



AUGUST 2021

ENCLOSED

Safety Topics

Hurricane Preparedness/Flood Emergency Preparedness

Sample Safety Practices: Employee Onboarding; Ladder Safety; Safe Cylinder Handling

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

Traffic Bulletin

Entry Level Driving Training (ELDT) – Becomes effective February 2022

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQs: Liquid Nitrogen in Lab Freezers
2. Recent FDA Observations
3. August Medical Gas Roundtable (8/27/2021) – Subpart G – Packaging and Labeling Control; GAWDA Professional Compliance Training (10/25-29/2021)
4. 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 **August 11th** @ 1PM Eastern.

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 _____

August 2021

This month the topics will focus on Hurricanes and recent publications by the GAWDA Safety Committee. Any of these topics may be used as a safety training or identify training for your employees:

Hurricane Preparedness / Flood Emergency Preparedness
GAWDA Safety Committee - Sample Safety Practices:
Employee Onboarding
Ladder Safety
Safe Cylinder Handling

**Hurricane Preparedness**

Both OSHA and National Weather Service and National Oceanic and Atmospheric Administration (NWS/NOAA) websites have Hurricane preparedness pages. In particular, NWS/NOAA has a preparedness list that can be used for both home and business. The list includes seven Hurricane Preparedness Themes to address when preparing for a hurricane.

1. **Determine your Risk.** This includes five hazards that are often associated with hurricanes: storm surge, tornadoes, rip currents, strong winds and inland flooding.
2. **Develop an Evacuation Plan.** These steps include: determining if the property is in an evacuation zone (and what level zone), have a “go bag” for supplies, follow evacuation orders, plan alternate evacuation routes and plan for pets.



3. Assemble Disaster Supplies such as: food and water, full gas tank, money, medical supplies and prescriptions, radio, batteries and phone chargers.
4. Get an Insurance Checkup before storm season. You should check with your agent and know your policy terms/limitations, keep insurance documents with you and consider flood insurance.
5. Strengthen Your Home/Business including: cover windows, trim trees, secure doors and outdoor items (including cylinders), move vehicles to a safe location and consider lining trucks up next to each other.
6. Help Your Neighbor to prepare, check in after the storm passes and help them evacuate, if necessary.
7. Complete a Written Plan for businesses the Hurricane Preparedness information should be included in the Facility Emergency Action Plan. The plan should include a contact list, what/how to prepare and all personnel (or family members) should be trained on the plan.

Complete instructions, including Hurricane preparedness during COVID-19 and Hurricane tracking are available on the [NWS/NOAA](#) website. The GAWDA Safety Committee has prepared a Sample Safety Practice “Flood Emergency Preparation” that is available on the [GAWDA website/ Members Only Documents/ Sample Safety Practices](#). If you have further questions regarding how to prepare a Hurricane plan for your location, or would like your plan reviewed, please contact [Marilyn Dempsey](#).

Safety Committee - Sample Safety Practices

The GAWDA Safety Committee has reviewed or completed several Sample Safety Practices over the last quarter. This month “Employee Onboarding,” “Ladder Safety,” and “Safe Cylinder Handling” are featured.

Employee Onboarding is a comprehensive list of how to introduce the new employee to your company’s safety and learning culture. This begins with a review of the company’s history, contacts, policies and a tour of the facility. The document then outlines what trainings will apply to the job description of Driver, Inside/Outside Sales, Fill room and Administration/ Support. This list is a best practice from the committee members. It is not meant to cover the specialties of every GAWDA member.



Ladder Safety covers both Straight/Extension ladders and Step ladders. The two types of ladders have different applications and safety requirements that employees should be knowledgeable before using either type of ladder.

Safe Handling of Cylinders is one of the most important factors in our business. Injuries due to cylinder handling include: broken and pinched fingers, tendonitis of the elbow and torn rotator cuffs. These injuries not only make for a “bad day” but often have the employee out (or on modified duty) for weeks or months and significantly impact not only your productivity but also your Workers Compensation insurance “mod” rating for 3 years .

If you ever wondered what the most common practice for cylinder handling in our industry, then take a look at this document. It may not completely fit for your company but will give you foundation to create your policy, SOP and training.

If you have any comments, questions on this article or any other DHS, EPA or OSHA topic, please contact:

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Traffic Bulletin

Traffic Bulletin

August 2021

Entry Level Driving Training (ELDT)

Becomes effective Feb. 7, 2022

DOT website

- New Requirements for Entry-Level Driver Training—Information Available at <https://tpr.fmcsa.dot.gov/>

Final Rule

- Mandated by Congress, final rule issued in 2016 on driver training curriculum for entry-level CDL drivers; applicants for Class A or B CDL, or hazmat endorsements, required to complete knowledge and behind-the-wheel training from an instructor under FMCSA standards; training entities will self-certify compliance.
- List of certified training entities will be listed on FMCSA website on the Training Provider Registry.
- Compliance date extended to February 7, 2022; delay gave FMCSA time to develop the online Training Provider Registry, and States time to modify their information technology systems and procedures to accommodate their receipt of driver specific ELDT data from the TPR.

Who is Subject to ELDT Regulations?

- ELDT regulations establish minimum training requirements for entry-level commercial motor vehicle (CMV) operators in interstate and intrastate commerce who are applying for:
 - A Class A or Class B commercial driver's license (CDL) for the first time;
 - An upgrade of their CDL (e.g., a Class B CDL holder seeking a Class A CDL); or
 - A hazardous materials (H), passenger (P), or school bus (S) endorsement for the first time.
- The requirements do not apply to individuals holding a valid CDL or an H, P, or S endorsement issued prior to February 7, 2022. Individuals who obtain a commercial learner's permit (CLP) before the compliance date of February 7, 2022 are not subject to ELDT requirements as long as they obtain a CDL before the expiration date of the CLP or renewed CLP.



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When are the ELDT Rules Effective?

- Beginning February 7, 2022, applicants must complete the training required in 49 CFR part 380, prior to obtaining any of the following commercial license credentials for the first time: a Class A or Class B commercial driver's license (CDL); an upgrade to a Class B or a Class A CDL; or a hazardous materials (H) endorsement for the first time.
- Driver applicants must obtain training from a training provider listed on the Training Provider Registry.
- States may not issue CDL or HME without verification of training.

Who can be a Training Provider?

- Any entity (motor carrier, vocational or private school, etc.) may be a Training Provider. To be eligible for listing on the Training Provider Registry, an entity must meet the following requirements set forth in 49 CFR § 380.703:
 - Follow a curriculum that meets the applicable criteria in Appendices A-E of Part 380;
 - Use facilities meeting the criteria in § 380.709;
 - Use vehicles meeting the criteria in § 380.711;
 - Use instructors meeting the criteria in § 380.713;
 - Meet recordkeeping requirements in § 380.725;
 - Be licensed, certified, registered, or authorized to provide training in accordance with the applicable laws and regulations of any State where in-person training is conducted.
 - Training providers must attest that they meet the specified requirements. In the event of a FMCSA audit or investigation of the provider, they must supply documentary evidence to verify their compliance. Training providers must continue to meet the eligibility requirements to stay listed on the Training Provider Registry.

Role of State Driver Licensing Agency (SDLA)

- SDLAs must verify that an entry-level driver has completed the required training before allowing the driver to proceed with testing.
- Training provider must submit driver's information to SDLA by midnight of 2nd business day following completion of training.
- The point at which the SDLA must verify completion of entry-level driver training depends on the type of license or endorsement the applicant is seeking.



Traffic Bulletin

SDLA Verification

Type of license or endorsement:	SDLA must verify completion prior to allowing
Class A or Class B commercial driver's license (CDL) Passenger (P) endorsement School bus (S) endorsement	Skills test
Hazardous materials (H) endorsement	Knowledge test

Training Curriculum

- Driver must complete a mandatory theory (knowledge) and behind-the-wheel (BTW) training program to take the skills test for a CDL.
- In the case of a hazardous materials (H) endorsement, the driver must complete mandatory theory (knowledge) training provided by a training provider listed on FMCSA's Training Provider Registry prior to taking the knowledge test for the H endorsement.

Training Specifics

- No minimum number of hours for classroom or behind the wheel training
- Must complete the curriculum areas set out in 49 CFR Part 380
 - Appendix A has CDL Class A curriculum requirements.
 - Appendix E has HME curriculum requirements.
- BTW training must be conducted in the type of vehicle for which CDL is sought (Class A or B)
- Once training is complete, Training Provider submits info to SDLA in the State requested by driver applicant.

What Must Your Company Do?

- You are already required to verify that a driver has a CDL with a valid HME before allowing the driver to operate a commercial motor vehicle with a placarded load of hazmat.
- This rule does not impose new requirements on motor carriers (GAWDA distributors); it simply requires the drivers to meet training standards before obtaining or upgrading a CDL Class A or B or obtaining an initial HME.



Traffic Bulletin

I want to thank Rick Schweitzer for all the above materials.

Extremely helpful advice: If you have any drivers that need to get upgraded on the vehicle class or if you need to make any new drivers out of existing employees or if any driver needs to get a hazmat endorsement for the first time, please do it before Feb. 7, 2022, and you will avoid the new regulations and save a lot of money per driver.

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Medical, Food/Beverage and Specialty Gases Bulletin

08/01/2021

Frequently Asked Questions – Liquid Nitrogen in Lab Freezers

Q – Can I sell medical grade liquid nitrogen (LN₂, NF) for freezers in a lab doing research on stem cells or human/animal tissues?

A – Maybe – There are a few items to consider:

- If the liquid nitrogen never touches the tissue/cells, you can use industrial grade. In this case, the LN₂ is merely a non-contact refrigerant.
- If liquid nitrogen is in contact with the tissues and:
 - the tissues/products will be later used in humans or animals, then the LN₂ should be medical grade. The lab should be licensed/permitted to purchase drugs by the state Board of Pharmacy, Board of Health, etc.
 - the tissues/products will only be used for research, and **not** later used in humans or animals, you can use industrial grade.
- You may also have medically licensed/permitted customers who insist that their application requires medical grade LN₂. We can assume that they know more about their application than we do and, if they have a medical license, we can sell them the medical grade LN₂.

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. 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.

Labels and Labeling

Form 483 Observation-02-03 - Strict control is not exercised over labeling issued for use in drug product labeling operations. Specifically, on ____, I observed two rolls of product identification labels for Carbon Dioxide USP left unattended on a desk in Building ____, which is used for filling compressed Carbon Dioxide USP cylinders and is not a controlled label storage location.

How to prevent this from showing up in your inspection?

Assure medical gas labels are secured.



Medical, Food/Beverage and Specialty Gases Bulletin

GAWDA Professional Compliance Training – HOLD THE DATES

This year, the Fall Professional Compliance Training will be held via Teleconference
October 25 to 29, 2021

August Medical Gas Roundtable (08/27/2021) – Subpart G – Packaging and Labeling Control

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In September we will be discussing labeling issuance, labeling operation and expiration dating regulations and exemptions.

For your information, we are also conducting the following webinars in August:

- **Specialty Gas** - Gas Chromatography Fundamentals
- **Food Gas Roundtable** – Part 117 Subpart C - Reanalysis, Requirements for preventive controls qualified individual and a qualified auditor

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 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. **Portable Oxygen Manifolds** – If you are using a portable oxygen manifold, be sure you have validated and documented the manifold.
2. **Automatic, mechanical or electronic equipment** – Be sure all major equipment used to produce your medical gases are covered in a maintenance program. The equipment that needs calibration should be within the calibration date (gauges, thermometers, etc.).

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