

SAFETY & TECHNOLOGY ORGANIZER

AUGUST 2013

ENCLOSED

Safety Topic: “Global Harmonization Systems (GHS)”

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

Traffic Bulletin: “Special Permits”

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

Medical Gas Bulletin: FAQs, Medical Gas Roundtables and Micro-audit

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



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 _____

GLOBAL HARMONIZATION SYSTEM (GHS)

The Globally Harmonized System (GHS) is an international approach to hazard communication, providing agreed criteria for classification of chemical hazards, and a standardized approach to label elements and safety data sheets. The GHS was negotiated in a multi-year process by hazard communication experts from many different countries, international organizations, and stakeholder groups. It is based on major existing systems around the world, including OSHA's Hazard Communication Standard and the chemical classification and labeling systems of other US agencies.

The first compliance date of the revised HCS is December 1, 2013. By that time employers must have trained their workers on the new label elements and the SDS format. Please see the training link below. It will outline the minimum items that need to be covered in your training meeting. Below are several links that will give you the details you need to conduct your training meetings.

- **EFFECTIVE DATES:** <http://www.osha.gov/dsg/hazcom/effectivedates.html>
- **TRAINING REQUIREMENTS:** <http://www.osha.gov/Publications/OSHA3642.pdf>

QUICK CARDS:

- SDS http://www.osha.gov/Publications/HazComm_QuickCard_SafetyData.html
- Pictograms http://www.osha.gov/Publications/HazComm_QuickCard_Pictogram.html
- Labeling http://www.osha.gov/Publications/HazComm_QuickCard_Labels.html
- 9 page OSHA brief on labeling and pictograms
<http://www.osha.gov/Publications/OSHA3636.pdf>

Feel free to contact me on any of these items if you have questions.





TRAFFIC BULLETIN

August 2013

Special Permits

There are basically two kinds of DOT special permits (SP). There are permits for manufacturing packages that are different from approved specifications. There are also permits that let you do things differently than what is found in the published regulations.

On file at each location

If you have a package that has a SP on it, you must have a current copy of the permit on file at the location that ships or requalifies the package. You must follow the requirements outlined in the SP. Some SPs require a copy to be kept on the motor vehicle. It will state this in the SP.

Transporting a Special Permit package

It is possible that if you receive a cylinder that is being operated under a special permit that you can reoffer it for transportation without a grantee letter in your companies name. Example – if Honeywell fills a cylinder under a special permit and you order it from Honeywell you can then take it to your customer by using the Honeywell grantee letter and special permit. The key is that you did not fill the cylinder or modify the package when you shipped or transported it.

If you have to offer a special permit container to a common or contract carrier then you must provide them with a current copy of the special permit at or before the time of shipment. There are a few exceptions to this requirement but 98.5% of the time this requirement will apply.

You must enter the special permit number onto the hazardous material shipping paper in association with the proper shipping name. There are a very few exceptions to this rule but 99% or more of the special permits require this.

Training

All employees that handle the SP package must be trained on the requirements of the SP and the training is required every 3 years. You will need to document this training per 172.704 (d) and here is a brief summary of what you need to document:

- (d)(1) The hazmat employee's name;
- (d)(2) the most recent training completion date of the hazmat employee's training;
- (d)(3) a description, copy, or the location of the training materials used to meet the requirements;
- (d)(4) the name and address of the person providing the training; and
- (d)(5) certification that the hazmat employee has been trained and tested.





TRAFFIC BULLETIN

Do I need to be a “party to” the Special Permit?

If you read item 1. Grantee on the SP and see the words “See individual authorization letter”, then you need to have your company authorized by DOT to be a party to the SP in order to fill or use the SP.

How do I become a “party to” a Special Permit?

In the last few weeks, this has become very easy to do comparison to the old application process. Instead of taking weeks to get your authorization, you can now get it within minutes. Unfortunately, they have made finding the website link difficult to find. Here is where you start the PTE (party to exemption) process:

<http://www.phmsa.dot.gov/portal/site/PHMSA/menuitem.ebdc7a8a7e39f2e55cf2031050248a0c/?vgnextoid=00eaea51ab869310VgnVCM1000009ed07898RCRD&vgnnextchannel=ffe228df28887110VgnVCM1000009ed07898RCRD&vgnnextfmt=print>

You will want to click on the “PTE & Renewal Online Applications” link. It will take you to the PHNSA Portal where you will need to create an account and then log in to the portal. Then you will just answer the questions about becoming a party to a SP. Many of the questions can be skipped because they either don’t apply or are not needed.

Once you have completed the process, you will get email notification that your application has been received and shortly thereafter you will receive your authorization letter.

Your SP is the authorization letter stapled to the top of the SP that you will print off. You keep the two items together as your permit.

Special Permit Renewals

You use the same “PTE & Renewal Online Applications” link above for your renewals. The first permit is issued for 2 years and the renewals are issued for 4 years after that.

It is extremely important that the renewal takes place before the 60 days mentioned above. If you renew less than 60 days before the expiration date, your renewal may be delayed and/or additional questions may come from DOT.

If there are any questions regarding this Bulletin please contact:





MEDICAL GAS BULLETIN

08/01/2013

Frequently Asked Questions

Q – What if I ship some cylinders with an incorrect lot number? Should I recall the cylinders?

A – An incorrect lot number is certainly a non-conformance, but usually does not affect public health or product quality. Typically, a formal recall would not be required. Instead, consider the following actions:

- Document the investigation of the non-conformance on your Out of Specification or NCR forms. (See last month's Medical Gas Bulletin)
- Assure the QCU is involved in the investigation into the root causes and preventive measures of the incident.
- Document the issue on the affected Package Control Records with an annotation reference to your investigation report.
- Assure that, in the case of a product recall from your supplier, you would be able to find the affected cylinders with the incorrect lot number.
- Document the personnel retraining.
- Consider whether the non-conformance affects other lots (other operators, other gases, etc.). If other lots could be affected, widen your investigation to include those lots. Document your decision about whether or not to include other lots in your investigation.
- Make a business decision whether or not to replace the affected cylinders without a formal recall.

August Medical Gas Roundtable (08/02/2013) – CGMP – Practical validation for the cylinder plant

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In June we covered how to survive an FDA audit. In August we will be discussing practical validation techniques for cylinder fill operations:

- sample systems
- check valves
- fill processes
- portable fill manifolds
- analytical methods.

This seminar focuses on ways to save money while improving compliance

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

- **ISO 17025** - ISO 17025 – Establishing NIST Traceability for analytical measurements
- **Specialty Gas** - Fuel/Oxidizer Safe Practices

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 juliet@asteriskllc.com.





MEDICAL GAS BULLETIN

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.).

