GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

APRIL 2020

ENCLOSED

Safety Topic

Safety & Regulatory Update – Corona Virus (COVID-19)

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

Traffic Bulletin

Web Strap Inspection Guidelines

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

Medical, Food/Beverage and Specialty Gases Bulletin

1. Frequently Asked Questions – Converting Industrial Grade Cylinders to Medical Grade
2. Recent FDA Observations
3. April Medical Gas Roundtable: CGMP – Supplier Qualification (CGA M-7)
4. Training Webinars: April 24 - Specialty Gas; Food Gas Roundtables
5. Micro-Audit Suggestions

Please contact Tom Badstubner, GAWDA FDA Food, Medical & 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.

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

SAFETY TOPIC

February 2020

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 _____

Safety & Regulatory Update

Corona Virus (COVID-19)

OSHA has ruled that COVID-19 can be a recordable illness if a worker is infected as a result of performing their work-related duties. However, employers are only responsible for recording cases of COVID-19 if all of the following are met:

1. The case is a confirmed case of COVID-19 (individuals with at least one respiratory specimen that tested positive for the virus that causes COVID-19) (see CDC information).
2. The case is work-related, as defined by 29 CFR 1904.5.
3. The case involves one or more of the general recording criteria set forth in 29 CFR 1904.7 (e.g., medical treatment beyond first-aid, days away from work).

It will be difficult to prove work-relatedness because COVID-19 is highly communicable and wide spread. Our employees, unlike medical personnel (who have direct contact with known COVID-19 patients) do not have direct work with people who have confirmed COVID-19 infection.

However, it is vitally important that preventative measures are taken. Personal protective equipment and social distancing are two easy items to reinforce with your personnel. Several other measures are listed in the GAWDA Safety Alert 20 March 2020, based on exposure stages: Stage 1 - Pandemic declared; Stage 2 - Customer with Infection on site; Stage 3 - Presumptive infection at your location; Stage 4 - Confirmed infection. The Safety Alert, found on the bottom of the GAWDA website page, and employing Management by Walking Around (MBWA) equips you with the tools to implement and the opportunity (MBWA) to calm fears.

If there are questions or items that I can help you with, please contact me.

Marilyn R. Dempsey
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Traffic Bulletin

April 2020

Web Strap Inspection Guidelines

Have you checked your load securement straps lately? Many times, our drivers are using straps that should be taken out of service. This results in DOT out of service orders and possibly penalties. It has also resulted in personal injuries to employees while tightening the straps.

Pre-operational checks are required for all ratchet mechanisms, binders, and straps to ensure safe and proper working condition. The Commercial Vehicle Safety Alliance (CVSA) has the following Out-of-Service criteria for synthetic webbing straps:

- Knot(s)
- More than 25 percent of stitches separated
- Broken/damaged hardware
- Any repair or splice
- Overt damage
- Severe abrasion cumulatively for entire working depth of strap
- Cuts/burns/holes exceeding width of ¾ inch for 4-inch wide webbing, exceeding a width of 5/8 inch for 3-inch wide webbing or 3/8 inch for 1 ¾ -inch wide or 2-inch webbing. **Defects through the webbing are additive across the width of the strap face for its entire effective length.**

Feel free to contact me if you have questions.

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Medical, Food/Beverage and Specialty Gases Bulletin

Medical Gas Bulletin
04/01/2020

Frequently Asked Questions – Color Coding Medical Gases

Q – How can I convert industrial grade Oxygen cylinders to medical grade oxygen cylinders?

A - You can convert industrial to medical grade oxygen. The details are in CGA M-18, *Standard for the Change of Product and Change of Grade for High Pressure and Refrigerated Liquid Containers*. See https://portal.cganet.com/Publication/Details.aspx?id=M-18 This publication is **free** to GAWDA members by subscribing to the free CGA/GAWDA Safety Program. It is quick and easy to subscribe: https://www.gawda.org/resources/cga-subscription-program/

Check out section 6.2 in CGA M-18. It lists the process steps for converting from industrial grade to medical grade oxygen service for high pressure cylinders:

- Identification
- Odor test
- Valve removal, internal inspection and revalving
- Purging/evacuation/pressurization
- Filling
- Testing for conformance

See M-18 for the important details/specifications of each step.

M-18 also has instructions for changing the grade on liquid, cryogenic containers.

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.

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.

Medical, Food/Beverage and Specialty Gases Bulletin

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.

April Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. On Friday, April 24, we will cover **CGMP – Supplier Qualification (CGA M-7)**. 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.

Medical, Food/Beverage and Specialty Gases Bulletin

In addition, we will be conducting the following additional training on April 24:

- **Specialty Gas -** Gas Chromatograph Troubleshooting
- **Food Gas Roundtable** –
    - CGMP Training – 21 CFR 117, Subpart C – HARPC
    - 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 CO_2 and N_2)
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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Medical, Food/Beverage and Specialty Gases Bulletin

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)

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