

SAFETY & TECHNOLOGY ORGANIZER

APRIL 2019

ENCLOSED

Safety Topic: Flood Emergency Preparedness

Please contact Mike Dodd, GAWDA DOT, Security, OSHA & EPA Consultant for more information.

Traffic Bulletin: Load Securement

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. Recent FDA Observations: Cryogenic Fill Hose
2. FAQ: What is the Annual Records Review for drug manufacturers?
3. April Medical Gas Roundtable (26 April 2019): CGMP – Supplier Qualification. Specialty Gas – Analytical Method Validation for Medical Gases; Food Gas Roundtable- CGMP Training – 21 CFR 117, Subpart B Current Good Manufacturing Practice §117.10-117.110
4. Micro Audit Suggestions

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

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 _____

April 2019 Safety Topic

Flood Preparedness

The GAWDA Safety Committee has put together sample safety policies. Here is one of the more recent examples:

See Following Page



Flood Emergency Preparedness

(Insert Company Name Here)

PURPOSE	To provide a set of proposed guidelines for emergency preparedness of welding distributors and fill plants in the event of a flood
RESPONSIBILITY	All facility personnel
AUTHORITY	Facility manager and or fill plant manager

1. Personnel Safety

- a. Check with the county planning department and government sites flood maps for risk of flooding in your area
- b. Check your facility as it correlates to nearby bodies of water
- c. Establish an evacuation route that uses higher ground to escape
- d. Establish a meeting place for all personnel
- e. Establish an out of state contact who is not in the immediate area as the person personnel should check in with—this provides one person not in immediate danger to have information for personnel in danger
- f. If you must stay at your location or are trapped, choose the highest point at your facility with an end game escape route
- g. Generate local emergency contact data (phone, e-mail, and text) for municipal, and state agencies.

2. Protection of Assets

- a. Ensure all pertinent documents are kept in a high-water location
- b. Provide off site monitoring of all computers backed up daily
- c. It is suggested that off site monitoring of all camera systems with a backup system is in place
- d. Install an independent power generator in a high-water location
- e. Purchase flood insurance if you are in a flood plain so designated by the flood plain map
- f. Review, at regularly scheduled interval / 60 days prior to renewal, your property, liability and loss of business insurance coverage
- g. Store and constantly refresh insurance contact data
- h. Establish and maintain a backup product supply chain for critical customer deliveries
- i. Establish after hours contacts for emergency contact

The safety of employees and customers takes precedence over all tangible items and facilities.



Again, the purpose of this sample policy is to reduce accidents in the workplace and to provide our members with a template that they can use to write their own safety policy.

Feel free to contact me if you have any questions.

Michael Dodd

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April 2019
Load Securement

Protection against shifting and falling cargo, better known as load securement, is covered in the Code of Federal Regulations sections 393.100-136. The following sections have been selected because they relate to our industry.

393.100 Which types of commercial motor vehicles are subject to the cargo securement standards of this subpart, and what general requirements apply?

- (a) Applicability. The rules in this subpart are applicable to trucks, truck tractors, semitrailers, full trailers, and pole trailers.
- (b) Prevention against loss of load. Each commercial motor vehicle must, when transporting cargo on public roads, be loaded and equipped, and the cargo secured, in accordance with this subpart to prevent the cargo from leaking, spilling, blowing or falling from the motor vehicle.
- (c) Prevention against shifting of load. Cargo must be contained, immobilized or secured in accordance with this subpart to prevent shifting upon or within the vehicle to such an extent that the vehicle's stability or maneuverability is adversely affected.

393.102 What are the minimum performance criteria for cargo securement devices and systems?

- (a) Performance criteria. Cargo securement devices and systems must be capable of withstanding the following three forces, applied separately:
 - (a)(1) 0.8 g deceleration in the forward direction;
 - (a)(2) 0.5 g acceleration in the rearward direction; and
 - (a)(3) 0.5 g acceleration in a lateral direction.
- (b) Performance criteria for devices to prevent vertical movement of loads that are not contained within the structure of the vehicle. Securement systems must provide a downward force equivalent to at least 20 percent of the weight of the article of cargo if the article is not fully contained within the structure of the vehicle. If the article is fully contained within the structure of the vehicle, it may be secured in accordance with § 393.106(b).
- (c) Prohibition on exceeding working load limits. Cargo securement devices and systems must be designed, installed, and maintained to ensure that the maximum forces acting on the devices or systems do not exceed the working load limit for the devices under the conditions listed in paragraphs (a) and (b) of this section.

393.106 What are the general requirements for securing articles of cargo?

- (a) Applicability. The rules in this section are applicable to the transportation of all types of articles of cargo, except commodities in bulk that lack structure or fixed shape (e.g., liquids, gases, grain, liquid concrete, sand, gravel, aggregates) and are transported in a tank, hopper, box or similar device that forms part of the structure of a commercial motor vehicle.
- (b) General. Cargo must be firmly immobilized or secured on or within a vehicle by structures of adequate strength, dunnage or dunnage bags, shoring bars, tiedowns or a combination of these.



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(c) Cargo placement and restraint. (1) Articles of cargo that are likely to roll must be restrained by chocks, wedges, a cradle or other equivalent means to prevent rolling. The means of preventing rolling must not be capable of becoming unintentionally unfastened or loose while the vehicle is in transit.

(c)(2) Articles or cargo placed beside each other and secured by transverse tiedowns must either:

(c)(2)(i) Be placed in direct contact with each other, or

(c)(2)(ii) Be prevented from shifting towards each other while in transit.

(d) Minimum strength of cargo securement devices and systems. The aggregate working load limit of any securement system used to secure an article or group of articles against movement must be at least one-half times the weight of the article or group of articles.

The aggregate working load limit is the sum of:

(d)(1) One-half of the working load limit of each associated connector or attachment mechanism used to secure a part of the article of cargo to the vehicle; and

(d)(2) One-half of the working load limit for each end section of a tiedown that is attached to an anchor point.

The hazardous materials regulations also address load securement for our cylinders.

177.834 General requirements.

(a) Packages secured in a motor vehicle. Any package containing any hazardous material, not permanently attached to a motor vehicle, must be secured against shifting, including relative motion between packages, within the vehicle on which it is being transported, under conditions normally incident to transportation. Packages having valves or other fittings must be loaded in a manner to minimize the likelihood of damage during transportation.

177.840 Class 2 (gases) materials.

(a) Floors or platforms essentially flat. Cylinders containing Class 2 (gases) materials shall not be loaded onto any part of the floor or platform of any motor vehicle which is not essentially flat; cylinders containing Class 2 (gases) materials may be loaded onto any motor vehicle not having a floor or platform only if such motor vehicle be equipped with suitable racks having adequate means for securing such cylinders in place therein. Nothing contained in this section shall be so construed as to prohibit the loading of such cylinders on any motor vehicle having a floor or platform and racks as herein before described.

(a)(1) Cylinders. Cylinders containing Class 2 gases must be securely restrained in an upright or horizontal position, loaded in racks, or packed in boxes or crates to prevent the cylinders from being shifted, overturned or ejected from the motor vehicle under normal transportation conditions. However, after December 31, 2003, a pressure relief device, when installed, must be in communication with the vapor space of a cylinder containing a Division 2.1 (flammable gas) material.



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There is a section above that needs particular emphasis or clarification for our members.

(b) Performance criteria for devices to prevent vertical movement of loads that are not contained within the structure of the vehicle. Securement systems must provide a downward force equivalent to at least 20 percent of the weight of the article of cargo if the article is not fully contained within the structure of the vehicle. If the article is fully contained within the structure of the vehicle, it may be secured in accordance with § 393.106(b).

If you are using pallets that only use gravity to hold them onto the vehicle then you would not be meeting the 20% downforce requirement. So several methods have been devised to accomplish this. I have seen hooks and strapping, clevis pins, and swinging bars used to secure the pallet to the vehicle.

If you are using carts to hold small cylinders or medical cylinders, then you need something to keep the cylinders in the carts besides just gravity. You can use rotating bars on the top of the carts, covers, or straps to secure the cylinders into the carts.

Most of our members use web straps to secure the cylinders to the vehicle. These should be continually inspected for wear and tear. The rejection criteria require web straps to be removed from service when there is damage of more than 25% of the width of the strap. The strap attachment devices (hooks, chains, clips, etc.) should also be checked.

For more details and suggestions please see the Load Securement sample safety practice that we have posted on the members only portion of the GAWDA website. If you have trouble accessing this just ask me and I will forward you a copy.

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

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin 04/01/2019

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.

Cryogenic Fill Hose

Form 483 Observation-03-02 - Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not followed. Specifically,

- A. One of the hoses used to fill the Liquid Oxygen USP PLC (portable liquid cryogenic) containers were observed to be located on the floor with the opening of the hose in direct contact to the floor.
- B. You do not use protective end caps on the hoses after they are cleaned which are used during filling operations for the Liquid Oxygen USP product which are located in the ___ Fill Manifold area.

How to prevent this from showing up in your inspection?

Assure cryogenic fill hoses are capped and the ends are not lying on the floor. An effective method to accomplish this is to solder/bolt a hose cap to a post near the cryogenic fill scale. Require operators to fasten the open hose end to the cap after each fill. Be certain that your fill hoses are protected by a relief valve, vent or weep hole to prevent liquid traps. See sample below.



Medical, Food/Beverage and Specialty Gases Bulletin

Frequently Asked Questions

Q – What is the Annual Records Review for drug manufacturers?

A – Per 21 CFR Subpart J, Part 211.180(e), all required written records are to be maintained so that the data can be used for evaluating at least annually, the quality standards of each drug product. This activity is used to identify the need for change in drug product specifications or manufacturing or process control procedures and evaluate impacts to equipment validation status.

We have attached a sample copy of a form to document the Annual Records Review at the end of this Medical Gas Bulletin. This is a simple process and has recently been mentioned during FDA investigations.

April Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, April 26, we will cover **CGMP – Supplier Qualification**. This will cover the recent FDA expectations for verifying that your bulk products have been produced by a properly “certified” original manufacturer. We also will have new procedures and forms to assist in your supplier qualification effort.

In addition, we will be conducting the following additional training on April 28:

- **Specialty Gas** - Analytical Method Validation for Medical Gases
- **Food Gas Roundtable** –
 - CGMP Training – 21 CFR 117, Subpart B Current Good Manufacturing Practice §117.10-117.110
 - The latest information about food gas regulations is reviewed –
 - The 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.

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. **Annual Record Review** – Verify that you have conducted and documented an annual records review for your medical gas production facility. See the last page for a sample form to easily document this requirement.
2. **Food Receipts** – Be sure that your food gas bulk receipt paperwork documents that you are receiving food or beverage grade product into your bulk tanks which are used to produce food gases (especially CO₂ and N₂)
3. **Food Lot Numbers** – Be sure you are using lot numbers on food grade gases. You must also have a lot number record of food gas shipments. This lot number record may be kept electronically.

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Sample document for the Annual Records Review

Annual Records Review

Product: _____

21 CFR Subpart J-Records and Reports - 211.180(e) General requirements.

Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

- (1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch.*
- (2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.*

1. Were records found to be readily accessible?

Yes _____ or No _____

2. Which batch production and control records were reviewed?

3. Which Lot Distribution and Shipping Records were reviewed?

4. Were the critical equipment validation status, changes (MOC), complaint file, recalls, investigation and deviation records reviewed?

Yes _____ or No _____

5. Are changes needed in drug product specifications or manufacturing or control procedures to ensure processes remain in control?

Yes _____ or No _____

6. Enter the date and name of the person conducting the Annual Records Review:

Date

Name (signature)