



## FEBRUARY 2021

### ENCLOSED

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#### Safety Topics

1. EPA SARA Tier II
2. COVID-19 Contact Tracing
3. COVID-19 OSHA Violations
4. Liquid Nitrogen and Dry Ice Safety for End User

Please contact [Marilyn Dempsey](#), GAWDA DHS, EPA, & OSHA Consultant for more information.

#### Traffic Bulletin

#### Vehicle Maintenance

Please contact [Mike Dodd](#), GAWDA DOT Consultant for more information.

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

1. GAWDA Medical Gas SOP Program
2. February Medical Gas Roundtable (2/26/2021);  
GAWDA Professional Compliance Seminars 2021 (3/22-26 & 10/25-29)
3. 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.**

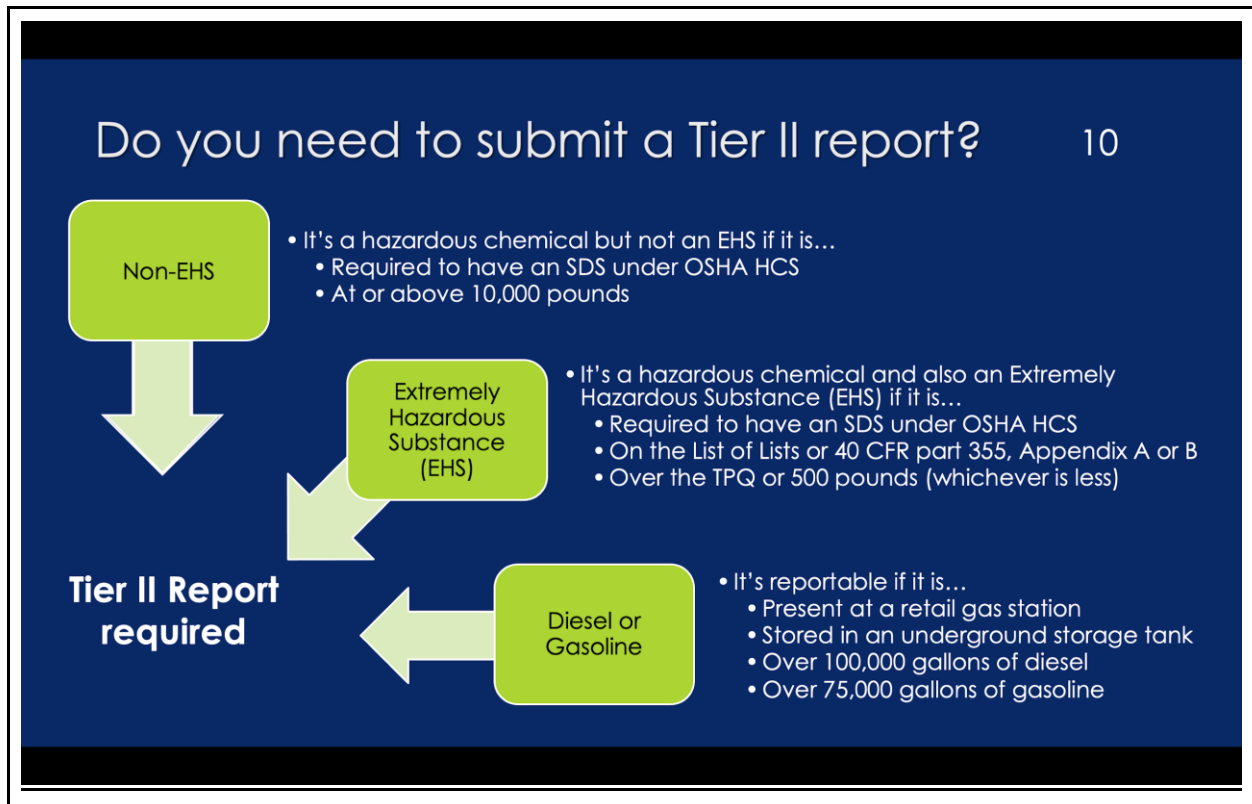
**ROUTE TO:**

- General Manager
- Safety Coordinator
- Supervisor Dept. \_\_\_\_\_
- Other \_\_\_\_\_
- Date of Meeting \_\_\_\_\_



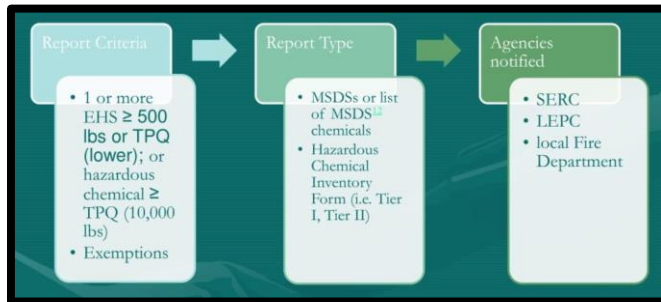
**February 2021**

**EPA SARA Tier II**



Every **March 1**, an EPA Tier II form is required to be filed under the Emergency Planning and Community Right-to-know Act (EPCRA), Section 312. The intent of the Tier II form is to provide information about the potential hazards at your worksite to emergency responders: State Emergency Response Commission, Local Emergency Planning Commission and your local Fire department.





The inventory form comes in three options:

- Tier II form— This information provides state and local officials and the public with specific information on the amounts and locations of hazardous chemicals present at a facility during the previous calendar year.
- State-equivalent form — Some states may require facilities to use a state reporting form (instead of Tier I or II forms) including electronic reporting and certification for submitting a hazardous chemical inventory. A facility should contact its state for the specific requirements in that state.

In addition to the products at your facility, you must also consider bulk products stored at your customer locations. For example:

Bulk storage tanks/trailers at customer locations owned by your company:

You have an obligation, under EPCRA 312, to notify the customer of their obligation to report under SARA Tier II for any hazardous material that is at or above the reporting threshold. Notification must be sent by February 15, in a letter stating the chemical(s) that require SARA Tier II reporting and where to find the appropriate forms.

- You are NOT obligated to notify the customer if they own the bulk tank...but it is good customer service.
- You are NOT obligated to file IF there is language in the contract that states the customer is responsible to comply with all EPCRA obligations.

Also, hospitals are exempt from the reporting and your notification requirement (EPCRA 311 and 40 CFR 370.2 and 355.2 (allows the exclusion of any “hazardous chemical” that is used for research, medical facility or hospital if they have a technically qualified direct supervisor.

**SARA Tier II Reporting DUE MARCH 1**

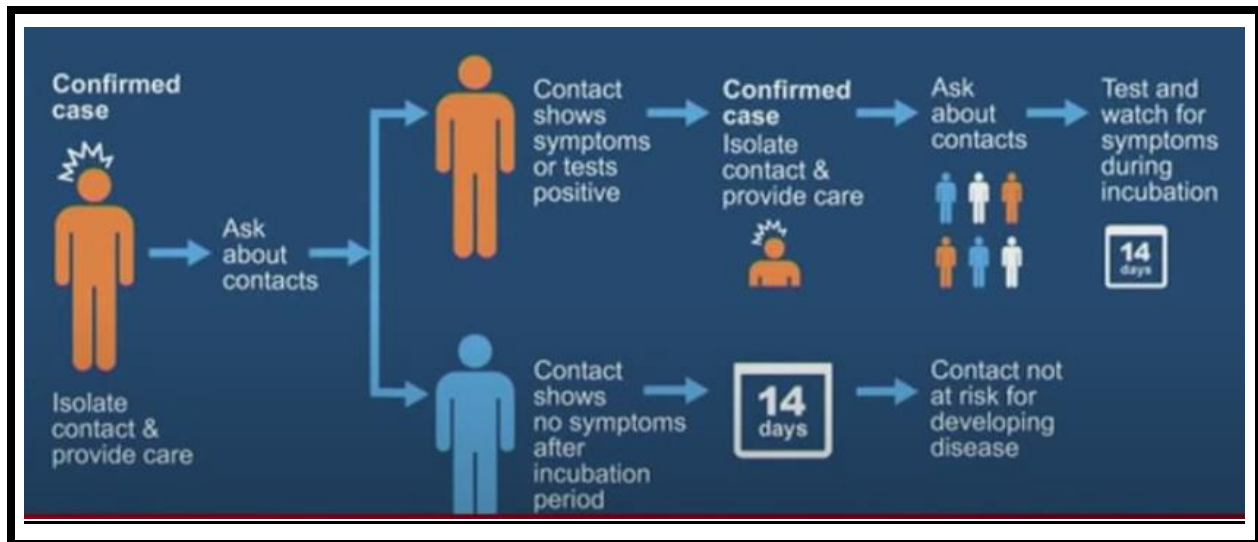


The most recent version of Tier2 Submit, links to state Tier II reporting requirements and contact information, and Tier I and II forms and instructions may be found at URL:

<https://www.epa.gov/epcra>

For questions regarding SARA Tier II you can ask on the [EPA FAQ page](#) or contact Marilyn Dempsey.

## COVID-19 Contact Tracing



[NYC Contact Tracing youtube](#)

Contact tracing is an interview process that:

- \* records the onset of COVID-19 symptoms or a positive COVID-19 test result
- \* uses that date to determine the contact tracing date (two days before symptom onset or positive result)
- \* identify contacts and activities beginning at the contact tracing date.

For our purposes, we use contact tracing with any employee that has tested positive for the COVID-19 virus or displays symptoms of COVID-19. Contact tracing of an employee may help prove the illness was not acquired at work and keeps the employee from putting other employees at risk.



Several states have enacted legislation that places the burden on businesses to prove COVID-19 was not contracted at work. According to a [December 19, 2020 publication by the National Council of State Legislatures](#) the following states have a list of **Type of Worker With Presumption of Occupational Disease**, for ease of listing I have broken these down into three categories:

1. Any worker who can establish that they contracted COVID-19 as a result of their job:  
AR, NY, WY
2. Essential workers:  
CT (contracted COVID-19 between March 10, 2020 and May 20, 2020),  
IL, MN, NJ, OH, RI
3. Anyone, except those working from home: CA

Note: for a complete list of states and their requirements, please refer to [December 19, 2020 publication by the National Council of State Legislatures](#).

In order to avoid inaccurate recording of COVID-19 case transmission, we need to consistently monitor (and record) employee health conditions and conduct contact tracing of all COVID-19 cases within our employee population. If you would like a copy of the Contact Tracing form or help administering the form, contact Marilyn Dempsey.

## COVID-19 OSHA Violations

November 2020, these were the most commonly [cited standards in COVID-19-related inspections](#):

- [1910.134](#) – Respiratory Protection
- [Subpart 1904](#) – Recording and Reporting Occupational Injuries and Illnesses
- [1910.132](#) – Personal Protective Equipment
- [5\(a\)\(1\)](#) – General Duty Clause

The basic problems noted by the agency include:

Respirator programs:

- Failing to provide medical evaluation before use of respirator.
- Failing to administer appropriate fit testing for workers using tight-fitting respirators.
- Failing to establish, implement and update respiratory protection program with worksite-specific procedures.
- Failing to provide NIOSH-certified respirators.
- Failing to store respirators and other PPE properly in a way that protects them from damage and contamination.



PPE and Reporting:

- **Failing to report fatalities to OSHA within eight hours, and failing to keep required records of work-related illnesses, injuries and fatalities.**
- **Failing to provide sufficient training on respiratory protection and other PPE use.**
- **Failing to assess the workplace to determine if hazards are present that require the use of personal protective equipment (PPE).** This finding is important to note because we work with Hazardous Materials and therefore we must conduct and record Hazard Assessments/evaluation of the processes employees may be exposed to during their normal work day.

## Dry Ice Safety

OSHA recently published “[Laboratory Safety: Cryogenics and Dry Ice](#)” an appropriate topic for many of our customers now handling dry ice for the COVID-19 Vaccine. The bulletin covers the temperature of liquid nitrogen and dry ice. The Quick Fact also covers General Precautions when working with Dry Ice or Liquid nitrogen and First Aid measures.

I encourage you to distribute this OSHA handout to all customers handling Liquid Nitrogen and Dry Ice for the COVID-19 vaccine.

## Training Reminder

One of the greatest hazards employees in our industry face are injuries from cylinder handling. Injuries range from: fractures, contusions of the hand/ foot / leg, back and shoulder strains. Soft tissue injuries are the most frequent and can require long recovery periods which will decrease your productivity and can affect workforce morale. The GAWDA Safety Committee developed a best practice for [Safe Cylinder Handling](#). This best practice can be modified to fit your company and can be used as a safety training.

You'll find the document on the GAWDA website in the Members Only Documents [Sample Safety Practices folder](#).

If you have any questions on the subject presented here or other questions related to DHS, EPA or OSHA, please contact me.

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# Traffic Bulletin

## Traffic Bulletin

February 2021

### Vehicle Maintenance

#### Inspection and Maintenance (396.3)

The carrier is required by 396.3 to "...systematically inspect, repair, and maintain, or cause to be systematically inspected, repaired, and maintained, all vehicles subject to its control."

The time periods between systematic vehicle inspections are to be determined by the motor carrier. The intervals can be established on a mileage or time basis. While the mileage or time intervals are at the discretion of the motor carrier, the program must be reasonable and systematic. The manufacturers suggested maintenance schedules are a good place to start.

In addition to being charged with systematically inspecting, repairing, and maintaining motor vehicles subject to their control, carriers are required to maintain records on all vehicles controlled for 30 days or more. Records to be maintained are as follows:

1. An identification of the vehicle including:
  - company number (if so marked),
  - make,
  - serial number,
  - year,
  - tire size, and
  - name of the person furnishing the vehicle if it is not owned by the carrier
2. A means to indicate the nature and the due date of the various inspection and maintenance operations to be performed.
3. A record of inspection, repair and maintenance indicating their date and nature

All records shall be retained where the vehicle is housed or maintained. Records shall be retained for 1 year, and for 6 months after the vehicle leaves the motor carrier's control.

This is easy to comply. Make a file for each commercial motor vehicle. On the outside of the folder list all the items from 1 above. It is a one-time only deal. Then place your annual DOT inspections and any maintenance or repairs into this file. You are required to keep the annual inspection form for 14 months.

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

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# Medical, Food/Beverage and Specialty Gases Bulletin

**02/01/2021**

## **Big Changes in the GAWDA Medical Gas SOP Program**

The GAWDA Medical Gas SOPs have long been the industry standard procedures for medical gases. The procedures are practical methods to comply with FDA regulations and current enforcement. They are consistent with CGA positions on FDA compliance.

**Revision Schedule** – we make incremental procedure adjustments throughout the year as members request them through the change request form. These updates are typically implemented in a matter of a couple days. We also change the SOPs when the FDA issues new guidance or changes their interpretations. We digitally sign the revisions as they occur.

Annually, we digitally sign the current version and issue an update. This annual update, along with the update training, will occur during the January GAWDA Medical Gas Roundtable (1/30/2021). (A recording is available in case you missed the Roundtable.) The signed procedure files will be valid until the end of the following year (i.e up to 12/31/2022). This gives you plenty of time to migrate your SOPs to the most compliant and up-to-date version.

## **How you receive the GAWDA Medical Gas procedures**

**Paper** - Years ago, we distributed the procedures only in printed manuals. This was difficult to maintain and update. (FYI – we can still get the SOPs to you on paper if you prefer.)

**Dropbox** – We then added the “GAWDA SOP Support Documents” Dropbox to store and distribute the SOPs. This was a convenient solution at the time, but it eventually caused problems on some client PCs and networks. We needed a more universal solution with fewer security concerns. The Dropbox is being retired this month.

**FDATechSupport.com** – This website allows us to better deliver the content you need without the overhead and drawbacks of Dropbox. If you do not already have a user account on FDATechSupport.com, please let us know.

**Customized Procedures** - We have a new work process in place that allows you to have your own customized PDF version of the GAWDA Medical Gas SOPs. The consolidated PDF file will have your logo and it will contain only the procedures that you need. If you have not already received your customized SOPs, contact [tom@asteriskllc.com](mailto:tom@asteriskllc.com) or [andre@asteriskllc.com](mailto:andre@asteriskllc.com). We will get the SOP selection tool to you.





# Medical, Food/Beverage and Specialty Gases Bulletin

## February Medical Gas Roundtable (26 February 2021)

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In this roundtable, we will cover **21 CFR 211 Subparts A & B - Organization and Personnel**.

This presentation will include discussions about the responsibilities, authorities and procedures of the Quality Control Unit. We will also review the types of training required for operators, drivers and counter personnel.

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

- **Specialty Gas – ISO 12963** - Gas analysis based on one- and two-point calibrations.
- **Food Gas Roundtable** – the latest information about food gas regulations is reviewed – **Part 117 Subpart A - Qualified Individuals, Exemptions**. *The new 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).

## GAWDA Professional Compliance Seminars - 2021

March 22 - 26

October 25 – 29



# 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. Cryogenic Hoses** - Be sure that your cryogenic fill hoses are capped when not in use. (Homecare vans and large cryogenic containers)
- 2. Quarantine** – Be sure you are quarantining cylinders that have been filled but not yet “released” by the Quality Control Unit.
- 3. Nitrous Oxide** – Be sure that your nitrous oxide is secure. Download CGA P-50 for specific guidance on nitrous oxide security.

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