



**MARCH 2020**

## ENCLOSED

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### Safety Topic

#### Safety & Regulatory Update – Corona Virus (COVID-19)

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

### Traffic Bulletin

#### Previous Employer Alcohol and Drug Test Information Inquiries

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

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

1. Frequently Asked Questions – Color Coding Medical Gases
2. Recent FDA Observations
3. GAWDA Professional Compliance Seminars 2020: March 10-12 & 17-19, Ball Ground, GA and October 27-29 & November 3-5, Aurora, IL.
4. March Medical Gas Roundtable
5. 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 \_\_\_\_\_



## Safety & Regulatory Update

### Corona Virus (COVID-19)

The Corona Virus (COVID-2019) is in the same family as MERS and SARS viruses. It is a respiratory virus which spreads primarily from contact with an infected person through respiratory droplets generated when a person, for example, coughs or sneezes, or through droplets of saliva or discharge from the nose.

As of Feb 19, 2020 the World Health Organization (WHO) reported 73,332 cases Globally with 72,528 cases in China. The number of deaths in China is 870 while in the rest of the world only 3 deaths. The Centers for Disease Control (CDC) reported 19 confirmed cases of COVID-19 in the US, as of Feb 11, 2020.

According to the WHO, infection can cause mild symptoms including a runny nose, sore throat, cough, and fever. It can be more severe for some people and can lead to pneumonia or breathing difficulties. More rarely, the disease can be fatal. Older people, and people with pre-existing medical conditions (such as, diabetes and heart disease) appear to be more vulnerable to becoming severely ill with the virus.

COVID-2019 displays the same symptoms as the flu and involves the respiratory system. The CDC has articles on "Healthy Habits to Help Prevent the Flu" and "Helping Prevent the Spread of Flu in the Workplace". These articles have tips to keep your employees safe including company plans that deal with a flu (or other illness) outbreak and sending sick employees home.

**Sources:**

World Health Organization. "Corona Virus 2019." *World Health Organization*, WHO, 18 Feb. 2020, [www.who.int/emergencies/diseases/novel-coronavirus-2019](http://www.who.int/emergencies/diseases/novel-coronavirus-2019).

National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases. "Coronavirus Disease 2019 (COVID-19) Situation Summary." *Centers for Disease Control and Prevention*, USA.gov, 16 Feb. 2020, [www.cdc.gov/coronavirus/2019-ncov/summary.html#illness-severity](http://www.cdc.gov/coronavirus/2019-ncov/summary.html#illness-severity).

OSHA. "COVID-2019." *OSHA.GOV*, USA.GOV, 11 Feb. 2020, [www.osha.gov/SLTC/covid-19/standards.html](http://www.osha.gov/SLTC/covid-19/standards.html).

Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases (NCIRD). "Healthy Habits to Help Prevent the Flu." *CDC.gov*, USA.gov, 7 Nov. 2019, [www.cdc.gov/flu/prevent/actions-prevent-flu.htm](http://www.cdc.gov/flu/prevent/actions-prevent-flu.htm) and 8 Apr. 2019, [www.cdc.gov/flu/business/prevent-flu-workplace.html](http://www.cdc.gov/flu/business/prevent-flu-workplace.html).



## Trending Now

I began as a GAWDA consultant on February 3, 2020 and the questions I have received so far are complex; 60% of the inquiries received have been in reference to the components of a Safety Program. This includes policy development, proper PPE, emergency response, audits and where do I start?

There are four basic components to a Safety Program and each component has several pieces. First, Upper Management must be the head Cheerleader of this program. Then you can begin:

1. Policies
  - a. Company Safety Policy
  - b. Working safety policies: Substance Abuse, PPE, Blood Borne Pathogen, Smoking, Safe driving to name a few. Recommended policies can be found on the GAWDA website/members resource page, OSHA website, CGA publications and don't forget to ask your employees where they think structure is needed.
2. Procedures - standardized procedures help increase productivity and decrease the number of variables that may cause an incident
3. Training - all employees must be trained on policies/procedures and training must be Documented!
4. Audits - audits are not to "catch someone doing something wrong," they are :
  - i. Management by walking around
  - ii. A coaching opportunity for the manager
  - iii. A chance to correct a situation before it becomes the scene of an incident
  - iv. Must be Documented and Issues Addressed in order to be effective

Note: Safety Audits templates can be found on state websites.  
Procedure audits can be a review with the operator and/or an observation of the operator.



## Training - Emergency Action Plan

OSHA states that the emergency action plan covers the “designated actions that employers and employees must take to ensure safety from fire and other emergencies.” OSHA requires that employers record emergency action plans in writing unless there are 10 or fewer employees. If there are 10 or fewer employees, the employer may verbally communicate the plan. 29 CFR 1910.38.

An **Emergency Action Plan** must include at a minimum:

### ***Procedures:***

1. Procedures for reporting a fire or other emergency
2. Procedures for emergency evacuation, including type of evacuation and exit route assignments
3. Procedures to be followed by employees who remain to operate critical plant operations before they evacuate
4. Procedures to account for all employees after evacuation. I recommend using a sign-in sheet
5. Procedures to be followed by employees performing rescue or medical duties; and
6. The name or job title of every employee who may be contacted by employees who need more information about the plan or an explanation of their duties under the plan.

### ***Employee alarm system.***

An employer must have and maintain an employee alarm system. The employee alarm system must use a distinctive signal for each purpose and comply with the requirements in § 1910.165. The signal may be mechanical or verbal.

### ***Training.***

An employer must designate and train employees to assist in a safe and orderly evacuation of other employees.

### ***Review of emergency action plan.***

An employer must review the emergency action plan with each employee covered by the plan:

- When the plan is developed or the employee is assigned initially to a job;
- When the employee's responsibilities under the plan change; and
- When the plan is changed.

NFPA Fire and Life Safety: Developing a Preparedness Plan and Conducting Emergency Evacuation Drills is a good resource on how to effectively run a fire drill.



If there are questions or items that I can help you with, please contact me.

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# Traffic Bulletin

## Traffic Bulletin

March 2020

### Previous Employer Alcohol and Drug Test Information Inquiries

#### Requirements of Prospective Employers of Commercial Drivers

§391.23 (e) requires prospective employers must make inquiries about drug and alcohol information in addition to requesting information about previous employment and DOT accident records from previous employers. This Traffic Bulletin focuses on the drug and alcohol inquiries.

§40.25 vs. §391.23 The previous-employer investigation requirements of Parts 40 and 391 differ, with the most significant difference being that Part 40 requires employers to investigate two years' worth of information, rather than three. However, the DOT has indicated that an employer who complies with the FMCSA's three-year investigation requirements in 391.23 will be deemed to be in compliance with 40.25.

§382.413 (which points to §40.25) requires that prospective employers of commercial drivers, after first obtaining the consent of the driver, obtain and review the following information from all the driver's previous employers during the past two years:

1. Alcohol tests with a result of 0.04 or higher alcohol concentration;
2. Verified positive drug tests;
3. Refusals to be tested (including verified adulterated or substituted drug test results);
4. Other violations of DOT agency drug and alcohol testing regulations; and
5. With respect to any employee who violated a DOT drug and alcohol regulation, documentation of the employee's successful completion of DOT return-to-duty requirements (including follow-up tests). If the previous employer does not have information about the return-to-duty process (e.g., an employer who did not hire an employee who tested positive on a pre-employment test), you must seek to obtain this information from the employee.

The prospective employer may obtain the information directly from the driver but must make sure that the copies of a former employer's records are true and accurate.

As the employer, you must also ask the employee whether he or she has tested positive, or refused to test, on any pre-employment drug or alcohol test administered by an employer to which the employee applied for, but did not obtain, safety-sensitive transportation work covered by DOT agency drug and alcohol testing rules during the past two years. If the employee admits that he or she had a positive test or a refusal to test, you must not use the employee to perform safety-sensitive functions for you, until and unless the employee documents successful completion of the return-to-duty process.

40.333 (a)(2) requires previous employers of commercial drivers to maintain information about violations not only committed while employed, but also committed within the past three years **that are obtained from other former employers.**



# Traffic Bulletin

## Traffic Bulletin

### Three Year Look Back

This information must be obtained from any employer for which the driver performed safety-sensitive functions under Part 382 regulations during the last three years. The prospective employer must provide to each of the driver's previous employers a written authorization from the driver for release of the required information. The release of this information may take the form of personal interviews, telephone interviews, letters, or any other method that ensures confidentiality. Each employer must maintain a written, confidential record with respect to each past employer contacted.

### 30-Day Review Period

An employer must obtain and review the information within **30 days** after the driver first performs safety-sensitive functions, even if the driver quits or stops performing safety-sensitive functions during the period.

A new employer must make a **good faith** effort to obtain the information. An employer, who documents a good faith effort and is unable to obtain the information, may continue to use the driver.

**Good faith** in this context means a documented request of each former employer listed on the driver's employment application or known to exist. If information is not forthcoming, follow-up is necessary, preferably by telephone, unless a former employer refuses to transmit the information. It is extremely important to document all attempts to obtain the test information.

### Unsatisfactory Test Results

If records show that a driver tested positive for drugs, had an alcohol test result of 0.04 or greater, or refused testing, the driver cannot perform safety-sensitive functions until the employer has evidence that the driver has met the return-to-duty requirements. Specifically, the driver must have been evaluated by a substance abuse professional, completed all required counseling, passed a return-to-duty test, and satisfied all follow-up testing requirements. A pre-employment test directed by the hiring employer may serve as a return-to-duty test under such circumstances.

An employer may obtain from any previous employer of a driver — provided the driver has given his/her written consent — **any** information concerning the driver's participation in an alcohol or drug testing program.

### Clearinghouse

Until Jan. 6, 2023, you will be required to do the 3-year lookback inquiry with past employers where the new hire worked as a CDL driver using the old method described above. You are also required to do the full inquiry of the clearinghouse. After Jan. 6, 2023 you will no longer need to check with previous employers because there will be 3 years of data in the clearinghouse.



# Traffic Bulletin

## Pre-Employment Queries

- Company (or C/TPA) must conduct full query of driver's record in Clearinghouse database before allowing new hire CDL driver to perform safety sensitive functions (SSF)
- Driver must provide electronic consent for query (requires driver to register with Clearinghouse)
- If driver's record in Clearinghouse database shows positive drug or alcohol tests, refusal to take a test, or other D&A violations, without completing return to duty process, company may not allow driver to perform SSF

## Additional Clearinghouse Info

- Violations prior to January 6, 2020 are not reportable to the database
- Non-DOT test results are not reportable, either
- FMCSA proposed 3-year extension of State queries to Clearinghouse before issuing, renewing, upgrading or transferring a CDL; States may voluntarily query the database during that period

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

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# Medical, Food/Beverage and Specialty Gases Bulletin

## Medical Gas Bulletin 03/01/2020

### Frequently Asked Questions – Color Coding Medical Gases

**Q** – Are there acceptable alternatives to the Draeger tubes?

**A – Yes.** There are three good ways to save significant labor and detector tube costs for your medical gas analyses. Your approach would be influenced by the volume of each medical gas you fill and test.

**Alternate Tubes** - USP used to specify the Draeger part numbers for certain tests – for example the Carbon Monoxide test in Nitrogen, NF. However, USP now specifies the chemistry inside the tube rather than the part number. This opens up the possibility to use competitive (and potentially less expensive) detector tubes for medical gas analyses. We have qualified the chemistry in the “Gastec” and “KwikDraw by Uniphos” tubes and prepared a cross reference guide. The cross reference guide includes a section for your Quality Control Unit to approve the new tubes and part numbers. Let [tom@asteriskllc.com](mailto:tom@asteriskllc.com) know if you want the Detector Tube Cross Reference Guide.

**Alternate Instruments** - Also, if you perform a large quantity of detector tube analyses, you may be able to use alternate technology to eliminate using detector tubes completely (e.g. Non-dispersive Infrared). These alternate analytical methods are often faster, more accurate and less expensive to use. These alternate analytical technologies would require validation to be equivalent to the USP/NF methods. Let us know if you are considering an alternative analytical method and we may be able to make it simpler for you.

**Process Validation** - Lastly, if you validate your production process, you may be able to reduce the testing requirements to eliminate many detector tube analyses. For example, it is possible to perform a process validation and prove that the Carbon Monoxide test is unnecessary for high pressure Nitrogen NF analyses.

### 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.

### Lot Stickers

**Form 483 Observation-03-01** - Procedures designed to assure that correct labels are used for drug products are not written and/or followed. Specifically, the labels which you include in your batch records (lot stickers) for your Liquid Oxygen USP product, which contain lot number information, are not maintained and controlled as numerous labels (>25) were observed on the floor by filling manifold no. \_\_\_\_, where the liquid oxygen are filled and



# Medical, Food/Beverage and Specialty Gases Bulletin

labeling operations for these "lot stickers" occur. These labels (lot stickers) were used on Liquid Oxygen USP lot \_\_\_ which was filled and distributed on \_\_\_.

**Form 483 Observation-01-04** - Strict control is not exercised over labeling issued for use in drug product labeling operations. Specifically, labels are not properly reconciled by your firm. For example, during the walk-through on \_\_\_, we viewed returned product lot labels on the floor of the production area.

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

Assure your pumpers clean the old lot numbers off the floor after each cylinder filling activity.

## GAWDA Professional Compliance Seminars – 2020 Spring - FDA/DOT/OSHA Certified Training



## GAWDA Professional Compliance Seminars - 2020

March 10 to 12 and 17 to 19 - Ball Ground, GA (at Chart)

October 27 to 29 and November 3 to 5 - Aurora, IL (at Weldcoa)

[Click here for more information or to register!](#)



# Medical, Food/Beverage and Specialty Gases Bulletin

## March Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, March 27, we will cover **Subparts D - Equipment**. *Sample equipment maintenance records will be available for downloading during the training.*

In addition, we will be conducting the following additional training that day:

- **Specialty Gas** – Measuring and Controlling Uncertainty in Gravimetric Fill Systems (ISO 6142).
- **Food Gas Roundtable** –
  - CGMP Training – Part 117 Subpart B – Current Good Manufacturing Practices
  - The latest information about food gas regulations is reviewed –
  - 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](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. **Servomex Filter Check** – Verify that the filter inspection record is current for your Servomex oxygen analyzer. The frequency of inspection is listed in the operator's manual for your instrument.
2. **Calibrations** – Be sure that your thermometers, vacuum gauges and high-pressure gauges are calibrated according to your SOPs.
3. **Daily Vacuum Gauge Verification** – Be sure you have a record that your vacuum gauge needles read zero at atmospheric pressure. This record should be made each day the vacuum gauge is used.

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