



FEBRUARY 2022

ENCLOSED

Safety Topics

EPA SARA Tier II

Leaking Cylinder Guidelines

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

Traffic Bulletin

Road Test

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. GAWDA Medical Gas SOP Program Updates
2. How do you receive the GAWDA Medical Gas procedures?
3. CARES Act Update
4. FDA Compliance To Do List
5. February Medical Gas Roundtable (2/25/2022) -- 21 CFR 211 Subparts A & B -
Organization and Personnel
6. Micro-Audit Suggestions

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

**** Join us for our Monthly LIVE “Safety Managers’ Safety Meeting” ****

Our next meeting is [February 9th](#) @ 1PM Eastern. Visit us at www.gawda.org/safety-meeting/ to learn more and sign up today.

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 2022**EPA SARA Tier II
Leaking Cylinder Guidelines****EPA SARA Tier II**

Since 1986, any facility, public or private, that has hazardous materials present at or above established EPA threshold amounts (TPQ) may potentially be subject to the Emergency Planning and Community Right-to-Know Act (EPCRA) and must report inventory levels on a SARA Tier II report. Generally the TPQ for the hazardous materials we inventory is 10,000 lbs, unless the material is considered an Extremely Hazardous Substance, then the TPQ is significantly lower (see [EPA List of Lists](#)).

The purpose of a SARA Tier II report is to provide State and local officials and the public with specific information on hazardous chemicals present at your facility (quantities, location and storage conditions) during the past year. This information is



used by local Fire Departments for personnel training, hazmat pre-planning and local/regional response to spills and releases. Tier II data is also used in mapping hazmat facilities and their distance to sensitive populations, such as schools and nursing homes.

In addition to the products at your facility, you must also notify your customers (by February 15) of their reporting obligations for any hazardous material stored at their locations above the threshold planning quantity (TPQ), as listed in the EPA List of Lists.

For example:

- Bulk storage tanks/trailers at customer locations and owned by your company that contain hazardous material at or above the TPQ.
- 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.

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

Tier II forms, instructions and state reporting requirements can be found at [EPA.gov/epcra](https://www.epa.gov/epcra).

Dates to note:

February 15 - written notification due for customers with bulk tanks at/above TPQ

March 1 - SARA Tier II filing due





Leaking Cylinder Guidelines

Leaking cylinders are not unknown in our industry - how we respond to a leaking cylinder is where we demonstrate our expertise...or do we have the expertise? Have your employees been trained on how to respond to a leaking cylinder? Responding to leaking cylinders is similar to responding to a fire - never plan alone and never respond alone.

The GAWDA Safety Committee has developed “ Guidelines for Handling Leaking Cylinders at Customer Locations.” This document is a practical approach to leaking cylinders and an easy to use document for training your employees. The document includes the definitions of Minor and Major leaks, easy to follow flowcharts and a form to record customer complaints concerning leaking cylinders.

“Guidelines for Handling Leaking Cylinders at Customer Locations” can be found on the GAWDA website/ Members only documents/ Sample Safety Practices.

If you have any questions about Leaking cylinders, SARA Tier II or other EPA, DHS, OSHA questions, please contact:

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GAWDA Professional Compliance Webinar
Hold the dates – March 22 – 26, 2021
[Click here for information or to register](#)



Traffic Bulletin

February 2022

Road Test

The “Road Test”, do I have to give it or not to a new driver?

The regulations start out in 391.31 by saying that a person shall not drive a commercial motor vehicle unless he/she has first successfully completed a road test and has been issued a certificate of driver's road test.

Then in 391.33 the regulations give you a few exceptions. Please note, if the driver operates doubles, triples, or a vehicle requiring a tank endorsement, then you must always give the new driver a road test. However, if the driver operates any other type of vehicle, the motor carrier may accept in place of a road test the following:

- A valid CDL from a state that requires a road test as part of obtaining the CDL; or
- A copy of a valid certificate of road test issued within the previous 3 years.

Even though you may accept a current CDL or certificate of road test from another motor carrier, I highly recommend that you always give each new driver a road test. This is the only way you know that the driver really can drive your vehicle and do it in a safe and proper manner. I continue to receive thanks from our members for reminding them to always do road tests. You would be amazed by the number of drivers that have a CDL but don't know up from down when driving a truck or they do it very poorly. Doing the actual road test will point this out to you.

The Road Test

The road test must be done in a vehicle of the type the driver will be assigned. There are minimum items and things you are required to do when administering a road test. These are:

1. A pre-trip inspection;
2. Coupling and uncoupling a combination, if the driver may drive such equipment;
3. Placing the vehicle in operation;
4. Using the vehicle's controls and emergency equipment;
5. Driving in traffic and passing other vehicles;
6. Turning;
7. Braking, and slowing by means other than braking; and
8. Backing and parking.



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The person that gives the test must rate the performance of the driver and this rating shall be on the form used to give the test and the person giving the test must sign the form. If the road test is completed successfully, the person giving the test must complete a certificate of road test that contains substantially the following:

- Driver's name
- Social Security No.
- Driver's license number
- State
- Type of power unit
- Type of trailers (if applicable)
- If a passenger carrier, the type of bus
- This certification:

This is to certify that the above-named driver was given a road test under my supervision on _____, 20____, consisting of approximately ____ miles of driving.

It is considered my opinion that this driver possesses sufficient driving skills to operate safely the type of commercial motor vehicle listed above.

- Signature of the tester
- Title of the tester
- Organization and address of the tester
- Date of the certification

JJ Keller includes a good road test form and certification in their driver qualification files.

Who can give the test?

A person who is competent to evaluate and determine whether the person who takes the test has demonstrated that he/she is capable of operating the commercial motor vehicle shall give the test. The road test must be of sufficient duration to enable the person who gives it to evaluate the skill of the driver in the above minimum items.



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Recordkeeping

A copy of the certificate shall be given to the driver who was examined.

The motor carrier shall retain in the driver qualification file of the person who was examined:

- The original of the signed road test form; and
- The original or a copy of the certificate of the road test
- If an employer accepts a previous road test certificate or operator's license in lieu of a road test, the employing carrier must retain a legible copy of the certificate or license in the driver's qualification file.

If there are any questions, please contact:

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Medical, Food/Beverage and Specialty Gases Bulletin

02/01/2022

GAWDA Medical Gas SOP Program Updates

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 occurs during the January GAWDA Medical Gas Roundtable (1/28/2022). (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 12/31/2023). This gives you plenty of time to migrate your SOPs to the most flexible, compliant and up-to-date version.

How do 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.)

FDATechSupport.com – This website allows us to better deliver the content you need. If you do not already have a user account on FDATechSupport.com, please let us know.

Customized Procedures - We can also deliver 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 or andre@asteriskllc.com. We will get the SOP selection tool to you.

CARES Act Update

The deadline for submitting your medical gas releases for 2020 is 15 February 2022. The deadline for submitting your medical gas releases for 2021 is 16 May 2022.

If you have any questions about templates or submitting your information to the FDA, please contact jodie@asteriskllc.com.



Medical, Food/Beverage and Specialty Gases Bulletin

February Medical Gas Roundtable (25 February 2022)

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.

GAWDA Professional Compliance Seminars - 2022

February 28 to March 4, 2022 - Audit Excellence

October 17 to 21, 2022 - Compliance Training

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



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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