Distractions Personal Communication Devices
- Dry Ice Sample Safety Practice End User Guide
- Earthquake Emergency Preparedness
- Electronic Submission of Injury and Illness Records to OSHA
- Emergency Preparedness
- Ergonomics in the Workplace
- Facility Securement
- Fall Protection
- Fill Plant PPE
- Fire Emergency Preparedness
- Flood Emergency Preparedness
- Forklift Cylinder Safety
- Load Securement
- LPG - Vendor Audit Checklist
- Mechanical Lifting Devices
- Regulatory Agency Visit Guideline
- Slips, Trips, and Falls Guidelines
- Tornado Emergency Preparedness
- Transport of Pressurized Cryogenic Liquid Containers in an Elevator
- Vehicular Accident/ Incident Considerations
- Walking Working Surfaces

Pick a subject that is pertinent to your location and use it for your monthly safety training.
May I suggest Slips, Trips and Falls.

If you need assistance accessing the documents, please contact Andrea Levy at alevy@gawda.org.
If you have any questions regarding the safety practices please contact me.

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Traffic Bulletin

September 2022

Medical Marijuana and CDL Drivers

Recently some members have asked some questions regarding the DOT's position on the use of medical marijuana by drivers of commercial motor vehicles. The following is DOT's official policy. The basic answer is No, it will not be allowed.

DOT OFFICE OF DRUG AND ALCOHOL POLICY AND COMPLIANCE NOTICE

Recently, the Department of Justice (DOJ) issued guidelines for Federal prosecutors in states that have enacted laws authorizing the use of "medical marijuana."

<http://www.justice.gov/opa/documents/medical-marijuana.pdf>.

We have had several inquiries about whether the DOJ advice to Federal prosecutors regarding pursuing criminal cases will have an impact upon the Department of Transportation's longstanding regulation about the use of marijuana by safety-sensitive transportation employees – pilots, school bus drivers, truck drivers, train engineers, subway operators, aircraft maintenance personnel, transit fire-armed security personnel, ship captains, and pipeline emergency response personnel, among others.

We want to make it perfectly clear that the DOJ guidelines will have no bearing on the Department of Transportation's regulated drug testing program. We will not change our regulated drug testing program based upon these guidelines to Federal prosecutors.

The Department of Transportation's Drug and Alcohol Testing Regulation – 49 CFR Part 40, at 40.151(e) – does not authorize "medical marijuana" under a state law to be a valid medical explanation for a transportation employee's positive drug test result.

That section states:

§ 40.151 What are MROs prohibited from doing as part of the verification process?

As an MRO, you are prohibited from doing the following as part of the verification process:

(e) You must not verify a test negative based on information that a physician recommended that the employee use a drug listed in Schedule I of the Controlled Substances Act. (e.g., under a state law that purports to authorize such recommendations, such as the "medical marijuana" laws that some states have adopted.)

Therefore, Medical Review Officers will not verify a drug test as negative based upon information that a physician recommended that the employee use "medical marijuana." Please note that marijuana remains a drug listed in Schedule I of the Controlled Substances Act.



Traffic Bulletin

It remains unacceptable for any safety sensitive employee subject to drug testing under the Department of Transportation's drug testing regulations to use marijuana.

We want to assure the traveling public that our transportation system is the safest it can possibly be.

Jim L. Swart
Director
Office of the Secretary of Transportation
Office of Drug and Alcohol
Policy and Compliance
Department of Transportation
October 22, 2009

So please remember, there are no exceptions to a CDL driver with a positive test for marijuana. Driver's need to be very careful with the use of any CDB items. They need to use a reputable source but also need to understand if they exceed the THC levels permitted by DOT testing, then it could result in a positive test result. A positive test is a positive test and there is no way around it.

If you have any questions on the above, please contact me at:

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Medical, Food/Beverage and Specialty Gases Bulletin

09/01/2022

New Proposed Medical Gas Regulations

UPDATE – CGA and GAWDA submitted a joint letter to the FDA in response to the proposed new medical gas regulations. We agree with many of the FDA proposals and have pointed out to the agency where additional adjustments need to be made.

For example, one of the proposed regulations calls for a “No Smoking/No Vaping” statement and pictogram to be on medical oxygen cylinders. This could be a revision to labels, or it could be a separate sticker. The pictogram has not been designed, proposed or approved. We will work with the FDA to finalize this issue.

The FDA will review industry comments and...eventually... issue final regulations. We have no idea when the final regulations will be published. However, we will have 18 months to implement the new regulations when they are finalized.

We recommend not changing labels or procedures in response to the proposed regulations. We will have time later to make changes, if needed.

Frequently Asked Questions – DSCA

Q – I hear that the Drug Supply Chain Security Act (DSCSA) must be implemented by November 2023. What do I need to do?

A – Nothing – DSCA does not apply to medical gases. The definitions in DSCA exempt medical gases. Specifically, in Section 581 of the Federal Food Drug and Cosmetic Act the definitions applicable to DSCA exempt medical gases:

- Paragraph (13) defining the term “product”
- Paragraph (24)(B)(xvii) defining the term “transaction”

If you are being asked for interoperable electronic track and trace systems by your customers, explain that medical gases are exempt from the Drug Supply Chain Security Act.

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.



Medical, Food/Beverage and Specialty Gases Bulletin

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.

GAWDA Professional Compliance Training

This year, the Fall Professional Compliance Training will be held via teleconference and in-person (seats are limited)

October 18-20, 2022

[Click here to register or for more information.](#)

September Medical Gas Roundtable (09/30/2022) CGMP - High Pressure Prefill Inspection and Filling High Pressure Cylinders

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In October we will be discussing basic procedures to conduct a prefill inspection and how to fill medical high-pressure cylinders.

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

- **Specialty Gas Operations** - High Pressure Prefill Inspection and Filling High Pressure Cylinders.
- **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.



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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