GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

SAFETY & TECHNOLOGY ORGANIZER

DECEMBER 2016

ENCLOSED

Safety Topic: Top 10 OSHA Citations

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

Traffic Bulletin: SP-14175, the 10 Year Retest on Clusters

Please contact Mike Dodd for more information.

Medical Gas Bulletin:

1. FDA Compliance ToDo List
2. Frequently Asked Questions – Drug Establishment Registration
3. Medical Gas Roundtable (12/23/16) Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products.
3. Webinars: ISO 17025 - ISO 17025 - Propagation of Errors (developing an uncertainty budget); Specialty Gas - Gas Chromatography Fundamentals
4. Food Gas Roundtable –21 CFR Part 117 - Subpart G - Supply-Chain Program
5. Micro Audit Suggestions

Please contact GAWDA Medical Gas Consultant, Tom Badstubner 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
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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 _____

Top 10 OSHA Citations

The following data was taken from the OSHA website:
http://www.osha.gov/pls/imis/citedstandard.html

You can plug in the number of employees in a location and the NAISC code of the business and get the top cited items by OSHA in the past year. I plugged in 1-99 employees to see what happens and I got the following information. The good news is that our industry is not getting a lot of inspections, but there are still some dollars being assessed for the citations they are finding.

Listed below are the standards which were cited by **Federal OSHA** for the specified NAISC during the period October 2015 through September 2016.

423830 *Industrial Machinery and Equipment* (this would our distributor locations with welding supplies as the primary sales)

Standard	#Cited	#Insp	$Penalty	Description
19100134	13	2	$3,150	Respiratory Protection.
19100178	9	3	$11,525	Powered industrial trucks.
19260501	6	1	$294,000	Duty to have fall protection.
19100177	5	1	$62,355	Servicing multi-piece and single piece rim wheels.
19101200	4	2	$1,750	Hazard Communication.
19100107	3	1	$1,050	Spray finishing using flammable and combustible materials.
19100147	3	2	$4,900	The control of hazardous energy (lockout/tagout).
19100133	2	2	$4,350	Eye and face protection.
19100184	2	1	$2,800	Slings.
19100252	2	1	$7,000	General requirements.

424690 *Chemicals and Allied Products, Not Elsewhere Classified* (this would be cylinder fill plants or locations where gas sales outweigh the hardgoods sales)

Standard	#Cited	#Insp	$Penalty	Description
19100119	42	2	$203,310	Process safety management of highly hazardous chemicals.
19100147	8	2	$4,350	The control of hazardous energy (lockout/tagout).
19100132	5	4	$6,195	General requirements.
19100178	4	3	$3,430	Powered industrial trucks.
19100024	2	1	$0	Fixed industrial stairs.
19100103	2	1	$12,471	Hydrogen.
19100303	2	2	$3,150	General requirements.
19100305	2	1	$2,499	Wiring methods, components, and equipment for general use.
19100307	2	1	$6,300	Hazardous (classified) locations.
19101000	2	1	$17,958	Air contaminants.

Please note that the Hazardous Communication Program and forklifts (Powered Industrial Trucks) are always near the top on citations.

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

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Traffic Bulletin

December 2016

SP-14175, the 10 Year Retest on Clusters

Here is a helpful item for anyone that uses clusters, 12 packs, 6 packs, banks, or whatever else you may call them. For all these years, we have had to do the cylinder requalification on a 5-year schedule. Wouldn't you love to be able to do the retest on these cylinders every 10 years? Think of the savings on the hydrotest and the labor needed to take apart and rebuild the packs.

There is a special permit (SP-14175) that allows certain cylinders in certain flammable and nonflammable gases in bundles up to 24 cylinders to go 10 years on the requalification.

Here is a brief recap of the provisions in the special permit:

- The cylinders must be 3A or 3AA
- The gases must be air, argon, helium, hydrogen, oxygen, nitrogen, compressed gas n.o.s. (mixture of hydrogen, argon, helium, oxygen, and / or nitrogen), or compressed gas flammable n.o.s. (mixture of hydrogen, argon, helium, and / or nitrogen)
- The cylinder may be requalified by either the hydrostatic testing and visual inspection or by ultrasonic examination (UE) in accordance with existing DOT special permits. The 10 year requalification period applies only to cylinders that meet all requirements specified in 180.209 (b) except they are not removed from bundles and hammer tested prior to each refill.
- Carbon dioxide in any concentration cannot be added to the cylinders in the bundle.
- Gases that are either toxic and / or corrosive cannot be added to cylinders in the bundle.
- Each cylinder covered by this special permit must be plainly and durable marked "DOT–SP 14175" in proximity to existing DOT markings (near the other stamping on the cylinder shoulder). Additionally, one cylinder on each side of a bundle must be marked with letters at least 1 inch high on a contrasting background.
- You must keep a current copy of this special permit at each location that ships these bundles.

Traffic Bulletin

Please read the entire special permit for all the details and fine print. Also review the Traffic Bulletin from October 2015 for more details and training requirements.

To take advantage of this special permit, you will need to apply to for and receive back from DOT a grantee letter that has your company name listed and then follow the terms of the special permit. To apply for grantee status, follow the instructions found in 49 CFR 107.107 which are very simple to do. I highly suggest that you use the email instructions they provide. You will get your authorization approval back much sooner.

Remember, not everyone gets granted the party to status. If you have never been DOT audited and don't have a satisfactory safety rating or are currently having a problem with your DOT Safety Management System score, then you may either get a visit or denied.

If you need a sample letter for an example of how to do this application, then please contact me.

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Medical Gas Bulletin

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12/01/2016

FDA Compliance ToDo List

Review your FDA Drug Listings – the regulations specify that you review your drug listings twice a year (June and December) and make revisions as needed.

Log on to: http://dailymed.nlm.nih.gov/dailymed/search.cfm. You can enter your NDC Code (Labeler Code) or the product name. Unfortunately a gas like "Oxygen" will yield over 190 search pages. Your previous listings are the easiest places to find the NDC Code.

Review the image of your label and be sure the most recent copy (GHS Compliant) is listed with the FDA. Also verify that the medical gas is assigned to the proper locations.

While you are reviewing your drug listing, be sure the medical gas has the proper Marketing Status. It will be either:

- Unapproved medical gas
- New Drug Application

Your marketing status should be "New Drug Application". If your marketing status is still "Unapproved medical gas", contact your registration agency to have this changed.

If you have any questions about registration or listing, contact tom@asteriskllc.com.

Frequently Asked Questions – Drug Establishment Registration

Q – How can I be sure that all my medical gas manufacturing locations are properly registered with the FDA?

A – The only way you can be completely certain that your registration is current is by logging onto the FDA registration search website: http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm. Enter a portion of your firm's name and press the "Submit Query" button. Your search results will be displayed along with the Expiration Date of your registration.

Medical Gas Bulletin

December Medical Gas Roundtable (12/23/2016) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products.

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In December we will be discussing the various records required by the FDA. In addition, we will have an easy to use handout about how to document your Annual Records Review.

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

- ***ISO 17025* -** ISO 17025 - Propagation of Errors (developing an uncertainty budget)
- ***Specialty Gas*** - Gas Chromatography Fundamentals
- **Food Gas Roundtable** – 21 CFR Part 117 - Subpart G - Supply-Chain Program

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. **Complaints -** Verify that your complaint file has any instances of customers asking for credit because they thought the cylinder was not full. (Even if the complaint was found to be without merit).
2. **QCU Review -** Verify that your QCU reviews all complaints.
3. **Other Lots? –** Be sure your complaint investigations consider whether any other cylinders from the same or different lots should be investigated. Document your decision to not investigate other cylinders/batches on the complaint record.

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