



JANUARY 2022

ENCLOSED

Safety Topics

OSHA 300A Annual Submission

Driver Policy

COVID-19 ETS by Rick Schweitzer and Marilyn Dempsey

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

Traffic Bulletin

Driver Disqualifications and Penalties

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. GAWDA Medical Gas SOP Program – 2022 Update

2. CARES Act Update

3. FDA Compliance To Do List

4. January Medical Gas Roundtable (1/28/2022) -- Practical validation for the cylinder plant

5. 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 January 19th @ 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 _____

January 2022**OSHA 300A Annual Submission****Driver Policy****COVID-19 ETS** *authored by Rick Schweitzer and Marilyn Dempsey***OSHA 300A Annual Submission**

The new year is here and it's time to gather your workplace illness and injury data to complete the OSHA 300A. Last January (2021), I wrote on the submission process and that article can be reviewed on the GAWDA website/Members only documents/ Safety Organizer January 2021.

OSHA 300A records are generally reviewed by an inspector and there can be five common mistakes:

1. Combining locations onto one OSHA 300A. Each physical location must have an OSHA 300A completed and posted.
2. If a location is opened anytime during the year, a 300A must be completed and posted; even if it is opened on the last day of the year.
3. If a location is closed anytime during the year then a 300A is NOT required to be completed.
4. If a signature from a company executive does not sign the form.
5. The 300A form must be posted from Feb 1 to Apr 30 each year, even if filed electronically.
6. The 300A form must be posted in an area where employees are likely to view it; e.g. next to the OSHA safety posters or time clock.



Driver Policies

Companies generally consider fleet exposure for commercial motor vehicles, with little attention to employees driving personal vehicles for company business; however, the same safety issues, liability and risk apply to these vehicles. Just because someone (e.g. sales, administrative or executive personnel) has a driver's license does not mean they are a safe driver, operate a safe vehicle or have adequate insurance coverage. Companies may want to consider managing the risk through a Safe Driver Program that includes both CMV drivers and other employees who drive on company business.

Program Components:

1. Safe Driving Policy - outlining the expectations, responsibilities and consequences for operating a vehicle on company business.
2. Safe Driving Promise - a commitment by the employee to operate a vehicle safely. This is not a rule from the company but a promise from the driver.
3. Annual Motor Vehicle Reports (MVR) supplied by employee as part of an annual drive performance review.
4. Encourage regular maintenance of vehicles
5. Train drivers on:
 - a. Vehicle inspection: tire pressure, adequate tire tread depth, how to check fluids, belt condition, windows, mirrors, lights and warning devices.
 - b. Defensive driving.
 - c. Intentional driving: situational awareness, maintaining adequate space around the vehicle, avoiding pedestrian traffic and parking with a plan.
6. Review Insurance coverage for coverage amounts and the company as additional insured.

Employees who drive for business purposes, operate as “agents of the company.” The company is now responsible for the employee’s behavior - similar to a CMV driver. If the driver is not insured as well as trained - the company may be deemed culpable in the event of an accident.

An employee’s vehicle insurance does not necessarily remove liability from the company. The insurance company may subrogate a claim to the employer if the accident occurred while performing a job function, or if the employee has not informed the insurance company the vehicle is being used for business purposes the insurance company may deny the claim. The employee should have adequate insurance coverage (generally suggested by the company’s insurance carrier) and the company should be listed as an additional insured.

OSHA COVID-19 Vaccination and Testing Emergency Temporary Standard

-- authored by Rick Schweitzer and Marilyn Dempsey

OSHA’s new Emergency Temporary Standard (ETS) will go into effect on January 10, 2021 unless the Supreme Court places a stay on the ETS or rules that OSHA does not have grounds to issue the ETS. The Supreme Court has scheduled oral arguments for January 7 on whether to reinstate the stay while the merits of the challenge is pending. In the meantime, we can take steps in the event the ETS is allowed to go into effect. Currently, OSHA has extended the deadline for compliance with the ETS as follows: January 10 for developing a list of vaccinating/unvaccinated employees, and generating a written policy on how to meet the vaccine/testing mandate; February 9 for requiring all employees be fully vaccinated or submit to weekly COVID testing.

Basic requirements of the COVID-19 ETS:

By January 10, 2022 - Employers with 100, or more, employees must:

1. Determine vaccination status of each employee (see attached form).
2. Collect vaccination information, including date of vaccination, receipt of vaccination and type of vaccine (see attached form).
3. Develop a company policy on vaccination and testing requirements.



Employers that allow employees to undergo weekly testing, rather than receive the vaccine, must begin testing on or before February 9, 2022.

The COVID-19 policy should include:

1. Purpose of the policy.
2. Scope of the policy (what employees are covered and beginning date).
3. Policy statement (include information on vaccination requirement and testing requirements, if you're company chooses that option)
4. Documentation requirements (when reporting necessary, what information is required and proof of vaccination / testing results).
5. Documentation retention (who will retain them, privacy and who has access to the records).
6. Consequences of non-compliance.
7. Validation of information (forms should be reviewed for accuracy and completeness at a regular frequency and the policy should be reviewed annually).

Additionally, a company may consider including mask requirements, cleaning protocols, isolation and quarantine requirements into the policy.

**Best Safety Practices may be found on the Member's Only Section of the GAWDA Website.*

If you have any questions or concerns regarding these topics, or any other DHS,EPA or OSHA topic, please contact:

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Traffic Bulletin

January 2022

Driver Disqualifications and Penalties

This bulletin outlines the penalties and/or suspensions of CDL licenses for certain infractions committed by a driver. Remember, the primary purpose of this regulation is to get drivers convicted of serious violations in either trucks or personal vehicles off the road. There are 4 categories of offenses: major, serious, railroad grade crossing, and violating out-of-service orders.

Disqualification for major offenses:

Table 1 to 383.51

If a driver operates a motor vehicle and is convicted of:	For a first conviction or refusal to be tested while operating a CMV, a person required to have a CLP or CDL and a CLP or CDL holder must be disqualified from operating a CMV for ***	For a first conviction or refusal to be tested while operating a non-CMV, a CLP or CDL holder must be disqualified from operating a CMV for ***	For a first conviction or refusal to be tested while operating a CMV transporting hazardous materials as defined in § 383.5 , a person required to have a CLP or CDL and a CLP or CDL holder must be disqualified from operating a CMV for ***	For a second conviction or refusal to be tested in a separate incident of any combination of offenses in this Table while operating a CMV, a person required to have a CLP or CDL and a CLP or CDL holder must be disqualified from operating a CMV for ***	For a second conviction or refusal to be tested in a separate incident of any combination of offenses in this Table while operating a non-CMV, a CLP or CDL holder must be disqualified from operating a CMV for ***
1) Being under the influence of alcohol as prescribed by State law.	1 year	1 year	3 years	Life	Life
2) Being under the influence of a controlled substance.	1 year	1 year	3 years	Life	Life
3) Having an alcohol concentration of .04 or greater while operating a CMV.	1 year	Not applicable	3 years	Life	Not applicable
4) Refusing to take an alcohol test as required by a State or jurisdiction under its implied consent laws or regulations as defined in 383.72 of this part.	1 year	1 year	3 years	Life	Life



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5) Leaving the scene of an accident.	1 year	1 year	3 years	Life	Life
6) Using the vehicle to commit a felony, other than a felony described in paragraph (b)(9) of this table	1 year	1 year	3 years	Life	Life
7) Driving a CMV when, as a result of prior violations committed operating a CMV, the driver's CLP or CDL is revoked, suspended, or cancelled, or the driver is disqualified from operating a CMV.	1 year	Not applicable	3 years	Life	Not applicable
8) Causing a fatality through the negligent operation of a CMV, including but not limited to the crimes of motor vehicle manslaughter, homicide by motor vehicle and negligent homicide.	1 year	Not applicable	3 years	Life	Not applicable
9) using the vehicle in the commission of a felony involving manufacturing, distributing, or dispensing a controlled substance.	Life-not eligible for 10 year reinstatement	Life-not eligible for 10 year reinstatement	Life-not eligible for 10 year reinstatement	Life-not eligible for 10 year reinstatement	Life-not eligible for 10 year reinstatement
(10) Using a CMV in the commission of a felony involving an act or practice of severe forms of trafficking in persons, as defined and described in 22 U.S.C. 7102(11) Life - not eligible for 10-year reinstatement Not applicable Life - not eligible for 10-year reinstatement Life - not eligible for 10-year reinstatement Not applicable.	(10) Using a CMV in the commission of a felony involving an act or practice of severe forms of trafficking in persons, as defined and described in 22 U.S.C. 7102(11) Life - not eligible for 10-year reinstatement Not applicable Life - not eligible for 10-year reinstatement Life - not eligible for 10-year reinstatement Not applicable.	(10) Using a CMV in the commission of a felony involving an act or practice of severe forms of trafficking in persons, as defined and described in 22 U.S.C. 7102(11) Life - not eligible for 10-year reinstatement Not applicable Life - not eligible for 10-year reinstatement Life - not eligible for 10-year reinstatement Not applicable.	(10) Using a CMV in the commission of a felony involving an act or practice of severe forms of trafficking in persons, as defined and described in 22 U.S.C. 7102(11) Life - not eligible for 10-year reinstatement Not applicable Life - not eligible for 10-year reinstatement Life - not eligible for 10-year reinstatement Not applicable.	(10) Using a CMV in the commission of a felony involving an act or practice of severe forms of trafficking in persons, as defined and described in 22 U.S.C. 7102(11) Life - not eligible for 10-year reinstatement Not applicable Life - not eligible for 10-year reinstatement Life - not eligible for 10-year reinstatement Not applicable.	(10) Using a CMV in the commission of a felony involving an act or practice of severe forms of trafficking in persons, as defined and described in 22 U.S.C. 7102(11) Life - not eligible for 10-year reinstatement Not applicable Life - not eligible for 10-year reinstatement Life - not eligible for 10-year reinstatement Not applicable.



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Disqualification for serious traffic offenses:

Table 2 to 383.51

If the driver operates a motor vehicle and is convicted of:	For a second conviction of any combination of offenses in this Table in a separate incident within a 3-year period while operating a CMV, a person required to have a CLP or CDL and a CLP or CDL holder must be disqualified from operating a CMV for * * *	For a second conviction of any combination of offenses in this Table in a separate incident within a 3-year period while operating a non-CMV, a CLP or CDL holder must be disqualified from operating a CMV, if the conviction results in the revocation, cancellation, or suspension of the CLP or CDL holder's license or non-CMV driving privileges, for * * *	For a third or subsequent conviction of any combination of offenses in this Table in a separate incident within a 3-year period while operating a CMV, a person required to have a CLP or CDL and a CLP or CDL holder must be disqualified from operating a CMV for * * *	For a third or subsequent conviction of any combination of offenses in this Table in a separate incident within a 3-year period while operating a non-CMV, a CLP or CDL holder must be disqualified from operating a CMV, if the conviction results in the revocation, cancellation, or suspension of the CLP or CDL holder's license or non-CMV driving privileges, for * * *
(1) Speeding excessively, involving any speed of 24.1 kmph (15mph) or more above the posted speed limit***	60 days	60 days	120 days	120 days
(2) Driving recklessly, as defined by State or local law or regulation, including but, not limited to, offenses of driving a motor vehicle in willful or wanton disregard for the safety of persons or property***	60 days	60 days	120 days	120 days
(3) Making improper or erratic traffic lane changes***	60 days	60 days	120 days	120 days
(4) Following the vehicle ahead too closely ***	60 days	60 days	120 days	120 days



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(5) Violating State or local law relating to motor vehicle traffic control (other than a parking violation) arising in connection with a fatal accident ***	60 days	60 days	120 days	120 days
(6) Driving a CMV without obtaining a CLP or CDL.	60 days	Not applicable	120 days	Not applicable
(7) Driving a CMV without a CLP or CDL in the driver's possession ¹ .	60 days	Not applicable	120 days	Not applicable
(8) Driving a CMV without the proper class of CLP or CDL and/or endorsements for the specific vehicle group being operated or for the passengers or type of cargo being transported.	60 days	Not applicable	120 days	Not applicable
(9) Violating a State or local law or ordinance on motor vehicle traffic control prohibiting texting while driving a CMV. ²	60 days	Not applicable	120 days	Not applicable
(10) Violating a State or local law or ordinance on motor vehicle traffic control restricting or prohibiting the use of a hand-held mobile telephone while driving a CMV. ²	60 days	Not applicable	120 days	Not applicable

- 1 Any individual who provides proof to the enforcement authority that issued the citation, by the date the individual must appear in court or pay any fine for such a violation, that the individual held a valid CDL on the date the citation was issued, shall not be guilty of this offense.
- 2 *Driving, for the purpose of this disqualification*, means operating a commercial motor vehicle on a highway, including while temporarily stationary because of traffic, a traffic control device, or other momentary delays. Driving does not include operating a commercial motor vehicle when the driver has moved the vehicle to the side of, or off, a highway and has halted in a location where the vehicle can safely remain stationary.



Traffic Bulletin

Disqualification for railroad-highway grade crossing offenses:

Table 3 to 383.51

If the driver is convicted of operating a CMV in violation of a Federal, State or local law because...	For a first conviction a person required to have a CLP or CDL and a CLP or CDL holder must be disqualified from operating a CMV for ***	For a second conviction of any combination of offenses in this Table in a separate incident within a 3-year period, a person required to have a CLP or CDL and a CLP or CDL holder must be disqualified from operating a CMV for ***	For a third or subsequent conviction of any combination of offenses in this Table in a separate incident within a 3-year period, a person required to have a CLP or CDL and a CLP or CDL holder must be disqualified from operating a CMV for ***
(1) The driver is not required to always stop, but fails to slow down and check that tracks are clear of an approaching train ***	No less than 60 days	No less than 120 days	No less than 1 year
(2) The driver is not required to always stop, but fails to stop before reaching the crossing, if the tracks are not clear ***	No less than 60 days	No less than 120 days	No less than 1 year
(3) The driver is always required to stop, but fails to stop before driving onto the crossing	No less than 60 days	No less than 120 days	No less than 1 year
(4) The driver fails to have sufficient space to drive completely through the crossing without stopping ***	No less than 60 days	No less than 120 days	No less than 1 year
(5) The driver fails to obey a traffic control device or the directions of an enforcement official at the crossing ***	No less than 60 days	No less than 120 days	No less than 1 year
(6) The driver fails to negotiate a crossing because of insufficient undercarriage clearance ***	No less than 60 days	No less than 120 days	No less than 1 year



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Disqualification for violating out-of-service orders:

Table 4 to 383.51

If the driver operates a CMV and is convicted of ...	For a first conviction while operating a CMV, a person required to have a CPL or CDL and a CPL or CDL holder must be disqualified from operating a CMV for ...	For a second conviction in a separate incident within a 10-year period while operating a CMV, a person required to have a CPL or CDL and a CPL or CDL holder must be disqualified from operating a CMV for ...	For a third or subsequent conviction in a separate incident within a 10-year period while operating a CMV, a person required to have a CPL or CDL and a CPL or CDL holder must be disqualified from operating a CMV for ...
(1) Violating a driver or vehicle out-of-service order while transporting nonhazardous materials...	No less than 180 days or more than 1 year	No less than 2 years or more than 5 years	No less than 3 years or more than 5 years
(2) Violating a driver or vehicle out-of-service order while transporting hazardous materials as defined in 383.5, or while operating a vehicle designed to transport 16 or more passengers, including the driver...	No less than 180 days or more than 2 years	No less than 3 years or more than 5 years	No less than 3 years or more than 5 years

If there are any questions, please contact:

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Medical, Food/Beverage and Specialty Gases Bulletin

01/01/2022

GAWDA Medical Gas SOP Program – 2022 Update

The GAWDA Medical Gas SOP Program undergoes continuous improvement via the SOP request and deviation process. We will issue formal, annual updates in January of each year. These updates are available as individual procedures or as a digitally signed and customized, secure PDF file.

If you subscribe to the GAWDA Medical Gas SOP Program, be sure to join us during the GAWDA Medical Gas roundtable on 1/28/2022. We will be sending out invitations to log into the Roundtable. During the Roundtable, we will be covering the update process and conducting documented training on the SOP changes. This will be recorded so you can use the presentation to train your personnel later.

If your company subscribes to the GAWDA Medical Gas SOP Program and you are not receiving invitations to the Roundtable, please notify tom@asteriskllc.com.

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 submitting your information to the FDA, please contact jodie@asteriskllc.com.

FDA Compliance ToDo List

1. **Food Supplier Qualification** – Obtain a certificate of Conformance from your bulk food gas suppliers.
 - a. Assure that your bulk product meets one of the following grades:
 - i. For Carbon Dioxide –
 - FCC (Food Chemical Codex)
 - CGA G-6.2 Commodity Specification for Carbon Dioxide QVL H or I
 - ISBT (International Society of Beverage Technologists)
 - ii. For Nitrogen –
 - FCC
 - NF (National Formulary)
 - ISBT
 - CGA G-10.1 Commodity Specification for Nitrogen QVL B



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- iii. Other gases
 - FCC (Food Chemical Codex)
 - Another acknowledged food specification
 - b. Verify that your supplier is registered with the FDA for food production
 - c. Document your food/beverage gas supplier qualification in accordance with CGA F-3 and GAWDA sample supplier qualification procedures and checklist. See the following sections in the sample SOPs:
 - i. 6.60 Product Supplier Qualification Evaluation
 - ii. 6.61 Bulk Supplier Quality Agreement (One Way) Form (example)
 - iii. 8.2 Supply-chain program
 - iv. 8.2.1 Product supplier qualification requirements
 - v. 8.2.2 Supplier status
 - vi. 8.2.3 Supplier verification activities and evaluation tools
2. **Medical Gas Supplier Qualification** – assure that your
- a. Contract actually specifies USP/NF (Medical Gas)
 - b. Supplier is registered with the FDA and licensed in your state
 - c. Supplier has a valid NDA (New Drug Application) and NADA (New Animal Drug Application)
 - d. Assess the type of verification needed for your incoming medical gas
 - e. Document the existence of a “Quality Agreement” with your supplier
 - f. Document your medical gas supplier qualification in accordance with CGA M-7. If you subscribe to the GAWDA Medical Gas SOP Program, see the following
 - i. E 105 Bulk Supplier Approval
 - ii. E 105 a1 Supplier Agreement Letter
 - iii. E 105 a2 Annual Supplier Quality Review
 - iv. E 105 a3 Supplier Quality Risk Assessment

Contact tom@asteriskllc.com for checklists and sample procedures to qualify your supplier in accordance with current FDA expectations.

GAWDA Professional Compliance Seminars - 2022

March 1 - 3

Audit Excellence



Medical, Food/Beverage and Specialty Gases Bulletin

January Medical Gas Roundtable (28 January 2022)

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In this roundtable, we will cover **Practical validation for the cylinder plant**:

- 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 that day:

- **Specialty Gas** - Gas Chromatograph Method Development & Analytical Math
- **Food Gas Roundtable** – Allergen Awareness & Personal Hygiene

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 tom@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. **Quality Control Unit Training** – Verify that your QCU has received CGMP training within the last year. This training should be documented. The GAWDA Medical Gas Roundtables are examples of CGMP training.
2. **Personnel Training** – Verify that your operations personnel and drivers have received documented CGMP and function specific training.

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