

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

SEPTEMBER 2018

### ***ENCLOSED***

#### **Safety Topic: Facility Securement**

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

#### **Traffic Bulletin: Hazmat Security Program Update**

*Please contact Mike Dodd for more information.*

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

- 1. Recent FDA Observations: Employee Training**
- 2. FAQ's: Can I use the "MR Safe" marking on aluminum high-pressure cylinders and stainless steel liquid containers?**
- 3. SEMINARS: GAWDA Professional Compliance Seminar (10/16/18): DOT Audit Survival, FDA PCQI & Drug CGMP Training. September Medical Gas Roundtable (09/28/2018) – CGMP Subpart G – Packaging and Labeling Control. WEBINARS: Food Gas Roundtable – Part 117 Subpart C - Reanalysis, Requirements for preventive controls qualified individual and a qualified auditor. Specialty Gas - Fuel/Oxidizer Mixtures-Alternative Approaches.**
- 4. Micro Audit Suggestions.**

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

*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 \_\_\_\_\_

## Facility Securement

The GAWDA Safety Committee just completed another sample safety practice and I wanted to pass it along to the membership. This will be posted along with all the other sample safety practices on the membership side of the GAWDA website.

### Facility Securement (Insert Company Name Here)

<b>PURPOSE</b>	<b>To provide a set of proposed guidelines for the securement of welding distributors and fill plants.</b>
<b>RESPONSIBILITY</b>	<b>All personnel of the facility</b>
<b>AUTHORITY</b>	<b>Facility manager and or fill plant manager</b>

#### 1. Property Safety

- a. Procedure for vetting legitimate customers—See CGA P-52
- b. Procedure for handling non-customers
- c. Procedure for reconciling inhalation hazard gases, including ammonia
- d. Have a protocol for securing the facility when closing
- e. Assign specific tasks to specific personnel for securing facility
- f. A camera/DVR system to ensure consistent monitoring of the facility with security system with alarm
- g. Have an established hours of operation posted for all to see
- h. Ensure all exits and entrances be kept free and clear and marked properly
- i. Total perimeter fencing with locking gates
- j. Secondary fencing for nitrous cylinders—See CGA P-50 for general security

#### 2. Cash control

- a. Concerning cash registers, have a designated maximum amount allowable
- b. Once the maximum amount is reached, have a protocol for what to do with the excess
- c. Remove all cash from drawer at the end of the day
- d. Have an end of day process for making deposits where at least two employees or an employee accompanied by security leaves the premises with said deposit
- e. In the event the deposit cannot be made, have a procedure in place with what to do with the excess, i.e., use a floor safe or similar device

#### 3. Break-ins and Burglaries



- a. In the event of a break-in or burglary, have an alarm company with a listing of individuals to call including 911
  - b. Once notified, a designated person or persons should meet with the authorities as soon as possible
  - c. Once an all clear is given, assess the damage and or shrinkage
  - d. Make a report with the insurance company with an accompanying police report
  - e. Notify proper repairmen for services to secure facility immediately
  - f. Consider modifications to facility to mitigate future break-ins
4. Internet Security
- a. Firewall system in place for securing internet
  - b. Protocol in place for backing up the day's receipts, preferably off-site
  - c. Program for changing passwords at predetermined intervals

Many thanks to the members of the Safety Committee for their work on the new sample program.

Michael Dodd

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# Traffic Bulletin

## Traffic Bulletin

September 2018

### Hazmat Security Program Update

**Back in 2010**, the Pipeline and Hazardous Materials Safety Administration published a final rule in HM-232F narrowing the list of materials subject to the security plan requirements and reducing the regulatory costs and paperwork burden. The final rule, issued in consultation with the Transportation Security Administration, was developed in response to petitions from industry groups arguing that not all placardable amounts of hazardous materials were capable of being used as weapons and thus did not require security plans.

PHMSA published its final rule so that the list of materials requiring a security plan corresponds with the United Nations Model Regulations for the Transport of Dangerous Goods and the TSA's list of Highly Security Sensitive Hazardous Materials. A variety of changes have been made to the requirements for various classes of hazardous materials. Please refer to 49 CFR 172.800 for all the details on whom this applies to. The following table is a summary of the hazard classes that affect most of our members.

Class	Current threshold	Proposed threshold	Change
2.1	A quantity requiring placarding	>3,000 L in a single packaging	Security plan not required for 3,000 L (793 gallons) or less.
2.2	A quantity requiring placarding	Not subject except for oxygen and gases with a subsidiary 5.1 hazard (<3,000 L (793 gallons) in a single packaging).	Security plan not required for most non- flammable, non-poisonous compressed gas shipments.
2.3	Any quantity	Any quantity	None.
3	A quantity requiring placarding	>3,000 L (793 gallons) in a single packaging and any quantity of Class 3 desensitized explosives.	Security plan not required for 3,000 L (793 gallons) or less except for desensitized explosives.
5.1	A quantity requiring placarding	PG I and II liquids, perchlorates, ammonium nitrate (including fertilizers) in quantities >3,000 L (793 gallons) in a single packaging.	Security plan not required for PG III liquids or unlisted solids.
6.1	A quantity requiring placarding; any quantity of PIH material.	Any quantity of PG I; >3,000 L (793 gallons) for PG II and III.	Security plan not required for 3,000 L (793 gallons) or less of PG II and III.



# Traffic Bulletin

Here is the list of gases in the final rule that have a subsidiary hazard of 5.1 and still require the security plan.

Proper shipping name	Hazard class	Identification Nos.	Label code
Air, refrigerated liquid, (cryogenic liquid)	2.2	UN1003	2.2, 5.1
Air, refrigerated liquid, (cryogenic liquid) non-pressurized	2.2	UN1003	2.2, 5.1
Compressed gas, oxidizing, n.o.s.	2.2	UN3156	2.2, 5.1
Gas, refrigerated liquid, oxidizing, n.o.s. (cryogenic liquid)	2.2	UN3311	2.2, 5.1
Liquefied gas, oxidizing, n.o.s.	2.2	UN3157	2.2, 5.1
Nitrous oxide	2.2	UN1070	2.2, 5.1
Nitrous oxide, refrigerated liquid	2.2	UN2201	2.2, 5.1
Oxygen, compressed	2.2	UN1072	2.2, 5.1
Oxygen, refrigerated liquid (cryogenic liquid)	2.2	UN1073	2.2, 5.1

The final rule became effective on October 1, 2010, but voluntary compliance was authorized as of April 8, 2010. **This means that many of the GAWDA members were no longer required to have the hazmat security plan as of 4-8-2010.**

For those still required to have a security plan, there are some new changes required in the written plan. Please read 49 CFR 172.802 for details on all the required components of the written security plan. Here is a sample of the changes that came with the 2010 revision:

172.802 (b) The security plan must also include the following:

- (1) Identification by job title of the senior management official responsible for overall development and implementation of the security plan;
- (2) Security duties for each position or department that is responsible for implementing the plan or a portion of the plan and the process of notifying employees when specific elements of the security plan must be implemented; and
- (3) A plan for training hazmat employees in accordance with § 172.704 (a)(4) and (a)(5) of this part.



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## Traffic Bulletin

### Summary

If you do not exceed the thresholds in the above table, then you are not required to have a written security plan and are not required to do the security in-depth training every 3 years.

This is location specific so even though you may need a written security plan at one of your locations it does not mean that all your locations need to have one, only those locations that exceed the thresholds.

This does not affect the Hazmat and security awareness training requirements for companies that ship or transport hazardous materials that require placards.

If you have any questions about whether you are still in the program or not, please contact:

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# Medical, Food/Beverage and Specialty Gases Bulletin

09/01/2018

## 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.

### 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.

## Frequently Asked Question

**Q** – Can I use the “MR Safe” marking on aluminum high-pressure cylinders and stainless steel liquid containers?

**A** – Short answer.... No. The Magnetic Resonance (MR) task group of the American Society for Testing and Materials (ASTM) International has developed a set of MR safety terms that are being used since 2005. Before 2005, the MR definitions were less consistent.

The new definitions are:

**MR SAFE** - is an item that poses no known hazards in all MRI environments. Using the new terminology, "MR Safe" items include non-conducting, non-metallic, non-magnetic items such as a plastic Petri dish. The "MR Safe" icon consists of the of the letters "MR" in green in a white square with a green border - or - the letters "MR" in white in a green square.



# Medical, Food/Beverage and Specialty Gases Bulletin

**MR CONDITIONAL** - is an item that has been demonstrated to pose no known hazards in a specified MR environment as long as specified conditions of use are met. The "MR Conditional" icon consists of the letter "MR" in black inside a yellow triangle with a black border. The item labeling must include the results of testing and the specific conditions of use sufficient to characterize the behavior of the item in the MRI environment.



For more details, see:

- FDA Guidance: <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm107708.pdf>
- ASTM Publication: <https://www.astm.org/Standards/F2503.htm>

Clearly HP and Liquid cylinders are metallic and conducting and therefore do not qualify for the "MR Safe" label. According to ASTM standards and FDA guidance you could mark your conforming cylinders as "MR Conditional". Also, be certain that no other magnetic components (valve parts, wheels, etc.) would create a magnetic hazard if your cylinders are marked "MR Conditional".

## **GAWDA Professional Compliance Seminar – Audit Survival**



Hold The Date (October 16-18, 2018)... GAWDA Professional Compliance Seminar at Weldcoa, Aurora, IL. [Click here for more information.](#)

This seminar focuses on:

- DOT Audit Survival
- FDA PCQI and Drug CGMP Training

## **September Medical Gas Roundtable (09/28/2018) – Subpart G – Packaging and Labeling Control**

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In September we will be discussing labeling issuance, labeling operation and expiration dating regulations and exemptions.



# Medical, Food/Beverage and Specialty Gases Bulletin

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

- **Specialty Gas Operations** - Fuel/Oxidizer Mixtures - Alternative Approaches – we recommend that you purchase ISO 10156, CGA P-36 and CGA P-58 prior to attending the seminar.
- **Food Gas Roundtable** – Part 117 Subpart C - Reanalysis, Requirements for preventive controls qualified individual and a qualified auditor

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](mailto:jodie@asteriskllc.com).

## 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](mailto:jodie@asteriskllc.com) for a sample customer notification letter if needed.

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