



JUNE 2022

ENCLOSED

Safety Topics

Hurricane and Flood Preparedness

Safe Handling of Cylinders

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

Traffic Bulletin

LPG Filling and Storage

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. FDA Proposes New Medical Gas Regulations
2. FDA Compliance To Do List
3. Nitrous Oxide and Other High Risk Security Chemicals (HRSC)
4. June Medical Gas Roundtable (6/24/2022) – CGMP – Subpart E – Control of Components
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 **June 15th** @ 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

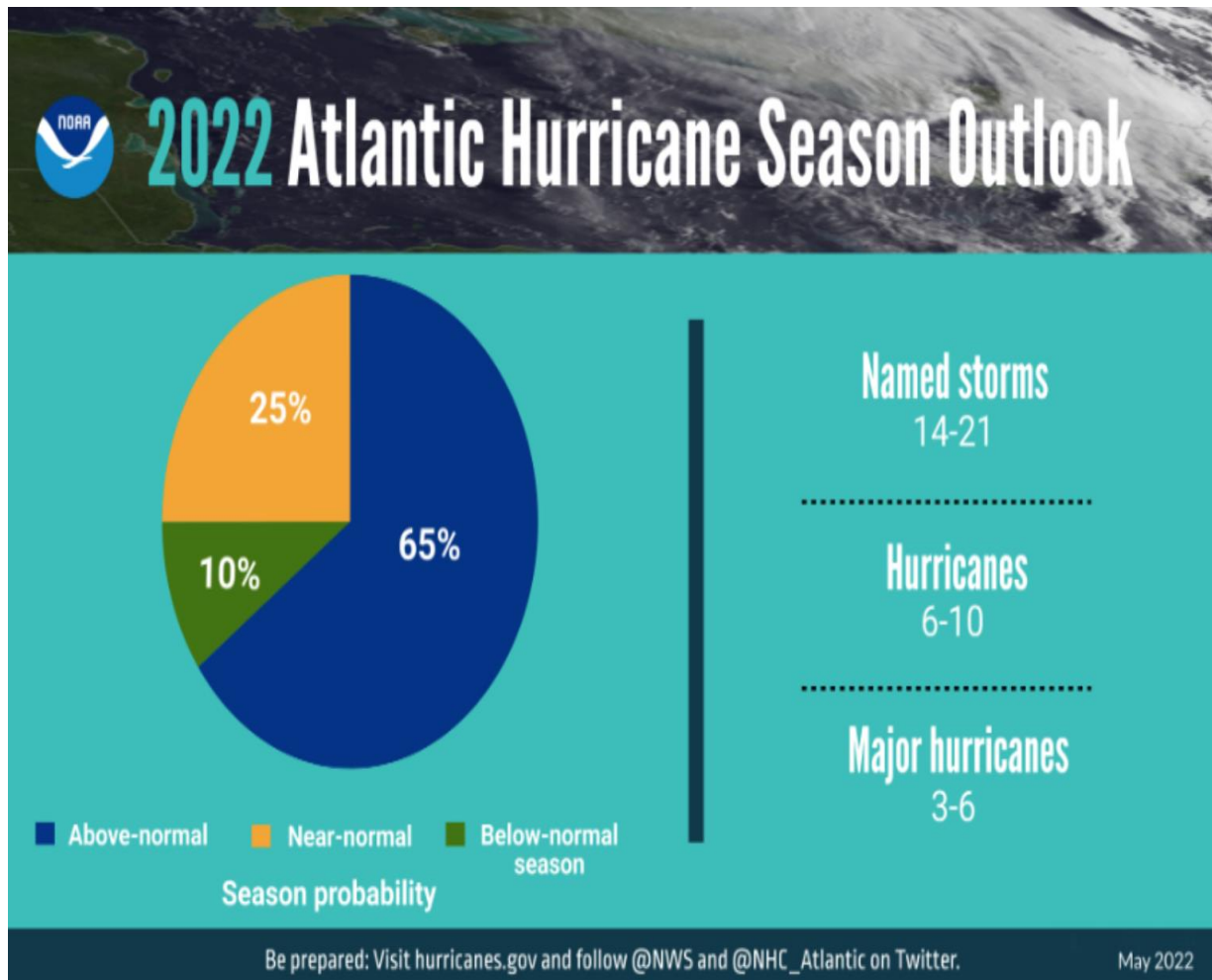
We are happy to provide you with a monthly topic for your agenda.

ROUTE TO:

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

June 2022

Hurricane and Flood Preparedness Safe Handling of Cylinders



The Atlantic hurricane season runs from June 1 to November 30 and again this year the National Oceanic and Atmospheric Administration (NOAA) has predicted that there will be an above-average number of hurricanes, for the seventh year in a row.

The Eastern Pacific season runs from May 15th through November 30th. NOAA's prediction for the Eastern Pacific is much more positive with a 60% chance of a below-normal hurricane season.

NOTE: These predictions are for the number of hurricanes and do NOT predict the number of hurricanes that may make landfall.

PREVENTION IS KEY!

As FEMA Administrator Deanne Criswell said, "Hurricane Ida spanned nine states, demonstrating that anyone can be in the direct path of a hurricane and in danger from the remnants of a storm system. It's important for everyone to understand their risk and take proactive steps to get ready now by visiting [Ready.gov](https://www.ready.gov) and [Listo.gov](https://www.listo.gov) for preparedness tips, and by downloading the FEMA App to make sure you are receiving emergency alerts in real-time." Nadeau.Robert. "Seasonal Outlook: 2022 NOAA Hurricane Season Outlook."



Hurricane Preparedness
Determine Your Risk



-  Storm surge
-  Strong winds
-  Tornadoes
-  Flooding & rainfall
-  Rip currents

weather.gov 

1. Determine your Risk. This includes five hazards that are often associated with hurricanes: storm surge, tornadoes, rip currents, strong winds and inland flooding.
2. Develop an Evacuation Plan. These steps include: determining if the property is in an evacuation zone (and what level zone), have a “go bag” for supplies, follow evacuation orders, plan alternate evacuation routes and plan for pets.
3. Assemble Disaster Supplies such as: food and water, full gas tank, money, medical supplies and prescriptions, radio, batteries and phone chargers.
4. Get an Insurance Checkup before storm season. You should check with your agent and know your policy terms/limitations, keep insurance documents with you and consider flood insurance.
5. Strengthen Your Home/Business including: cover windows, trim trees, secure doors and outdoor items (including cylinders), move vehicles to a safe location and consider lining trucks up next to each other.
6. Help Your Neighbor to prepare, check in after the storm passes and help them evacuate, if necessary.
7. Complete a Written Plan for businesses the Hurricane Preparedness information should be included in the Facility Emergency Action Plan. The plan should include a contact list, what/how to prepare and all personnel (or family members) should be trained on the plan.

Along with Hurricanes comes the risk of flooding; the GAWDA Safety Committee has prepared a Flood Preparedness Best Safety Practice.

This document, found on the following page, outlines ways to keep both your personnel, assets and reminds us of steps to take.



PURPOSE	To provide a set of proposed guidelines for emergency preparedness of welding distributors and fill plants in the event of a flood
RESPONSIBILITY	All facility personnel
AUTHORITY	Facility manager and or fill plant manager

Flood Emergency Preparedness

The safety of employees and customers takes precedence over all tangible items and facilities.

Personnel Safety

- Check with the county planning department and government sites flood maps for risk of flooding in your area
- Check your facility as it correlates to nearby bodies of water
- Establish an evacuation route that uses higher ground to escape
- Establish a meeting place for all personnel
- Establish a contact out of the local area who is not in the immediate area as the person personnel should check in with—this provides one person not in immediate danger to have information for personnel in danger
- If you must stay at your location or are trapped, choose the highest point at your facility with an end game escape route
- Generate local emergency contact data (phone, e-mail, and text) for municipal agencies
- Add information to Facility Emergency Action plan and train personnel on procedures

Protection of Assets

- Ensure all pertinent documents are kept in a high-water location
- Provide off site monitoring of all computers backed up daily
- It is suggested that offsite monitoring of all camera systems with a backup system is in place
- Consider installing a backup generator in a high-water location.
- Consider flood insurance
- Review, at regularly scheduled interval / 60 days prior to renewal, your property, liability, and loss of business insurance coverage
- Store and constantly refresh insurance contact data
- Establish and maintain a backup product supply chain for critical customer deliveries
- Establish after hours contacts for emergency contact
- Consider where to park vehicles and securing tanks or cylinders if expecting a flood situation

After the Flood

- Consider reviewing, and updating as necessary, the recovery plan and communicating it with staff. That way you're ready for cleanup and restarting operations when the flood subsides. CGA SA-30, Safety Alert, HANDLING Cylinders After Natural Disaster Exposure and SA-31, Safety Alert, Receiving Cylinders After Natural Disaster Exposure are good reference documents.



PURPOSE	To provide guidelines for the safe handling and use of cylinders
RESPONSIBILITY	All individuals handling and/or using 6 packs, 12 packs, manifolded, cradled or stand-alone cylinders
AUTHORITY	Plant Manager, Operations Manager, Distribution Manager

Safe Handling of Cylinders

Introduction

Cylinder handling is the greatest source for employee injuries in our industry and we are committed to the health and safety of all employees. The safe handling of cylinder practice decreases the chance of injury or incident.

The safe cylinder handling practice applies to all employees that handle compressed cylinders, portable cylinders banks (aka ,banks, clusters, packs) or liquid dewars. Any employee handling cylinders must be fully trained on Hazard Communication and the Personal Protective Equipment policy. When handling cylinders safety glasses, leather palmed cotton-backed gloves and safety shoes must be worn.

Key Considerations

1. Evaluate the path of movement prior to moving cylinders.
2. Manual rolling and lifting of cylinders is discouraged if other means or available. The use of hand carts, forklifts, pallet systems or similar material-handling devices are strongly encouraged.
3. If a cylinder is falling, DO NOT attempt to catch or stop its fall.
4. Always wear the proper personal protective equipment:
 - Safety Glasses
 - Leather or other suitable gloves
 - Safety Shoes
5. Consideration should be given to the employees' physical condition and ability to perform and handle the task.



Handling of Individual Cylinders

1. Manual rolling of cylinders shall be minimized as much as possible to prevent loss of control and possible injury to employees.
 - An adequate hand cart should be used for moving cylinders distances of greater than 15 feet (4.6 m) for improved efficiency and safety.
 - Hand carts should be easy to maneuver and designed such that the user has clear vision of the path of movement.
2. Only approved cylinder handling equipment shall be used for the movement of cylinders. Approved cylinder handling equipment includes, but is not limited to the following:
 - Cylinder hand trucks of suitable design, size, and strength
 - Portable liquid cylinder hand carts designed specifically for this purpose.
 - Pallet jacks of suitable design and strength
 - Forklifts of suitable capacity for expected loads.
3. Be alert and aware of the conditions in the areas in which cylinders are to be moved:
 - Debris or objects in the path of cylinder movement
 - Water, snow, ice, or other slippery conditions
 - Uneven or irregular surfaces
 - Areas with ascending or descending surfaces
 - Inadequate aisle width (at least 36 inches is recommended)
3. Never move cylinders over power cords.
4. Avoid pinch points when positioning cylinders on handling equipment for movement.
5. Ensure that cylinders equipped with provisions for protective caps, have caps in place and tightened.
6. Avoid dropping cylinders or allowing them to strike violently against each other, however, when moving cylinders, if cylinders start to fall, let them fall.
Attempting to catch a falling cylinder may result in personal injury

Handling Clusters or Portable Banks

1. The movement of clusters or portable cylinder banks requires special considerations because the combined weight of cylinders and framework can be more than 2000 lbs. (909 kg).
2. Whenever possible, use mechanical means, including hoists, forklifts, and cranes to move clusters and portable banks onto vehicles or within facilities.
3. When mechanical means is unavailable or impractical, use two people to move clusters or portable banks.



4. When manually moving a cluster or portable bank use these precautions to avoid getting trapped by a moving cluster:
 - a. Push, NOT pull, and
 - b. Always leave an exit route.
5. Never manually move a cluster with damaged wheels. A cluster must have good maneuverability to ensure safe movement.
6. Avoid rolling clusters or portable banks over dock plates or levelers when possible.

Handling Portable Refrigerated Liquid Cylinders

1. The movement of portable refrigerated liquid cylinders requires special considerations because the weight of a full cylinder can be more than 800 lbs. (364 kg).
 - a. Excessive or rough handling can damage the liquid cylinder.
2. Use only approved and specifically designed hand carts to move portable liquid cylinders.
3. The minor repositioning or movement of short distances of portable refrigerated liquid cylinders is not advised without the use of hand carts, such as the movement onto and off of scale equipment.
4. Liquid cylinders equipped with wheels are especially prone to tipping due to a high center of gravity.
 - a. Whenever possible, get assistance when moving full liquid cylinders equipped with wheels.
 - b. When moving wheeled containers, travel slowly - these containers tend to be top heavy.
 - c. Never attempt to stop or catch a falling container. Quickly move clear of the container, and let it fall.
 - d. It is permissible for one person to move a wheeled container on a flat surface.
 - The upright, latched handle may be used to push the container in front of the operator.
 - Pushing the container in this manner always keeps the container in full view of the operator, lessens back strain from pulling, and encourages employees to move the container slowly and carefully.
 - e. The movement of a wheeled container up or down a slope, over a rough or bumpy surface or ridge may require two people. Whenever feasible, consider using two people (i.e., a co-worker or customer for this task.)
 - As a general rule, the handler should be in an uphill position from the cylinder.
 - Recommendations on handling a wheeled container on a slope:
 - Follow a wheeled container down a slope.
 - Pull a wheeled container up a slope.
 - If the container were to tip, it would then fall away from the operator.



- f. Where there is a great difference in height between the dock and the vehicle bed, a forklift may be used when loading or unloading a wheeled container.
 - o The liquid container must be properly secured with a strap around the container lifting eye and the forklift mast.
 - o Do not use a forklift for general liquid container handling duties around the plant floor, yard, etc. If not properly positioned and secured, the container is subject to damage from the forks.

Lifting Cylinders

1. To prevent injury, GAWDA does not recommend the manual lifting of cylinders. If manual lifting of cylinders is necessary, however, the following lifting techniques may be used to make injury less likely.
 - a. Position the cylinder close to the body and ensure a firm grip.
 - b. Keep feet at approximately shoulder width.
 - c. Keep elbows tucked close to the body.
 - d. Keep back straight and lift using leg strength.
 - e. Whenever possible, ask for assistance.
 - f. With pickup trucks, using the tail gate for leverage and using the dock as leverage.

Pickup trucks

1. When loading or unloading from a pickup to the ground, use the tailgate for leverage.
2. When loading or unloading from a pickup to the dock, use the dock for leverage.

Practices to Avoid When Handling/Moving Cylinders

1. Use of Electric Magnets.
2. Use of Slings (unless you have specified proper slings and SOPs).
3. Use of cylinders as rollers to move other objects (whether full or empty).
4. Lifting a cylinder by the valve protection cap, collar, or other valve protection device.
5. Moving a cylinder that is designed to have valve protection without the protection in place.

If you have any questions on this or any other OSHA, EPA, or DHS issues, please contact me.

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June 2022

LPG Filling and Storage

This month's bulletin is to remind people of the upcoming hot months of summer and the problems of overfilling LPG cylinders. This bulletin is not meant to provide all the details of proper filling and storage of LPG cylinders. See **Filling and Storage** later in this Topic.

Hot Summer Days

The extreme heat of the summer months will cause overfilled cylinders to begin venting product and this venting product can be liquid which expands 270 times the volume when going from a liquid to a gas. Provide an ignition source and you have the equation for big trouble.

Key Mistakes

A very common mistake that I find is an employee putting a cylinder on the scale and then sliding the weight on the beam or adding weight to the electronic scale to add the weight of the product to the weight indicated on the scale. This doesn't take into consideration any residual in the cylinder. If product or any foreign substance is inside the cylinder, the result is an overfilled cylinder.

You should be taking every opportunity to check the weight of the cylinder prior to filling. There are times that residual product will still be in the cylinder, but many times the cylinder is empty, and this lets you check the tare weight.

Another common mistake I find is the employee not taking into consideration the weight of the filling valve and hose assembly. This results in under filling the cylinder. Not a safety issue but certainly a weights and measures issue and a customer satisfaction issue.

Filling and Storage

There are many sources of information available on the proper procedures for filling and storage of LPG cylinders. Some of these sources are:

- NFPA 58, Liquefied Petroleum Gas Code; www.nfpa.org
- National Propane Gas Association; www.npga.org
- Your supplier

Some other storage issues to consider are:

Empties upside down on trucks and docks: The regulations require that the safety relief valve must be in contact with the gas vapor and not the liquid. Placing forklift style cylinders upside down on the truck or dock to denote they are "empties" is violating the regulations. If the safety would start to vent, you could be releasing liquid which expands about 270 times from liquid to gas.



Traffic Bulletin

Cylinders in racks at customers (not pin indexed): You should consider training your drivers and customers to place full or “empty” forklift cylinders into a storage rack with the safety relief valve pointed up. The index pins take care of this orientation while on the forklift, but many storage racks do not have the pins.

Too many together in one place: You should consider not storing too many flammable gas cylinders in one place or large groups. If you would ever have a problem, you will have a very big problem fast. Smaller groups and spread out between the groups will let you deal with smaller problems should you ever have a leaking / venting cylinders or a fire.

Training

OSHA requires employees to be trained in the jobs they perform.

DOT requires employees filling cylinders to be trained, tested and certified every 3 years. This falls under the “Function Specific” training requirements in 172.704.

There is an excellent LPG filling training program, “Dispensing Propane Safely”, available from the Propane Education & Research Council, that includes a test that along with an employer certification will satisfy the DOT requirements. It is available as a free download. <https://propane.com/resource-catalog/resources/new-dispensing-propane-safely-usb/>

Final Thoughts

One of the most important items is the correct filling limit.

Tare Weight + Product Weight + Filling Assembly = Full Cylinder Scale Weight. Check the full cylinder weight prior to removing the filled cylinder from the scale.

Another important item is proper storage. Keep the required distances in mind and think about your cylinder storage. Think about the worst scenario and ask yourself if the way you are storing your cylinders would be a problem if you had a fire situation.

Finally, are your employees properly trained on cylinder inspection, cylinder selection, filling procedures, proper marking and labeling, handling and storage, and what they should do in emergency situations?

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

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Medical, Food/Beverage and Specialty Gases Bulletin

06/01/2022

FDA Proposes New Medical Gas Regulations

The FDA announced on 5/23/22 that they will be proposing new medical gas regulations. You can download a copy of the notice at: <https://www.federalregister.gov/public-inspection/2022-10458/current-good-manufacturing-practice-certification-postmarketing-safety-reporting-and-labeling>

Executive Summary

- **Comment Period** - The proposed new regulations will have a comment period until August 21, 2022. This will give us time to respond to specific items of concern.
- **Likely effective in 2024** - The agency intends the final rule to become effective 18 months after it is published in the Federal Register. We should have ample time to understand and implement the final rule.
- **Labeling** – Most of the existing industry practice will not change. However, the FDA is proposing an additional warning and graphic to avoid smoking or vaping around oxygen.
- **CGMP** – The agency is proposing many of the safety and process suggestions which were requested by industry. There are a few exceptions we need to clarify.
- **NDA/NADA Requests** - The “certification” regulations for original manufacturers to receive New Drug Applications is being proposed. This is similar to the existing guidance.
- **Adverse Events** - The FDA is proposing clarifications and new regulations about reporting adverse events with medical gases. Most of the responsibilities fall on the original manufacturer. However, cylinder fill plants will also report if they become aware of an adverse event.
- **No Immediate Change** – This is an important step forward. We appreciate the long-term, consistent leadership from CGA and GAWDA to encourage the FDA to propose these new regulations. However, these are **NOT** final regulations. No change in operations, labels, procedures, or forms should be required until the shape of the final regulations becomes clear. We will keep you informed.



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FDA Compliance ToDo List

FDA Drug Listing Review – 21 CFR 207.30(a) specifies that drug manufacturers review their Drug Listings in June and December and make revisions, if needed. For example, verify that:

- The purity and cylinder sizes are correct
- The label is up-to-date. Be sure your GHS compliant label is posted to the FDA website.
- The locations distributing the drug are correctly identified.
- The “unapproved medical gas” marketing category has been removed and replaced with “New Drug Application”.

See item 2, below, under the “Micro-Audit” for website information. Contact jodie@asteriskllc.com if you need any assistance with this.

Nitrous Oxide and Other High Risk Security Chemicals (HRSC)

Handling and selling nitrous oxide presents some special challenges, over and above typical medical or specialty gases. Since it is a potential drug of abuse, we need to take precautions to assure the gas is used properly. There are some FDA requirements, CGA standards and good common-sense practices we should consider when establishing our own nitrous oxide handling procedures.

Regulations

The FDA regulations and guidance have requirements which impact nitrous oxide:

- 21 CFR 205.50(b)(1)(iii) – “Entry into areas where medical gases are held must be limited to authorized personnel.”
- 2003 Draft Guidance – “We recommend areas where nitrous oxide is held be especially secure.” Also, medical gases (including nitrous oxide) shall be segregated from industrial gases. Full and empty medical gases shall be segregated from each other.

In addition, several states have enacted specific nitrous oxide regulations. These regulations are often modeled after the National Association of Boards of Pharmacy, Model Act.

- Section 4(a) - All facilities at which Medical Gases and/or related device equipment is received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall... provide and maintain appropriate inventory controls in order to detect and document any theft of nitrous oxide.



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- Section 5(c) - All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft of nitrous oxide.
- Section 11(g) - Medical Gas and Medical Gas Related Equipment Wholesale Distributors shall establish, maintain, and adhere to written policies and procedures... for reporting criminal or suspected criminal activities involving the inventory of nitrous oxide to the Board, and applicable law enforcement agencies, within three (3) business days of becoming aware of the criminal or suspect criminal activity.

The key issues are establishing security, inventory systems and theft reporting procedures for nitrous oxide. These requirements are much different than for other gases we handle. The Compressed Gas Association has published several outstanding resources for us to define what are appropriate nitrous oxide security measures:

- CGA P-50-2021, *Site Security Standard*
- CGA P-51-2021, *Transportation Security Standard for the Compressed Gas Industry*
- CGA P-52-2021, *Security Standard For Qualifying Customers Purchasing Compressed Gases*
- CGA G-8.3-2019, *Safe Practices for Storage and Handling of Nitrous Oxide*

We highly encourage you to download these publications for free by joining the CGA/GAWDA Safety Program (<https://www.gawda.org/resources/cga-subscription-program/>). Here are some highlights of recommended nitrous oxide provisions:

- **Inventory control systems to detect theft or loss** – A computerized inventory management system that can show the number of full and empty nitrous oxide cylinders in stock may be appropriate for some state regulations. However, more rigorous requirements are in place in many states. These are very low-tech and simple to implement. Consider placing a running inventory sheet on a clipboard at the nitrous oxide storage area. This inventory sheet would show the incoming cylinders, the shipments and the balance. The balance should match the number of cylinders in storage and can easily be verified by counting. Be sure to include the signature or initials of the person adding or subtracting from the inventory. Also, periodically, do a physical count and document the reconciliation on the inventory record.
- **Theft reporting** – If you detect a cylinder shortage, report the possible loss to your local police and to your state board of pharmacy.
- **Access controls** – Assure that access is limited to the location where you store your nitrous oxide. This can be accomplished with a lock and controlled issuance of keys.
- **Property fencing** – This can be your first level of security for all medical gases.



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- **Secondary fencing for full and empty nitrous cylinders and bulk storage –** The FDA's "especially secure" requirement as well as the CGA specification can be accomplished by a fenced, gated and locked storage area for nitrous oxide. Nitrous oxide could also be stored in a separate, locked room. If you use a separate room for secondary security, assure the room is properly rated and ventilated for nitrous oxide storage and not accessible by the public. If you have a bulk nitrous oxide tank, assure you have secondary fencing, or equivalent, around the tank.
- **Lockout devices to secure valves on bulk storage –** Assure you are using locking devices to secure the valves on the bulk tank.
- **Security systems, alarms, etc. –** See CGA P-50, Table 2 for specific security systems. This would include "No Trespassing" signage, posted security advisories, perimeter lighting including the bulk tanks, Other optional security systems would include CCTV, sensors, alarms, etc.
- **Procedure to determine if a customer is legitimate –** We occasionally hear stories of new walk-in customers wanting to buy nitrous oxide with cash. This type of transaction may be appropriate for some welding supplies, but it is clearly inappropriate for a potential drug of abuse. Even if the customer is asking for food grade or industrial grade nitrous oxide, you should have a formal qualification program in place before approving sales of nitrous oxide to new or existing customers. Consistent with the standards and guidance from the CGA publications, we have developed a one-page survey you can use to qualify your nitrous oxide customers. The survey asks the type of questions that can help identify legitimate customers. Contact tom@asteriskllc.com for a Word version of the Nitrous Oxide and Other Chemicals of Concern - Customer Survey. (See the end of this document.)

June Medical Gas Roundtable – CGMP – Subpart E – Control of Components

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On June 24, 2022, we will cover **Subpart E – Control of Components Training**. This training covers the qualification of your raw materials (including bulk products) used in making medical gases.

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

- **Specialty Gas** - Robust and Efficient Gas Sampling Techniques
- **Food Gas Roundtable** – Part 117 Subpart C - Recall Plan & Preventive control management components and Monitoring – 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 Records Review** – Verify that you have looked at your records to determine if changes are needed in your medical gas program. This review can be easily completed and documented. Contact Tom if you need a form to document your annual records review.
2. **Electronic Registration and Listing** – Be sure your electronic registration and listing is correct. Print out the web pages with your information below to document your compliance:
Facility Registration - <http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>
Drug Listing - <http://dailymed.nlm.nih.gov/dailymed/search.cfm>

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