



**JULY 2019**

## **ENCLOSED**

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**Safety Topic: GAWDA Sample Safety Policy: Safe Handling of Cylinders**

*Please contact Mike Dodd, GAWDA DOT, Security, OSHA & EPA Consultant for more information.*

**Traffic Bulletin: Safety Management System**

*Please contact Mike Dodd for more information.*

### **Medical, Food/Beverage and Specialty Gases Bulletin**

1. Recent FDA Observations: QCU and Fill Log Errors
2. FAQ's: Can I use an alternative to the traditional lot numbering systems?
3. GAWDA Professional Compliance Seminar – October 29 to 31, 2019 at Weldcoa in Aurora, IL; July Medical Gas Roundtable (07/26/2019) – CGMP - Subpart F – Production and Process Controls; Specialty Gas – Making Highly Reliable Gravimetric Mixtures; Food Gas Roundtable- – CGMP Training – Part 117 Subpart C - Recall Plan & Preventive Control Management Components and Monitoring.
4. Micro Audit Suggestions

*Please contact Tom Badstubner, GAWDA FDA Food, Medical & Specialty Gases Consultant, for more information.*

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*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 \_\_\_\_\_

The GAWDA Safety Committee has put together sample safety policies. Here is an example of one of the many available off the member resources portion of the GAWDA website.

<b>Purpose</b>	To provide guidelines for the safe handling and use of cylinders
<b>Responsibility</b>	All individuals handling and/or using 6 packs, 12 packs, manifolded, cradled or stand-alone cylinders
<b>Authority</b>	Plant Manager

### **Safe Handling of Cylinders (Insert Company Name Here)**

#### **Key Considerations**

1. 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.
2. If a cylinder is falling, DO NOT attempt to catch or stop its fall.
3. Always wear the proper personal protective equipment:
  - Safety Glasses
  - Leather or other suitable gloves
  - Safety Shoes

#### **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.
  - a. An adequate hand cart should be used for moving cylinders distances of greater than 15 feet (4.6 m) for improved efficiency and safety.
  - b. 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
  - a. 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:
  - a. Debris or objects in the path of cylinder movement.
  - b. Water, snow, ice or other slippery conditions.
  - c. Uneven or irregular surfaces.
  - d. Areas with ascending or descending surfaces.
  - e. Inadequate aisle width (at least 36 inches is recommended) .
4. Never move cylinders over power cords.
5. Avoid pinch points when positioning cylinders on handling equipment for movement.
6. Ensure that cylinders equipped with provisions for protective caps, have caps in place and tightened.
7. 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 in excess of 2000 lb (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.



- a. When manually moving a cluster or portable bank use these precautions to avoid getting trapped by a moving cluster
    - Push, NOT pull
    - Always leave an exit route
4. Never manually move a cluster with damaged wheels. A cluster must have good maneuverability to ensure safe movement.
5. 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 in excess of 800 lb (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 approved 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 keeps the container in full view of the operator at all times, 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.
  - The liquid container must be properly secured with a strap around the container lifting eye and the forklift mast.
  - 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. The manual lifting of cylinders shall be avoided whenever possible, however when necessary, specific lifting techniques are to be used to prevent injury to employees.
2. Position the cylinder close to the body and ensure a firm grip.
3. Keep feet at approximately shoulder width.
4. Keep elbows tucked close to the body.
5. Keep back straight and lift using leg strength.
6. Whenever possible, ask for assistance.
7. 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.

Again, the purpose of this sample policy is to reduce accidents in the workplace and to provide our members with a template that they can use to write their own safety policy.

Feel free to contact me if you have any questions.

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# Traffic Bulletin

## Traffic Bulletin

**July 2019**

### **Safety Management System**

This is another installment of how to check your company record for accidents and inspections. This is another way for you to look up your record and then to look into the details of items such as your roadside inspections.

Have you received a warning letter from DOT asking you to review your record and improve your overall score? Several of our members have received their letters. This is not a letter that you want to get. It is a warning letter that in so many words mean that if you do not improve your score, then you may be visited, another way of saying that you may get an audit.

You may look at your overall record by going to the Safety Management System (SMS) website at this address: <https://ai.fmcsa.dot.gov/SMS/>

Type in your USDOT number or your company name and your profile will come up after selecting your company.

From your carrier information page, you can get more detail by either clicking on the "See Your Data" tab on the left or by clicking on any of the "BASIC" items (blue rectangles) shown across the page. You will only see information if they have entered something into one of the BASIC items. This is one of those "no news is good news" things. If there is no information under an item, that is great. You have not been written up in that area.

If there is information in one of the BASIC items, then you can investigate even more detail by clicking on "+ Inspection History" link found on the left under that graph. This will let you see the actual items that were written up on the inspection and the points assigned to the violation item.

#### **Why should a motor carrier log in to the SMS?**

Logging into the SMS provides additional functionality. Motor carriers that log in can view areas and information not available to the public. You will also get to see the driver name for each item written up.

If you need a PIN, please obtain one by following the links on the SMS websites or if you cannot locate your PIN or were never assigned one, please go to the link below and then follow the instructions to request a new one: [https://li-public.fmcsa.dot.gov/LIVIEW/PKG\\_PIN\\_START.PRC\\_INTRO](https://li-public.fmcsa.dot.gov/LIVIEW/PKG_PIN_START.PRC_INTRO) .





# Traffic Bulletin

Once you complete the PIN registration process, a notification letter with your PIN will be generated and mailed to the address that was submitted on your most recent Form MCS-150. You should receive this letter within two weeks. Assistance with PIN issues can be obtained by calling FMCSA technical support at 1-800-832-5660 during normal business hours. **Please note that you need a USDOT Number PIN, not the Docket Number PIN.**

If you receive a warning letter from DOT and would like me to help you review the data, then please send me an email or give me a call. I would be happy to help you through the websites and the data.

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

**Medical Gas Bulletin**  
**07/01/2019**

## **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](mailto: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.

### **QCU and Fill Log Errors**

**Form 483 Observation-02-02** - The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, the requirements of the SOP \_\_\_\_, titled "Quality Control Unit" have not being followed by QCU personnel as follows: I observed multiple deficiencies in the completion of Fill Log records for medical gas lots manufactured and repacked in \_\_\_\_, which were reviewed and approved by QCU personnel, including the following: The Fill Log record \_\_\_\_ for medical compressed Nitrogen, which was used to document the filling of lots \_\_\_\_ and \_\_\_\_ on \_\_\_\_, does not indicate that the Vacuum Gauge Operation Check-Zero was performed prior to performing the filling operations, as required by Fill Log \_\_\_\_.

#### ***How to prevent this from showing up in your inspection?***

Assure QCU knows the importance of correcting ALL errors and omissions on fill logs before signing the record and releasing the lot.

## **Frequently Asked Questions**

**Q** – Can I use an alternative to the traditional lot numbering systems?

**A** – Yes. You can devise a lot numbering system that works best for **YOUR** company. It simply needs to be unique (so you can recall a batch of your product). You should also be sure your lot numbering procedure is documented in your SOPs and that you strictly follow the procedure.

If you are using the industry standard, GAWDA Medical Gas SOP Program and want to use an alternative lot numbering system, just submit your preferred lot numbering procedure using the "Index 160 a1" form.

Some companies simply use a sequential lot number (00001, 00002, ...) Other companies use a combination of the date, time, vehicle numbers, etc.

There is a separate regulation that requires that the major equipment used to make a drug is identified on the Packaging Control Record (fill log). This is easily accomplished by embedding the Manifold Identifier ("A", "B", ...) in the lot number. However, if you choose to not identify the fill manifold in your lot number, you can have an entry for the manifold directly on the Packaging Control Record.



# Medical, Food/Beverage and Specialty Gases Bulletin

## Upcoming Training

- GAWDA Professional Compliance Seminar – October 29 to 31, 2019 at Weldcoa in Aurora, IL
  - DOT and FDA (Food/Beverage and Medical Gases) – Train the Trainer Training

## July Medical Gas Roundtable (07/26/2019) – CGMP - Subpart F – Production and Process Controls

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In June we covered how to survive an FDA audit.

In July, we will cover **Subpart F – Production and Process Controls** --- SOPs, filling cylinders, equipment identification, reprocessing, etc.

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

- **Specialty Gas** - Making Highly Reliable Gravimetric Mixtures
- **Food Gas Roundtable** – CGMP Training – Part 117 Subpart C - Recall Plan & Preventive Control Management Components and Monitoring
  - The latest information about food gas regulations is reviewed –
  - The sample Food Gas SOPs are available for downloading during the seminar.

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](mailto:jodie@asteriskllc.com).

## 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. **Authorized Procedures** – Verify that your Quality Control Unit has authorized your SOPs in writing.
2. **Following SOPs** – Be sure that your cylinder filling personnel are strictly following the authorized procedures. This is easily accomplished by taking a copy of the cylinder fill procedure to the manifold and watching the operator fill the cylinders.

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