



550 NW LeJeune Road
Miami, FL 33126
(877) 382-6440 p
(305) 442-7451 f
www.gawda.org
gawda@gawda.org

Safety & Technology Organizer for May 2011

ENCLOSED

Safety Topic: "Top 10 OSHA Citations"

Please contact GAWDA's OSHA and EPA Consultant, Mike Dodd for more information.

Traffic Bulletin: "Shipping Papers"

Please contact GAWDA's DOT and Security Consultant, Mike Dodd for more information.

Medical Gas Bulletin: "How to Survive an FDA Audit Training"

Please contact GAWDA Medical Gas Consultant, Tom Badstubner for more information.

May 2011

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



MONTHLY SAFETY TOPIC

ROUTE TO:

- General Manager
- Safety Coordinator
- Supervisor Dept. _____
- Other _____
- Date of Meeting _____

Safety Meetings are important. They 1) get your employees actively involved, 2) encourage safety awareness, 3) help identify problems before they become accidents and 4) motivate employees to follow proper safety meetings and is happy to provide you with a monthly topic for your agenda.

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 SIC 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 SIC during the period October 2009 through September 2010.

5084 Industrial Machinery and Equipment (this would our distributor locations with welding supplies as the primary sales)

Standard	#Cited	#Insp	\$Penalty	Description
19100178	17	7	31435	Powered industrial trucks.
19101200	16	5	5850	Hazard Communication.
19100146	11	2	15000	Permit-required confined spaces
19100037	9	5	2070	Maintenance, safeguards, and operational features for exit routes.
19100305	9	2	7450	Wiring methods, components, and equipment for general use.
19100184	8	3	6500	Slings.
19100134	7	4	4705	Respiratory Protection.
19100106	6	3	4080	Flammable and combustible liquids.
19100212	6	5	8400	General requirements for all machines.
19100179	5	2	0	Overhead and gantry cranes.



5169 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	47	5	344850	Process safety management of highly hazardous chemicals.
19100178	11	3	15225	Powered industrial trucks.
19100120	6	1	4500	Hazardous waste operations and emergency response.
19101200	6	3	1650	Hazard Communication.
19100132	5	4	2588	General requirements.
19040030	4	1	0	Multiple business establishments.
19100134	4	4	1000	Respiratory Protection.
19100151	4	4	1510	Medical services and first aid.
19100022	3	2	2250	General requirements.
19100023	3	2	3250	Guarding floor and wall openings and holes.

Please note that the Hazardous Communication Program and forklifts are always near the top on citations.

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

Michael Dodd
 GAWDA DOT, Security, EPA, & OSHA Consultant
 P.O. Box 93
 Poplar Bluff, MO 63902
 (573) 718-2887
 Email: MLDSafety@hotmail.com

Traffic Bulletin

Traffic Bulletin

May 2011

Shipping Papers

I receive several inquiries per month regarding shipping papers. The Hazardous Materials Regulations (HMR) 172.200 - .205 cover the items required on shipping papers. I cannot discuss the regulations fully due to size constraints of this bulletin, but I do want to discuss items that apply to our members and the 99% of the items we ship on a daily basis.

Although there are exceptions, the Hazardous Materials Regulations (HMR) generally requires each shipment of hazardous materials to be accompanied by properly prepared shipping papers. The shipping paper may be a bill of lading, waybill, manifest, or other document provided it contains all the required information.

I have a good example of a proper shipping paper that I can send you upon request.

Retention 172.201 (e)

The Hazardous Materials Transportation regulations require the retention of shipping papers for a period of two years. This may be a paper copy or an electronic image of the shipping paper. Therefore, you need a date on the paper even though the Hazardous Materials Regulations do not require it.

Continuation Page, 172.201 (c)

A shipping paper may consist of more than one page, if each page is consecutively numbered and the first page bears a notation specifying the total number of pages included in the shipping paper. For example, "Page 1 of 4 pages."

Hazardous/Non-Hazardous Materials, 172.201 (a)(1)

Whenever a shipping paper includes descriptions of both a hazardous material and a non-hazardous material, the description of the hazardous material must be:

- entered first on the shipping papers, or
- identified by an "X" or "RQ" (as appropriate) in a column designated "HM", or
- entered in a color that clearly contrasts with the non-hazardous entry.

Describing Hazardous Materials, 172.202 (a)

Any person who offers a shipment of hazardous materials for transport must describe the hazardous material on shipping papers in a specified manner using the applicable information from the Hazardous Materials Table. At minimum, this shipping description must include the:

1. UN/NA Identification Number
2. Proper Shipping Name
3. Hazard Class and subsidiary hazards shown in column 6 of the hazmat table
4. Packing Group, if required
5. The Total Quantity by net or gross mass, capacity, or as otherwise appropriate.

For cylinders of Class 2 (compressed gases) materials and bulk packagings, some indication of total quantity must be shown (e.g., "10 cylinders" or "1 cargo tank").

Basic Description, 172.202(b)

The first four (4) items — often referred to as the material's basic description — must be shown in sequence, with no additional information interspersed unless authorized by the regulations. The identification number must include the letters "UN" or "NA", as appropriate. The packing group must be shown in Roman numerals and may be preceded by the letters "PG" (e.g., UN 1203, Gasoline, 3, PG II).

Total Quantity and Type of Package, 172.202

The fifth required item, the material's total quantity and type of package, may be placed either before, after, or both before and after the basic description. In addition, it must include the appropriate unit of measure (such as pounds, gallons, kilograms, and liters). Please note that compressed gases do not require a unit of measure. While the regulations do not typically allow abbreviations, they are permitted when specifying the material's weight or volume (lbs, L) or the type of packaging (cyl.).

Shipper's Certification, 172.204

Another required entry on the shipping paper is a certification by the shipper that the shipment is properly classed, described, packed, marked and labeled and in proper condition for transport by a particular mode. For highway transportation this statement must be:

"This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation."

Note: the words "herein-named" may be substituted for the words "above-named".

There is a general certification, an alternate for air transport, a specified statement for radioactive material to be shipped by passenger-carrying aircraft, and a variation of the general certification required by the Environmental Protection Agency (EPA) on the hazardous waste manifest. See 172.204 for examples of these certifications.

This "shipper's certification," however, is not required when the hazardous material is offered for highway transport in a cargo tank supplied by the carrier, or when the material is transported by the shipper, operating as a private carrier – unless the material is to be reshipped or transferred from one carrier to another.

The shipper's certification must be printed manually or mechanically on the shipping paper. The certification must be legibly signed by a principal, officer, partner, or employee of the shipper or his agent. The signature may be manual, by typewriter, or by other mechanical means. PHMSA, in explaining the signature requirements, has noted that a "pre-printed signature is deficient," basically because such a signature is made before the conditions and acts actually exist to which the signature and certification apply.

Additional Shipping Paper Notations, 172.203

N.O.S. Entries 172.203 (k)(1)

If a hazardous material is a mixture or solution of two or more hazardous materials, the technical names of at least two components most predominantly contributing to the hazards of the mixture or solution must be entered on the shipping paper. For example, (UN1956, Compressed Gas, N.O.S., (Argon, Carbon Dioxide), 2.2).

Hazardous Substances/Reportable Quantities

For hazardous substances, which are transported in a quantity in one package at or above their reportable quantities, the letters "RQ" must be entered before or after the basic description, or in the column designated "HM".

Poisonous Materials

For materials which are poisonous by inhalation, the words "Poison-Inhalation Hazard" or "Toxic-Inhalation Hazard," followed by "Zone A, B, C, or D" for gases must be entered after the proper shipping name (e.g., UN1017, Chlorine, 2.3, Toxic Inhalation Hazard, Zone B).

DOT-Special Permits

For shipments made under a special permit, the notation "DOT-SP" followed by the appropriate special permit number must be located on the shipping paper near the description to which it applies. Some DOT exemptions do not require noting the exemption on the shipping paper. You should read the exemption to see if it requires noting on the shipping paper and/or if it requires a copy of the exemption to be carried on the vehicle.

Shipping Paper Accessibility, 177.817(e)

A driver of a motor vehicle containing hazardous material, and each carrier using such a vehicle, shall ensure that the shipping paper required by this section is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically, the driver and the carrier shall:

- Clearly distinguish the shipping paper, if it is carried with other shipping papers or other papers of any kind, by either distinctively tabbing it or by having it appear first; and

- Store the shipping paper as follows:
 - When the driver is at the vehicle's controls, the shipping paper shall be: (A) Within his immediate reach while he is restrained by the lap belt; and (B) either readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle.
 - When the driver is not at the vehicle's controls, the shipping paper shall be: (A) In a holder which is mounted to the inside of the door on the driver's side of the vehicle; or (B) on the driver's seat in the vehicle.

Emergency Response Information, 172.602

Emergency response information specific to the hazardous materials being transported must be presented on the shipping paper or in a separate document in conjunction with the shipping paper. The following information is required, as a minimum, by Part 172, Subpart G:

- description of the hazardous material;
- immediate hazards to health;
- risks of fire or explosion;
- immediate precautions to take in the event of an accident or incident;
- immediate methods for handling small or large fires;
- initial methods for handling spills or leaks in the absence of fire; and
- preliminary first aid measures.

Emergency Response Telephone Number, 172.604

An emergency response telephone number must be entered immediately after the description of the hazardous material, or it may be entered once on the shipping paper in a clearly visible location and indicated that it is for emergency response. This second option can be used only if the telephone number applies to each hazardous material entered on the shipping paper.

Company Name, 172.604

The name of the person, or contract number or other unique identifier assigned by an emergency response information provider, identified with the emergency response telephone number must be entered on the shipping paper immediately before, after, above, or below the emergency response telephone number unless the name is entered elsewhere on the shipping paper in a prominent, readily identifiable, and clearly visible manner that allows the information to be easily and quickly found.

Next month, I will be discussing the typical mistakes found on shipping papers and the different shipping descriptions that have changed over the past few years.

Feel free to contact me if you have questions.

Michael Dodd

GAWDA DOT, Security, EPA, & OSHA Consultant

P.O. Box 93

Poplar Bluff, MO 63902

(573) 718-2887

Email: MLDSafety@hotmail.com

Medical Gas Bulletin

Medical Gas Bulletin

MAY 2011

How to Survive an FDA Audit Training

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In April we covered Subpart E – Control of Components Training. In May, we will cover How to Survive an FDA Audit Training. This training covers the essential items you can do before, during and after an FDA audit to maximize your success.

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

- **Specialty Gas** - Making Your Own Working Standards (Servomex Standards, etc.)
- **Medical Device Gas Compliance** - QSR Subparts G, H, I & J - Production and Process Controls, Acceptance Activities, CAPA, Non-Conforming Product

These and other webinars are available live or 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.

FDA Draft Guidance and USP Update

In 2003, the FDA published the Draft Guidance and solicited industry comments. In each year since 2003, the FDA has indicated that the final guidance for medical gases would be published soon. We believe the final guidance will not be published any time soon.

Similarly, USP has proposed revised medical gas monographs. We made comments to the proposal and expected USP to publish the final medical gas monographs. USP does not seem to be close to publishing the final medical gas monographs.

For now, we recommend using the existing FDA enforcement and USP monographs in your compliance activities. As soon as FDA or USP publishes new monographs or guidance, we will inform GAWDA members. Even when USP/FDA publishes new information we will have plenty of time to make needed changes to our procedures.

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 Records Review** – Verify that you have looked at your records to determine if changes are needed in your medical gas program. This review can be easily completed and documented. Contact Tom if you need a form to document your annual records review.
2. **Electronic Registration and Listing** – Be sure your electronic registration and listing is correct. Print out the web pages with your information below to document your compliance:
Facility Registration - <http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>
Drug Listing - <http://dailymed.nlm.nih.gov/dailymed/search.cfm>

Tom Badstubner
GAWDA Medical Gas Consultant
Telephone: 508-883-0927
Fax: 508-883-3558
Email: tom@asteriskllc.com