



## AUGUST 2020

### ENCLOSED

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#### Safety Topic

Driver & Facility Security

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

#### Traffic Bulletin

Drug & Alcohol Policy

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

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

1. Appropriate Medical Gas Regulations
2. Recent FDA Observations
3. FAQs
4. GAWDA Professional Compliance Seminar: Fall -- October 27<sup>th</sup>-29<sup>th</sup> Webinar;  
August Medical Gas Roundtable (08/28/2020): CGMP – Practical Validation for the Cylinder Plant
5. Micro-Audit Suggestions

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

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**\*\* Visit GAWDA's COVID-19 Resource Center at [www.gawda.org/covid-19/](http://www.gawda.org/covid-19/) \*\***

*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 \_\_\_\_\_

## Driver & Facility Security - August 2020

### Driver Safety

Driver safety is paramount to our businesses and more importantly to our business families. Drivers are on the frontline for our exposure to COVID-19 and now they have to prepare for protests and driving in areas ravaged by riots. We can help them with a little preparation. Below are some suggestions to help keep your drivers safe:

**Communication is critical.**

- Call the customers in areas of unrest and ask about the situation: are any protests planned, have they changed their hours of operation
- Drivers should stay in close contact with dispatchers.
- Drivers and dispatchers should monitor local news to make sure routes are open to their destination.
- Consider a "No Stop" policy to thwart hijackings. Such a policy instructs drivers that in most situations, not to stop their vehicles if someone is attempting to get them to do so. Even at low speeds, large trucks are difficult to stop if the driver is intent on not stopping.

**Schedule Appropriately:**

- Timing of deliveries. Most of the violence, looting and rioting has happened at night so nighttime deliveries should be avoided.
- If you have regular runs, try to vary routes the drivers take in case cargo thieves are conducting surveillance on your trucks and have planned a hijacking along your known route of travel.

**Measures taken by the Driver:**

- Conduct thorough Pre-trip and Post-trip inspections to detect vehicle issues early.
- Lock doors at all times.
- Listen to the local news radio station.
- Avoid areas where large crowds gather



**After-dark deliveries:**

- Park in well-lit areas away from crowds.
- Nighttime breaks should be taken at well-lit truck stops with on-site security and video surveillance.

**If Driver encounters a crowd:**

- Open windows ½". Windows that are down approximately ½" are actually harder to break than windows that are tightly closed.
- Turn off the ventilation system so any smoke or tear gas that is in the air is not pulled into the vehicle.
- Make sure recording devices are on. Recorded events could assist the police if anything happens to the driver or truck.
- Don't leave the cab, assess the situation before leaving the cab and abort the delivery if it's too dangerous. Doors and windows should remain locked.
- Remove keys from unattended vehicles.
- Call the police if drivers see an emergency situation.



## Facility Security

During this time of unrest, we must also be mindful of site security. I have attached the GAWDA Safety Committee's Facility Securement and I would suggest that you include a site security review walk around on regular basis



### Facility Securement (Insert Company Name Here)

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

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

The Facility Securement plan is found in the Member's Only page under Sample Safety Practices. If you have any questions about either of these subjects or would like assistance building a Facility security plan, please feel free to contact me.

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# Traffic Bulletin

August 2020

## Drug and Alcohol Policy

Motor carriers are required to have written materials and a policy outlining their alcohol and drug program. These materials must be provided to each driver and written notice of the availability of these materials must be provided to union representatives. These materials must be distributed **prior** to the start of alcohol and drug testing. The regulations found in section **382.601** outline the eleven areas that **must** be covered in the education materials.

1. The name of the person designated by the employer to answer driver questions about the materials;
2. The categories of drivers who are subject to the provisions of Part 382;
3. Sufficient information about the safety-sensitive functions performed by those drivers to make clear what period of the work day the driver is required to be in compliance with Part 382;
4. Specific information concerning driver conduct that is prohibited;
5. The circumstances under which a driver will be tested for alcohol and/or drugs under Part 382;
6. The procedures that will be used to test for the presence of alcohol and drugs, protect the driver and the integrity of the testing processes, safeguard the validity of the test results, and ensure that those results are attributed to the correct driver;
7. The requirement that a driver submit to alcohol and drug tests administered in accordance with Part 382;
8. An explanation of what constitutes a refusal to submit to an alcohol or controlled substances test and the attendant consequences;
9. The consequences for drivers found to have violated Subpart B, including the requirement that the driver be removed immediately from safety-sensitive functions, and the procedures under Sec. 382.605;
10. The consequences for drivers found to have an alcohol concentration of 0.02 or greater but less than 0.04;



# Traffic Bulletin

11. Information concerning:

- The effects of alcohol and drug use on an individual's health, work, and personal life;
- Signs and symptoms of an alcohol or drug problem (the driver's or a co-worker's); and
- Available methods of intervening when an alcohol or drug problem is suspected, including confrontation, referral to any employee assistance program and or referral to management.

12. The requirement that the following personal information collected and maintained under this part shall be reported to the Clearinghouse:

- A verified positive, adulterated, or substituted drug test result;
- An alcohol confirmation test with a concentration of 0.04 or higher;
- A refusal to submit to any test required by subpart C of this part;
- An employer's report of actual knowledge, as defined in 382.107;
- On duty alcohol use pursuant to 382.205;
- Pre-duty alcohol use pursuant to 382.207;
- Alcohol use following an accident pursuant to 382.209; and
- Controlled substance use pursuant to 382.213;
- A substance abuse professional (SAP as defined in 40.3 of this title) report of the successful completion of the return-to-duty process;
- A negative return-to-duty test; and
- An employer's report of completion of follow-up testing.

**Optional Provision** — The materials may also include information on additional employer policies with respect to the use or possession of alcohol or drugs, including any consequences for an employee found violating the company policies. These additional policies must be clearly identified as based on the employer's independent authority.

Again, these materials must be provided to each driver and written notice of the availability of these materials must be provided to union representatives. These materials must be distributed **prior** to the start of alcohol and drug testing. **Each driver must sign a receipt that he/she has received a copy of the materials.**



# Traffic Bulletin

During audits of our members, if the member has written their own materials, I consistently find at least one if not many of these elements missing from their written policy. Please take some time to review your current written program to verify that the above items are covered.

A very easy way to comply with this requirement is to purchase a pamphlet from JJ Keller (825-H), ***Alcohol & Drug Testing: What Drivers Need to Know - Driver Handbook***. You simply write in a contact name and phone number on the last page of the pamphlet and then tear out and complete the first page, which is the required signed receipt. You do this for every CDL driver. I always suggest that this receipt be kept in the driver's drug and alcohol file. I also suggest that the receipt be stapled to the inside cover of the file so that it will never be tossed or misplaced by mistake.

Feel free to contact me if you have questions.

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# Medical, Food/Beverage and Specialty Gases Bulletin

## Medical Gas Bulletin 08/01/2020

### Appropriate Medical Gas Regulations - Postponed

We had expected that the FDA would be releasing proposed new regulations for medical gases by now. However, the FDA recently announced that the new target date for the new regulations will be August 2021.

### 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.

#### Labels and Labeling

**Form 483 Observation-02-03** - Strict control is not exercised over labeling issued for use in drug product labeling operations. Specifically, on \_\_\_\_, I observed two rolls of product identification labels for Carbon Dioxide USP left unattended on a desk in Building \_\_\_\_, which is used for filling compressed Carbon Dioxide USP cylinders and is not a controlled label storage location.

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

Assure medical gas labels are secured.

### Frequently Asked Questions

**Q** – Do I need to have my Servomex span gas certified?

**A** – Yes. You should have a certificate of analysis (CoA) listing the serial number and the actual purity of the span gas. Since 2014, the Servomex span gas should be 99.99+% Oxygen (typically UHP). Here are the six elements that should be on CoAs for the Servomex span gas:

1. Name and address of the supplier
2. Name of the Product (e.g. Oxygen, UHP)
3. Lot number or unique identification number specific for each cylinder
4. The analytical methodology used to assay the standard
5. The Actual Analytical results obtained, i.e., 99.995% Oxygen.
6. The responsible person's signature and the date signed



# Medical, Food/Beverage and Specialty Gases Bulletin

**Q** – What is the Servomex span gas for analyzing the purity of Medical Nitrogen?

**A** – It depends... The official assay test for Nitrogen, NF requires a gas chromatograph. However, if you are using a Servomex Oxygen Analyzer to test the assay of Nitrogen, NF, the instrument must be validated. Carefully review the validation report to determine the appropriate span gas. For example, we have reviewed a validation report for a Servomex 575 and the span gas is specified as 1% Oxygen in Nitrogen. Another validation report for the Servomex 5200 requires the span gas to be Oxygen 99.99%. This is very convenient since the Oxygen 99.99% is the also span gas for analyzing Oxygen USP.

**Hold The Date**

**GAWDA Professional Compliance Webinar – Audit Survival**

DOT, OSHA and FDA (Food/Beverage and Medical Gases) – Audit Survival Seminar  
October 27 to 29, 2020 - Webinar hosted by Weldcoa

## **August Medical Gas Roundtable (08/28/2020) – CGMP – Practical validation for the cylinder plant**

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In August we will be discussing practical process validation techniques for cylinder fill operations:

- sample systems
- check valves
- fill processes
- portable fill manifolds

This seminar focuses on ways to save money while improving compliance.

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

- **Specialty Gas** - Fuel/Oxidizer Safe Practices (2000 BTU & CGS P-36)
- **Food Gas Roundtable** – Part 117 Subpart C - Reanalysis, Requirements for preventive controls qualified individual and a qualified auditor

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).

# 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. **Portable Oxygen Manifolds** – If you are using a portable oxygen manifold, be sure you have validated and documented the manifold.
2. **Automatic, mechanical or electronic equipment** – Be sure all major equipment used to produce your medical gases are covered in a maintenance program. The equipment that needs calibration should be within the calibration date (gauges, thermometers, etc.).

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