

## ***SAFETY & TECHNOLOGY ORGANIZER***

**JULY 2018**

### ***ENCLOSED***

#### **Safety Topic: Leaking Cylinders**

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

#### **Traffic Bulletin: Tire and Load Checks**

*Please contact Mike Dodd for more information.*

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

- 1. Recent Recent FDA Observations (excerpts from actual FDA inspections at medical gas companies): QCU and Fill Log Errors**
- 2. Frequently Asked Questions: Q – What does PCQI mean for Food/Bev Gases?**
- 3. Upcoming Training & Dates: Webinars: PCQI Training; Internal Auditor Training. GAWDA Professional Compliance Seminar (DOT Audit Survival); FDA PCQI and Drug CGMP Training. July Medical Gas Roundtable (07/27/2018) – 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 and Specialty Gases Consultant, for*

*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 \_\_\_\_\_

## Leaking Cylinders

One of the sample safety practices that the GAWDA Safety Committee put together was how to handle leaking cylinders. Here is the sample practice.

If there are any questions regarding this Safety Topic, please contact:

Michael Dodd

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### Leaking Cylinders at Customer Locations

#### GAWDA Safety Committee

<b>Purpose</b>	Guidelines for handling leaking cylinders at customer locations
<b>Responsibility</b>	Operations and or Production Manager
<b>Authority</b>	Operations Manager

The purpose is to give safety guidelines with check list and flowcharts in the event a leak is detected on cylinders reported at customer locations.

- **Minor Leaks**

- Cylinders with minor leaks (non-major release of gas), that contain an inert gas, or non-flammable gas, may be contained by tightly closing the valve. Flammable, toxic, oxidizer, or corrosive minor gas leaks must be secured in a well-ventilated area or placed outside, and the valve tightly closed (if the cylinder cannot be moved, secure the area and remove all personnel).
- Leaking cylinders received from a supplier during a delivery should be brought to the attention of the driver or supplier immediately.



- The gas supplier should be notified of any cylinder leak, or concern, as soon as possible.
  - Cylinders with minor leaks (non-major leaks), containing an inert gas, or non-flammable gas, should be left outside where the gas will return to the atmosphere without harm. The cylinder should be secured from falling or being hit by an object or vehicle. Smoking should not be allowed anywhere near the cylinder.
  - Personnel should be kept away from cylinders with minor leaks (non-major leaks) containing flammable, toxic, oxidizer, or corrosive materials.
  - In the instance of a fire, remove all personnel and dial 911.
- **Major Leaks**
    - Cylinders with major leaks (considerable release of gas), that contain an inert gas, or non-flammable gas, should have the valve tightly closed and the cylinder secured from falling.
    - The customer should contact their supplier for assistance.
    - Cylinders with major leaks of a flammable, toxic, oxidizer, or corrosive gas should immediately secure the area, placing the cylinder (if it can be moved) in a well-ventilated area and removing all personnel from exposure. Additionally, 911 should be notified immediately for assistance on site; and then contact the gas supplier for information on the product and further assistance.
    - In the instance of a fire, remove all personnel and dial 911.
- **Gas Suppliers**
    - Distributors are able to assist with non-flammable gases through information on the Safety Data Sheets. They are also able to contact their gas supplier for additional assistance and information.
    - If the leak involves a flammable, toxic, oxidizer, or corrosive gas, the major gas supplier should be contacted right away as they have emergency teams and assistance around the country that might help the local fire department contain the leaking cylinder.

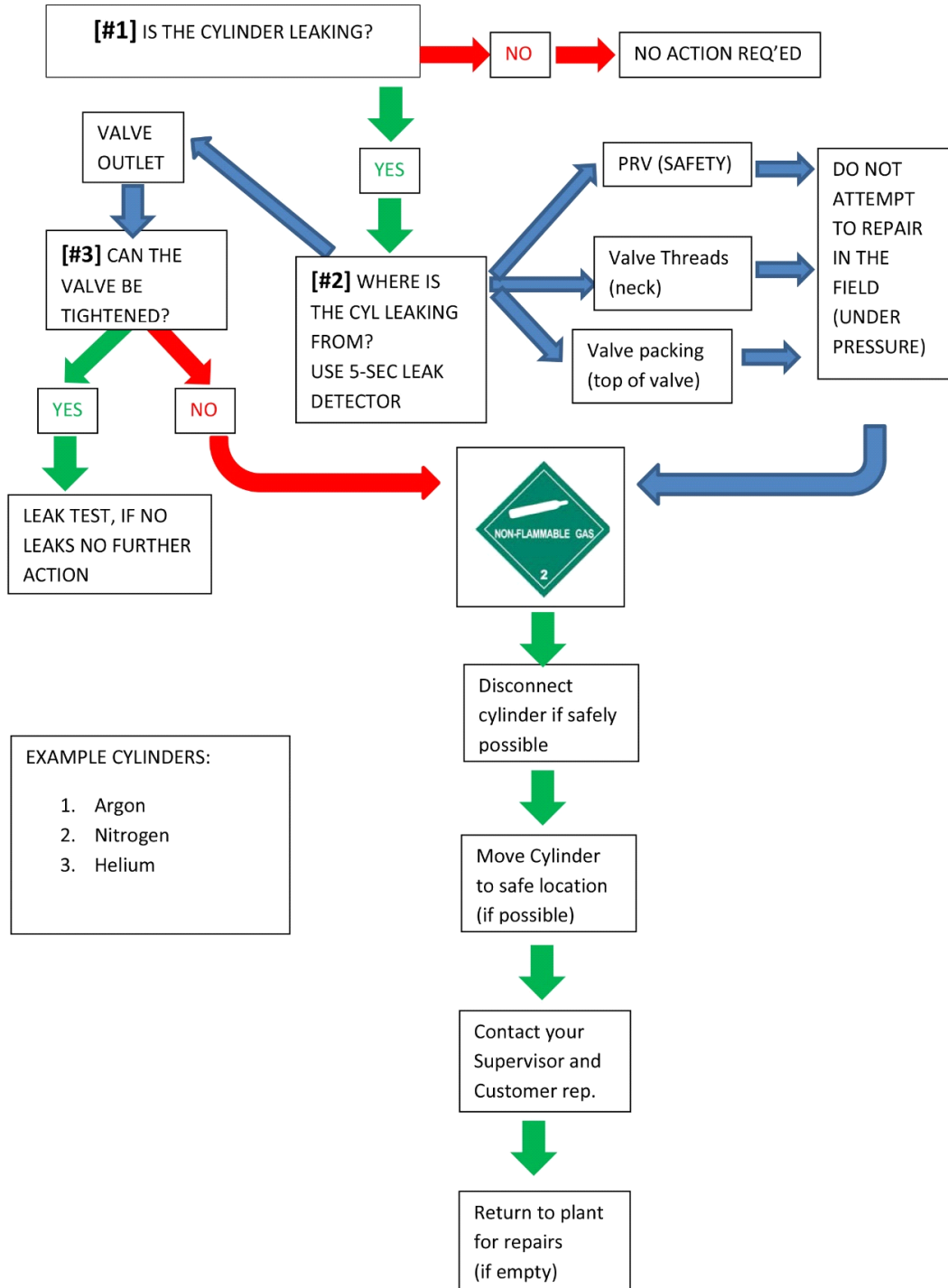


If a customer calls reporting that a cylinder is leaking, or they have a concern with a cylinder, the following information should be obtained:

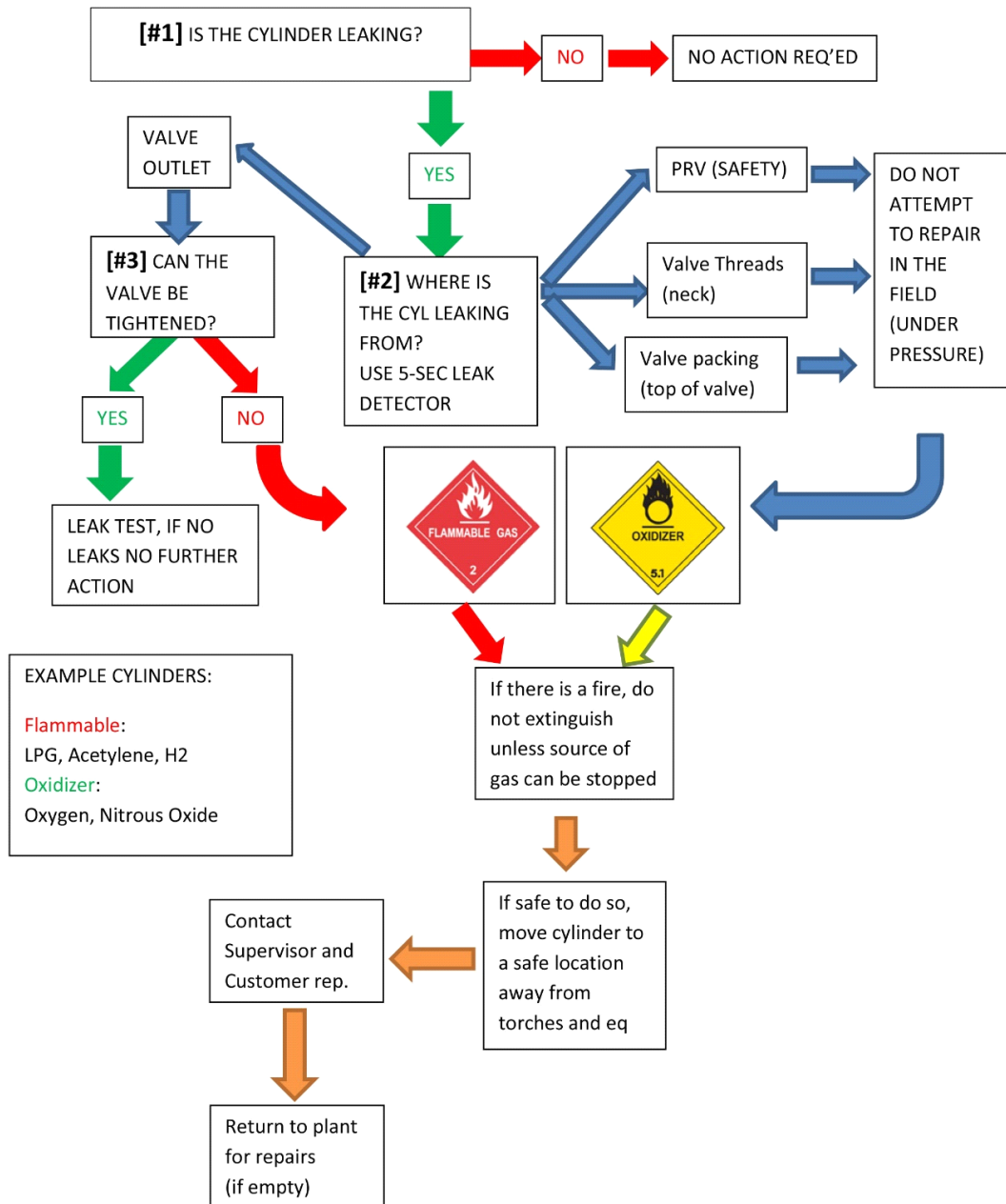
Date:	Time:
Customer Contact Name:	
Phone # (include cell phone and after hours contact info):	
Company Name:	
Company Location (full address):	
Product Name/Gas Name (have them spell the name):	
What color is the diamond? red ___ yellow ___ white ___ green ___ blue ___	
Is anyone injured? Yes No	
Where is the cylinder located (inside a building, in a yard, on a vehicle)?	
Was the Fire Department contacted? Yes No	
Who did the customer purchase the gas from (branch store)?	
When did the customer receive the gas?	
<b>Action to be taken:</b>	
<b>Alert</b> your immediate supervisor.	
Action taken to assist the customer (provided details):	
Investigation: Why did cylinder leak?	



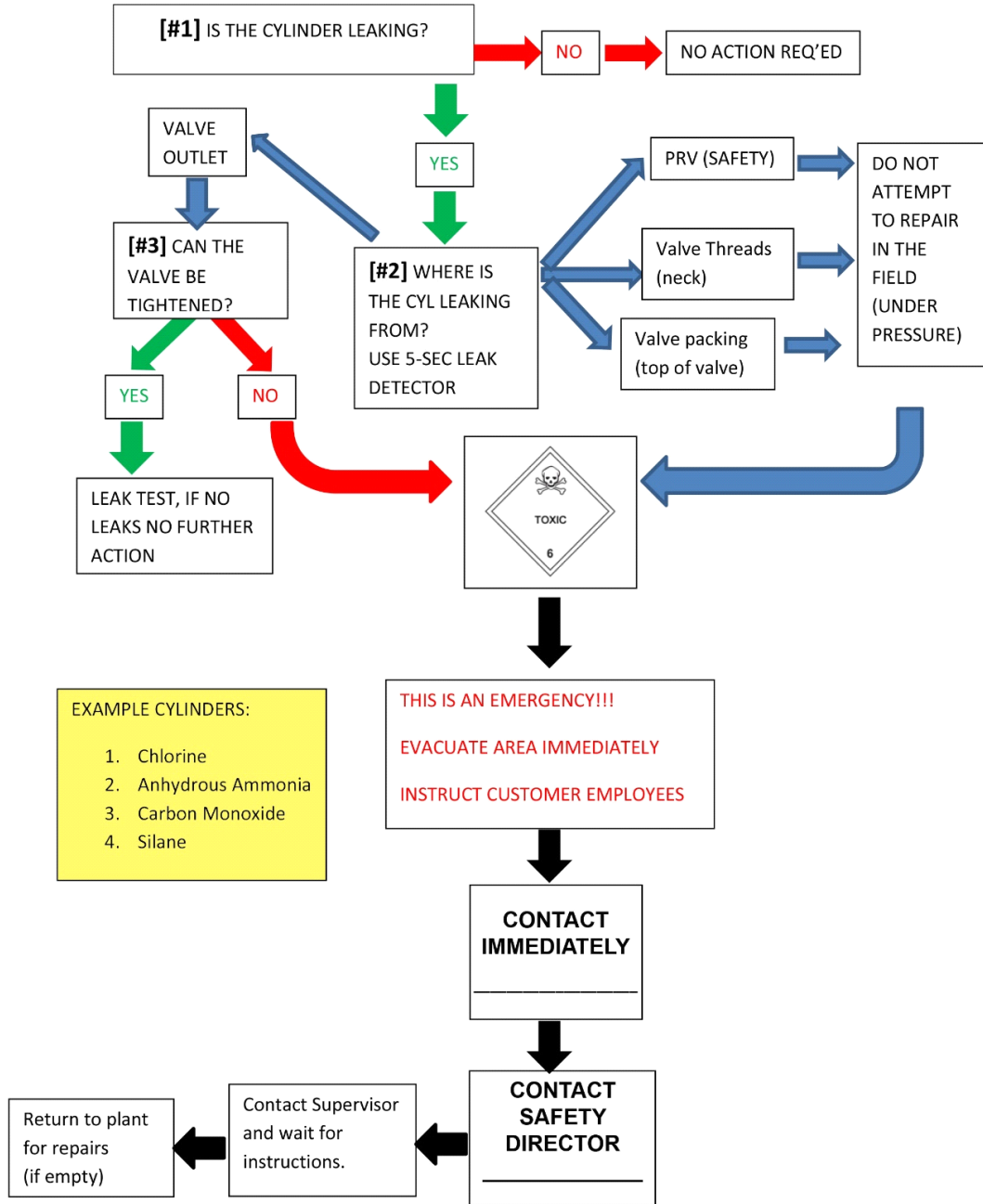
## NON-FLAMMABLE LEAKING CYLINDER FLOWCHART



## FLAMMABLE AND OXIDIZER LEAKING CYLINDER FLOWCHART



## TOXIC /CORROSIVE LEAKING CYLINDER FLOWCHART



# Traffic Bulletin

## Traffic Bulletin

July 2018

### Tire and Load Checks

The regulations can be confusing because they talk about tire checks in one part of the regulations and load securement checks in another part of the regulations and the time and miles for each don't always match up.

#### Tire Checks

Tire checks are only required at the beginning of each trip and **each time the vehicle is parked**. Here are the words from the regulations:

##### 397.17 Tires

(a) A driver must examine each tire on a motor vehicle at the beginning of each trip and each time the vehicle is parked.

(b) If, as the result of an examination pursuant to paragraph (a) of this section, or otherwise, a tire is found to be flat, leaking, or improperly inflated, the driver must cause the tire to be repaired, replaced, or properly inflated before the vehicle is driven. However, the vehicle may be driven to the nearest safe place to perform the required repair, replacement, or inflation.

(c) If, as the result of an examination pursuant to paragraph (a) of this section, or otherwise, a tire is found to be overheated, the driver shall immediately cause the overheated tire to be removed and placed at a safe distance from the vehicle. The driver shall not operate the vehicle until the cause of the overheating is corrected.

(d) Compliance with the rules in this section does not relieve a driver from the duty to comply with the rules in 397.5 (attendance and surveillance of motor vehicles) and 397.7 (parking).

When originally enacted, this rule was intended to prevent possible fires caused by overheated tube-type tires. Thus, hazardous material drivers with dual tires were required to stop every two hours or 100 miles to inspect their tires.

With advancements in tire technology, fires caused by overheating are much less common today. In addition, the terrorist attacks of September 11, 2001, stressed the importance of maintaining security around hazardous materials shipments, and





# Traffic Bulletin

reducing the number of stops required reduces the risk that a hazmat shipment could be stolen.

## Load checks

The safety regulations (under 49 CFR 392.9) require drivers to periodically check their cargo and securement devices to ensure that the cargo is properly secured, and make adjustments as necessary.

The regulations have the load being checked:

- Before the trip starts;
- Within the first 50 miles after beginning the trip; and
- Whenever the driver makes a change of his/her duty status or:
- After the vehicle has been driven for 3 hours or 150 miles, whichever occurs first.

## So, when do I check the tires and/or the load?

Here is a simple table to help with the decision process.

When	What to Check
Before starting trip	Tires and load securement
Within first 50 miles	Load securement (and tires since you are stopped)
Each time the vehicle is parked	Tires and load securement
Every 3 hours or 150 miles (whichever comes first)	Load securement (and tires since you are stopped)

If there are any questions regarding this Bulletin, please ask.

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# Medical, Food/Beverage and Specialty Gases Bulletin

07/01/2018

## 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** – What does PCQI mean for Food/Bev Gases?

**A** – PCQI means “Preventive Controls Qualified Individual”. In order to be considered a PCQI, you must have the education, training or experience to:

- Identify and manage food safety preventive controls
- Write, manage and audit the Hazard Analysis and Risk Prevention Controls (HARPC) program, if required.
- Establish and manage your Food Safety Program, consistent with the risks identified in the HARPC.

The FDA permits your PCQI to be an employee or a consultant.

We will help you to become trained as a PCQI or we can act as your PCQI.... your choice. Typically, larger GAWDA members will want their own internal PCQI.

# Medical, Food/Beverage and Specialty Gases Bulletin

## Upcoming Training

- PCQI Training Webinar – July 24 & 25, 2018 (12 hours)  
[Click here for more information.](#)
- Internal Auditor Training Webinar – July 25, 2018 (4 hours)  
[Click here for more information.](#)
- GAWDA Professional Compliance Seminar – October 16 to 18, 2018
  - DOT Audit Survival
  - FDA PCQI and Drug CGMP Training  
[Click here for more information.](#)

## July Medical Gas Roundtable (07/27/2018) – 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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