GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

JANUARY 2021

ENCLOSED

Safety Topic

OSHA Injury/Illness Year End Summary: OSHA 300A

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

Traffic Bulletin

Roadside Inspections

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. GAWDA Medical Gas SOP Program – 2021 Update
2. Safety Posters
3. FDA Compliance To Do List
4. GAWDA Professional Compliance Seminars 2021 (3/22-25 & 10/25-29); January Medical Gas Roundtable (1/29/2021): Practical Validation for the Cylinder Plant
5. Micro-Audit Suggestions

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

**** Visit GAWDA's COVID-19 Resource Center at 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.

GASES AND WELDING DISTRIBUTORS ASSOCIATION
One Oakwood Blvd., Suite 195, Hollywood, FL 33020 P(954)367-7728 F(954)367-7790

SAFETY TOPIC

January 2021

Safety Meetings are important!

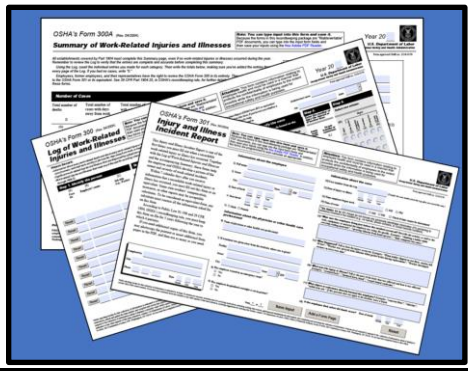
They: get your employees actively involved
encourage safety awareness
help identify problems before they become accidents
motivate employees to follow proper safety procedures

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 2021



OSHA Injury/Illness Year End Summary: OSHA 300A

As March approaches, it is time to prepare your company's OSHA 300A *Summary of Work-Related Injuries and Illnesses*. The OSHA 300A Summary must be completed even if there were NO work-related injuries or illnesses during the calendar year.

Overview for Recording Work-Related Injuries and Illnesses

Work-related Injuries and Illnesses recording process includes THREE forms:

- **OSHA Form 300** – Log of Work-Related Injuries and Illnesses
  any medical treatment beyond First Aid must be recorded on an OSHA 300 Log of Work-Related Injuries and Illnesses.

  What must be recorded?
  - Any medical treatment beyond First Aid must be recorded.
  - Death
  - Loss of consciousness
  - Days away from work
  - Restricted work activity or job transfer

  When?
  - Within 7 days after being informed of injury or illness
  - EXCEPTION:
    - Death - within 8 hours
    - Hospitalization, amputation, loss of eye - within 24 hours

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•**OSHA Form 301** – Injury and Illness Incident Report (or equivalent form) that records The detailed information about an injury /illness. A Worker's Compensation Report of Injury may be equivalent to the OSHA 301 IF the same information is required on the form.

•**OSHA Form 300A** – Summary of Work-Related Injuries and Illnesses
By the end of January, of each year, a summary of Injury and Illnesses (OSHA 300A) must be completed, reviewed, certified and posted (Electronically or Physically)

Physical posting due Feb. 1, 2021
Electronic Submission due March 2, 2020.

Process:

1. **Complete OSHA 300A using data from OSHA 300 log**
2. **End of the year review:**
   - Review the OSHA 300 log for accuracy
   - Correct any mistakes
   - Create the Annual Summary (Form 300A)
   - Certify the summary

3. **Certify the summary**
   - An owner of the company (only if the company is a sole proprietorship or partnership)
   - An officer of the Corporation
   - The highest-ranking company official working at the establishment; *or*
   - The immediate supervisor of the highest-ranking company official working at the establishment

4. **Post OSHA 300A:**
   Physical posting:
   OSHA 300A should be where notices to employees are usually posted.

   Electronic reporting:
   Any employer with establishments with 250 or more employees must report electronically.
   Employers that have 20 or more employees and are deemed to be HIGH RISK by OSHA must also report electronically.

HIGH RISK industries include those companies that fill cylinders, requalified cylinders, sell compressed gases or welding supplies.

NAICS codes of HIGH RISK industries include:
325120 industrial gas manufacturing
423840 industrial supplies Merchant; Welding Supply wholesalers
424690 welding gases, other chemical and Allied products Merchant Wholesalers
454390 other direct selling establishments.

Complete OSHA list of NAICS codes that must file electronically (20-250 employees)

COVID-19

Due to the COVID-19 pandemic, there is an additional burden to prove an employee did not contract an illness at work. OSHA requires an employer to conduct an investigation of all employee reported cases of COVID-19.

CAUTION: Some states have placed a higher burden on the employer to prove a case of COVID-19 was NOT contracted at the worksite, check your State requirements.

General Guidelines for determining Work-related transmission:

Evidence that a COVID-19 illness was contracted at work, if there is no other alternative explanation, other than:

1. Workers work closely together
2. Illness occurred shortly after exposure to a particular customer or co-worker with COVID-19 (aggregate exposure time of 15 minutes)
3. Employee's job duties have frequent, close exposure to the general public in an area with ongoing community transmission

NOT WORK-RELATED IF:

Only worker to contract COVID-19 in her vicinity and job duties do not include frequent contact with general public

if employee closely and frequently associates with someone who

1. Has COVID-19
2. Is not a coworker
3. Exposes the employee during the period the person is infectious

Revised Enforcement Guidance for Recording Cases of Coronavirus Disease 2019 (COVID-19), (Effective May 19, 2020).

1. The case is a confirmed case of COVID-19, as defined by the Centers for Disease Control and Prevention (CDC);[2]
2. The case is work-related as defined by 29 CFR § 1904.5;[3] and
3. The case involves one or more of the general recording criteria set forth in 29 CFR § 1904.7.[4]

[1] Memorandum from Lee Anne Jillings & Patrick J. Kapust, OSHA, "Enforcement Guidance for Recording Cases of Coronavirus Disease 2019 (COVID-19)," Apr. 10, 2020, www.osha.gov/memos/2020-04-10/enforcement-guidance-recording-cases-coronavirus-disease-2019-COVID-19.

[2] A confirmed case of COVID-19 means an individual with at least one respiratory specimen that tested positive for SARS-CoV-2, the virus that causes COVID-19. *See* www.cdc.gov/coronavirus/2019-ncov/php/reporting-pui.html.

[3] Under 29 CFR § 1904.5, an employer must consider an injury or illness to be work-related if an event or exposure in the work environment (as defined by 29 CFR § 1904.5(b)(1)) either caused or contributed to the resulting condition or significantly aggravated a pre-existing injury or illness. Work-relatedness is presumed for injuries and illnesses resulting from events or exposures occurring in the work environment, unless an exception in 29 CFR § 1904.5(b)(2) specifically applies. *See* www.osha.gov/laws-regs/regulations/standardnumber/1904/1904.5. As discussed below, OSHA is exercising enforcement discretion regarding work-relatedness in the context of employee COVID-19 illness.

[4] Under 29 CFR § 1904.7, an employer must consider an injury or illness to meet the general recording criteria, and therefore to be recordable, if it results in any of the following: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness. An employer must also consider a case to meet the general recording criteria if it involves a significant injury or illness diagnosed by a physician or other licensed health care professional, even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness. *See* www.osha.gov/laws-regs/regulations/standardnumber/1904/1904.7.

If you have any questions, please contact me.

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Traffic Bulletin

January 2021

Roadside Inspections

Roadside Inspections §396.9

Authorized state and Federal Motor Carrier Safety Administration officials perform inspections of motor vehicles on the highway, and in certain instances, at terminals. Motor vehicles likely to cause an accident or breakdown will be placed out of service. Vehicles declared out of service must not be operated, and the "Out of Service" vehicle sticker shall not be removed, until all required repairs have been satisfactorily completed.

Out–of–Service Criteria

Most states and provinces use the “North American Standard Out–of–Service Criteria”, which was developed by the Commercial Vehicle Safety Alliance. It identifies critical vehicle inspection items and provides criteria for placing a vehicle out of service. No motor carrier shall require or permit any person to operate nor shall any person operate any motor vehicle declared and marked "out of service" until all repairs required by the "out of service notice" have been satisfactorily completed.

Penalties for Violating the OSS Order

A driver who is convicted of violating an out-of-service order shall be subject to a civil penalty of not less than $1,100 nor more than $2,750, in addition to disqualification under §383.51(e).

If a driver operates a CMV and is convicted of…	For a first conviction while operating a CMV, a person required to have a CDL and a 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 CDL and a 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 CDL and a 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 90 days or more than 1 year.	No less than 1 year 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 required to be placarded under part 172, subpart F of this title, 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.

Traffic Bulletin

An employer who is convicted of a violation of §383.37(c) shall be subject to a civil penalty of not less than $2,750 nor more than $11,000.

Roadside Inspection Report

When a driver receives an inspection report from the state or FHWA official at a roadside inspection, the regulations specify the following:

1. The driver shall deliver the report to the motor carrier upon arrival at the next terminal or facility. If the driver is not scheduled to arrive at a terminal or facility within 24 hours, he/she shall immediately mail the report to the carrier.
2. Motor carriers shall correct all defects noted.
3. A motor carrier official is to certify on the form that violations have been corrected and mail the completed form to the address shown. This must be done within 15 days following the date of the inspection.

Motor Carrier Retention of Report

The motor carrier must retain a copy of the completed form at its principal place of business, or where the vehicle is housed, for 12 months.

A recommendation would be to file these in one of two ways.

1. Keep the roadside inspection forms in each respective vehicle maintenance file, or
2. Keep a separate file folder titled something like “Roadside Inspection Reports” and keep all of them in there.

Another recommendation is to staple a copy of any repair invoices to the back of the roadside inspection report if you had to make any repairs and you had to use an outside service to make the repairs. DOT will sometimes review your completed roadside inspection reports and ask for proof of repairs on reports sent in with the certification that the repairs have been completed.

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

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Email: MLDSafety@hotmail.com

Medical, Food/Beverage and Specialty Gases Bulletin

01/01/2021

GAWDA Medical Gas SOP Program – 2021 Update

The GAWDA Medical Gas SOP Program undergoes continuous improvement via the SOP request and deviation process (via SOP, "Index 160"). Beginning on 1/29/2021, we will be issuing formal, annual updates. 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 1/29/2021. 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.

Safety Posters Available

The Compressed Gas Association has republished outstanding safety posters that you can download and post in your plant or give to your customers. Most posters are available in English, Spanish and French. Check out: https://www.cganet.com

- SP-1 Safety Poster (Industrial), Valve Protection Caps
- SP-2 Safety Poster (Industrial), Securing Cylinders by Nesting
- SP-3 Safety Poster (Industrial), Oxygen and Oil Don't Mix
- SP-4 Safety Poster (Industrial), The Sleeping Giant
- SP-5 Safety Poster (Industrial), Transfilling Cylinders
- SP-6 Safety Poster (Industrial), Separating Incompatible Gases
- SP-7 Safety Poster (Industrial), Proper Cart Usage for Liquid Cylinders
- SP-8 Safety Poster (Industrial), Wear Recommended Personal Protective Equipment
- SP-9 Safety Poster (Industrial), Enclosed Spaces Can Be Unsafe
- SP-10 Safety Poster (Industrial), Misuse of Adaptors Can Be Dangerous
- SP-11 Safety Poster (Industrial), Plan Your Trip to Avoid a Tip
- SP-12 Safety Poster (End User), Home Oxygen Safety
- SP-13 Safety Poster (End User), Safe Use of Liquid Nitrogen in Food & Beverage Service Environments
- SP-14 Safety Poster (End User), Medical Oxygen Supply Chain
- SP-15 Safety Poster (End User), Safe Handling, Transport, and Use of Dry Ice

Medical, Food/Beverage and Specialty Gases Bulletin

FDA Compliance To Do 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
        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. Suppler 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

Medical, Food/Beverage and Specialty Gases Bulletin

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

GAWDA Professional Compliance Seminars - 2021

March 22 - 26

October 25 – 29

January Medical Gas Roundtable (29 January 2021)

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.

Medical, Food/Beverage and Specialty Gases Bulletin

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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