GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

NOVEMBER 2022

ENCLOSED

Safety Topics

Winter Safety

Safety Data

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

Traffic Bulletin

Placards for Customers

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. **FAQs – FDA Drug Listings**
2. **Recent FDA Observations**
3. **November Medical Gas Roundtable (11/18/2022) – *Instrument Qualification & Analytical Method Validation for Medical Gases***
4. **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 **November 9th** @ 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.

GASES AND WELDING DISTRIBUTORS ASSOCIATION
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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

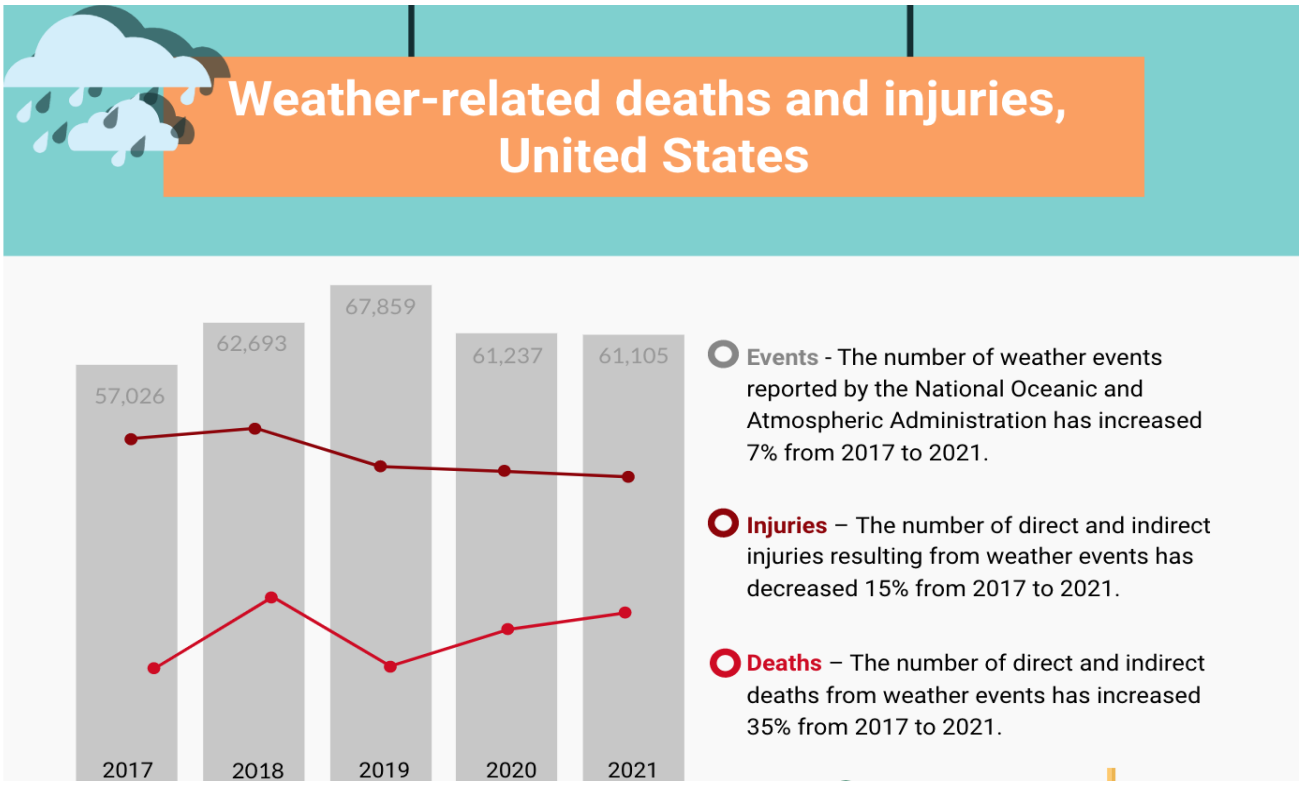
We are happy to provide you with a monthly topic for your agenda.

ROUTE TO:

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

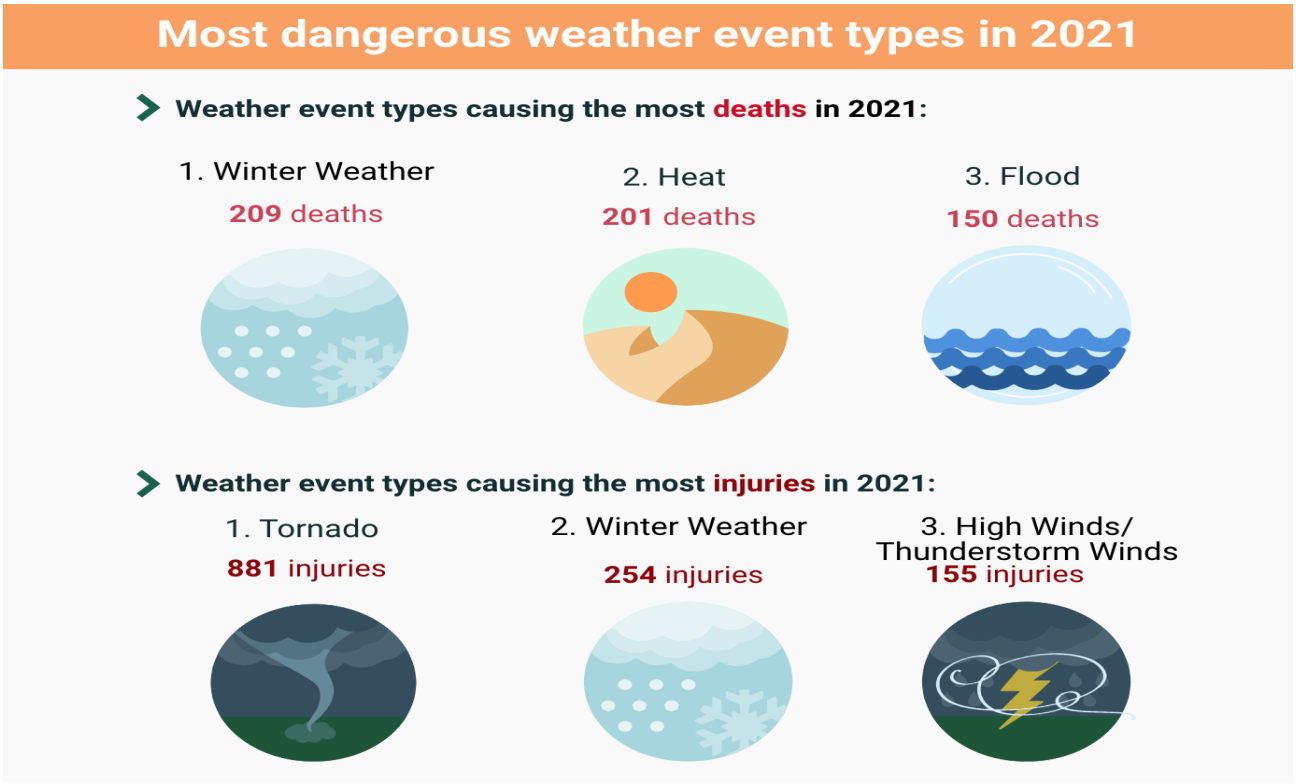
November 2022

Winter Safety



(National Safety Council Injury Facts, 2022)

The National Safety Council reported earlier this year that weather related deaths are up 35% since 2017. Winter weather caused the most deaths in 2021.



(National Safety Council Injury Facts, 2022)

Winter Safety

(NOAA website)

Anyone working in a cold environment may be at risk of cold stress. Some workers may be required to work outdoors in cold environments and for extended periods, for example, loaders and drivers; even fill plants often experience very cold temperatures.

What constitutes extreme cold and its effects can vary across different areas of the country. In regions that are not used to winter weather, near freezing temperatures are considered “extreme cold” in other areas it must be in the single digits before people consider the weather “extreme.” A cold environment forces the body to work harder to maintain its temperature.

Whenever temperatures drop below normal and wind speed increases, heat can leave your body more rapidly. Although OSHA does not have a specific standard that covers working in cold environments, employers have a responsibility to provide workers with employment and a place of employment which are free from recognized hazards, including cold stress (OSHA General Duty Clause)

Source: [Saskatchewan Health Authority]

What to do:

- Train workers on how to prevent and recognize cold stress illnesses/ injuries, how to apply first aid treatment and ways to reduce the risk of cold stress.
- Provide engineering controls. E.g., radiant heaters, work shields to break the wind, heated work environments.
- Use safe work practices:
    - Encourage employees to drink water or warm drinks. It is easy to become dehydrated in cold weather.
    - Schedule heavy work during the warmer part of the day.
    - Assign employees to tasks in pairs (buddy system) when working outdoors, so they can monitor each other for signs of cold stress.
    - Allow employees to interrupt their work, if they are extremely uncomfortable.
    - Give workers frequent breaks in warm areas.
    - Acclimatize new workers and those returning after time away from work, by gradually increasing their workload, and allowing more frequent breaks in warm areas, as they build up a tolerance for working in the cold environment.

Winter working/ walking surfaces

Slip and Fall injuries account for 15% of all work related injuries in the U.S. The risk of slip and fall injuries increase with the accumulation of snow and ice.

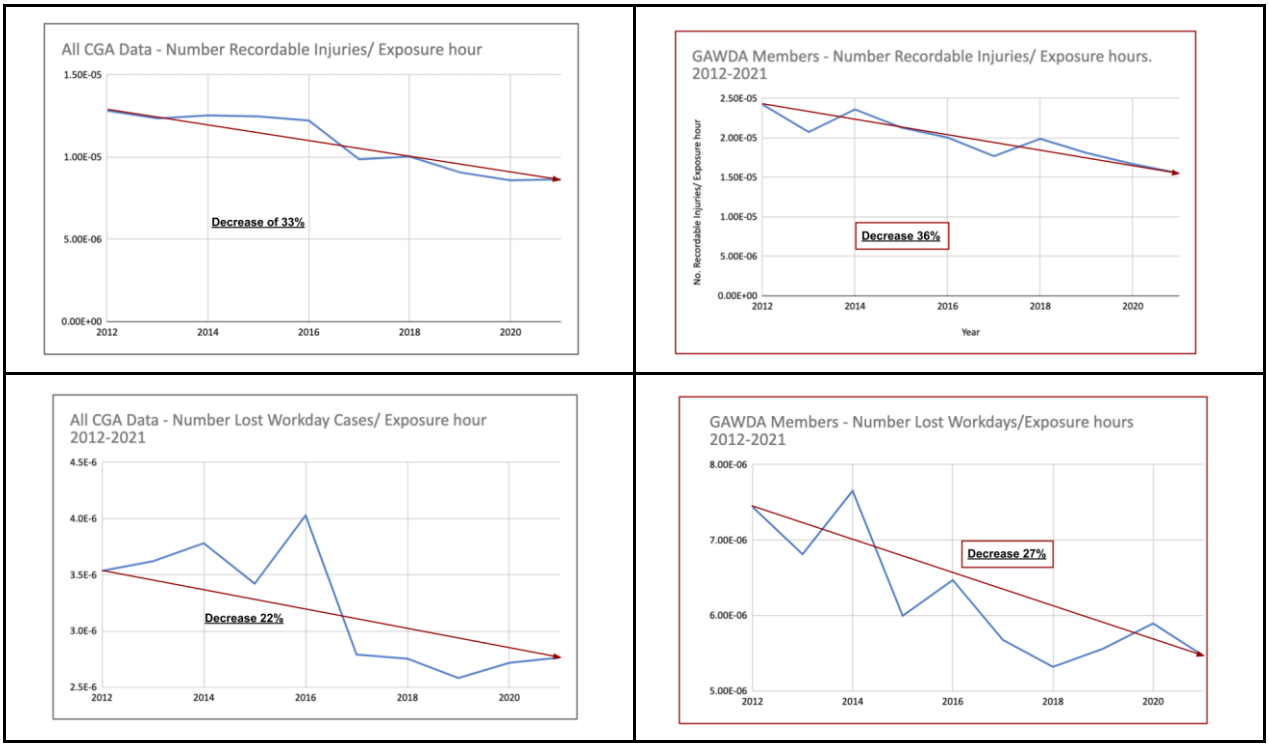
SIMA, the national nonprofit organization representing the snow removal industry, has some tips on safe winter walking.

- **Wear proper footwear.** Proper footwear should place the entire foot on the surface of the ground and have visible treads. Avoid a smooth sole and opt for a heavy threaded shoe with a flat bottom, and use your toes to 'grip'.
- **Accessorize to see and be seen.** Wear sunglasses so that you can see in the reflective light of the snow. Also, wear a bright coat or scarf so that drivers can easily see you.

- **Plan ahead.** While walking on snow or ice on sidewalks or in parking lots, walk consciously. Instead of only looking down, occasionally pause and scan from left to right to ensure you are not in the way of vehicles or other hazards.
- **Don't jump or slide**. Always focus on keeping your feet on the ground as much as possible while walking slowly. Sliding sounds like fun but can result in serious injury.
- **Be careful when you shift your weight.** When stepping off a curb or getting into a car, be careful since shifting your weight may cause an imbalance and result in a fall.

Safety Data from CGA

Since 2012 the Compressed Gas Association (CGA) has requested GAWDA members to share their OSHA 300A data, confidentially, to track trends concerning recordable injuries and illnesses. In return, CGA freely shared their publications in electronic format and the training video library. Recently, Rich Craig shared the cumulative data with me, and I am thrilled to share how well the combined CGA and GAWDA members performed. I am especially excited to share the amazing improvements participating GAWDA members have accomplished.



As you can see, from the larger scale increments for the GAWDA members, there is still quite a bit of room for improvement. However, the slope of the trend line for the GAWDA members is steeper than that of the trend line for All CGA data entries and demonstrates the greater amount of improvement from GAWDA members, particularly in the past few years.

This progress was possible, not because they shared their data, but because management, the C-Suite, demonstrated a commitment to improve the Safety Culture of their businesses.

Without investment from management:

- Physical investment - physically being present at the facility, asking people should safety improvements be made and supporting continuous training.
- Monetary investment - carving out time for employees to learn safe practices.

If you haven't subscribed to the CGA Safety Program, review the data below and find out how to subscribe.

If you have any questions about either of these topics, how to subscribe to the CGA program or any other OSHA, EPA or DHS questions please contact me.

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GAWDA DHS,EPA,OSHA Consultant

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Traffic Bulletin

November 2022

Placards for Customers

Hopefully everyone in our industry realizes that we are required to offer (for free) any placards that our customers (or any other carrier) may need to transport their cylinders or other hazardous materials that we sell or offer to them.

172.506 Providing and affixing placards: Highway

(a) Each person offering a motor carrier a hazardous material for transportation by highway shall provide to the motor carrier the required placards for the material being offered prior to or at the same time the material is offered for transportation, unless the carrier's motor vehicle is already placarded for the material as required by this subpart.

(a)(1) No motor carrier may transport a hazardous material in a motor vehicle unless the placards required for the hazardous material are affixed thereto as required by this subpart.

When do you offer the placards?

You must offer the appropriate placards whenever the total weight of the gases and the cylinders exceed 1000 pounds of the combined hazard classes of **Flammable** and **Non-flammable** gases. (Any cylinder labels colored red, green, or yellow (oxygen))

You must offer placards for any amount of **Inhalation Hazard** (poison gas) and any amount of **Dangerous When Wet** (calcium carbide).

Are there any exceptions to be aware of?

172.504
(f)(3) A NON–FLAMMABLE GAS placard is not required on a transport vehicle which contains non-flammable gas if the transport vehicle also contains flammable gas or oxygen and it is placarded with FLAMMABLE GAS or OXYGEN placards, as required.

(f)(7) For domestic transportation of oxygen, compressed or oxygen, refrigerated liquid, the OXYGEN placard in §172.530 of this subpart may be used in place of a NON–FLAMMABLE GAS placard.

I always recommend using the Non-Flammable gas placard for oxygen because the Oxygen placard is 100% optional, which means one less placard to worry about. You are never required to have the Oxygen placard.

Traffic Bulletin

Documentation of offering the placards.

There are no regulatory requirements to document whether the customer (or carrier) accepts or refuses the placards offered to them. Personally, I have always recommended that we don't document this in an effort to keep things simple. If DOT would ever want to verify that you are do the offering, they would come to your location and ask you the placarding requirements and verify that you have the appropriate placards available to hand out. Not having the placards on hand and doing the offering is worth up to $9000 in possible penalties. I have always suggested that you have the cheap vinyl peel and stick placards kept under the counter and that your counter salespeople are able to explain the placarding rules.

Duty to Inform

Just because the customer refuses to take the offered placard does not mean they are off the hook. The moment they require placards, they fall under all the same regulations that you must follow. I always suggest that you inform the customer of some of the regulations they will fall under once they require placards. For example, CDL with hazmat endorsement, medical cards, hazmat registration, driver qualification files, random drug & alcohol testing, vehicle maintenance programs, and many more.

Again, you must offer the placards, but they probably will not take them. You inform them of some the rules they would fall under and they may decide to ignore them. Not your problem. DOT will say, you inform them, but leave the enforcement to us.

Feel free to contact me on any of these items if you have questions.

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Medical, Food/Beverage and Specialty Gases Bulletin

11/01/2022

Frequently Asked Questions – FDA Drug Listings

Q – What is the difference between "Food Grade" Carbon Dioxide and "Beverage Grade" Carbon Dioxide?

A – First…some background on the use of the term "Beverage" vs "Food Grade".

1. **To the FDA**, "Beverage Grade" simply means "Food Grade". There are not separate beverage specifications in the FDA regulations.
    - The **manufacturing process** is regulated by 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*
    - The **testing specifications** are contained in the Food Chemical Codex (FCC). E.g., the purity is not less than 99.5% and several other impurity specifications
    - The **test plan** is determined by your Hazard Assessment (HARPC) – usually no testing is required for cylinders. Most companies would do some testing on bulk trailers, though it is not required by the FDA (unless your HARPC indicates that testing is needed).
2. To the International Society of Beverage Technologists (**ISBT**), "Beverage Grade" means "ISBT Beverage Grade"
    - **The manufacturing process** is regulated by 21 CFR 117, and supplemented with specific instructions in ISBT's "Bulk Carbon Dioxide Quality & Food Safety Guidelines And Analytical Methods And Techniques Reference" and "Fountain Carbon Dioxide Quality & Food Safety Guideline" (for cylinders).
    - The **testing specifications** are contained in ISBT's "Bulk Carbon Dioxide Quality & Food Safety Guidelines And Analytical Methods And Techniques Reference". E.g., the purity is not less than 99.9% and several other impurity specifications.
    - The **test plan,**
        - For **bulk production** - is determined by ISBT's "Bulk Carbon Dioxide Quality & Food Safety Guidelines And Analytical Methods And Techniques Reference"
        - For filling **trailers** or "mini-bulk transports"- is determined by agreement between the supplier and the customer
        - For filling **cylinders -** is determined by your Hazard Assessment – usually no testing is required for filling cylinders

If you are selling "ISBT Beverage Grade" CO_2, you should follow the FDA regulations and ISBT guidelines (2, above). If you are selling "Food Grade" or "Beverage Grade", you can use the FDA requirements (1, above).

We have sample SOPs, specifications and training available. Please contact tom@asteriskllc.com if you need access to the sample Food/Beverage Gas procedures or training.

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.

Annual Record Review

Form 483 Observation-03-02 - Written procedures are not followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected. Specifically, your firm does not perform an annual product review of each medical gas by reviewing the batch records, complaints, returned products, investigations and or recalls to determine the need for changes in the process or control procedures for the following medical gases: _____

How to prevent this from showing up in your inspection?

Document your Annual Records Review. Contact tom@asteriskllc.com for a sample SOP and Annual Records Review form.

November Medical Gas Roundtable (11/18/2022) – Instrument Qualification & Analytical Method Validation for Medical Gases

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In November we will be discussing Instrument Qualification & Analytical Method Validation for Medical Gases.

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

- **Specialty Gas** - Fuel/Oxidizer Safe Practices (2000 BTU model & CGA P-36)
- **Food Gas Roundtable** – Part 117 Subpart D & E - Modified Requirements and Qualified Facility Exemption

These and other webinars are 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

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. **Servomex Filter -** Verify that you have records that the filter on the Servomex has been inspected according to the frequency in your instrument manual. Keep in mind that Servomex allows a longer inspection period for analyzing clean, dry gases (medical gases). Read the manual or your SOP carefully.

2. **Segregation** – Be sure your full medical gas cylinders are segregated from your industrial gas cylinders.

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