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Safety & Technology Organizer for May 2010

ENCLOSED

Safety Topic: “Globally Harmonized System of Classification and Labeling of Chemicals (GHS)”
Please contact GAWDA's OSHA and EPA Consultant, Mike Dodd for more information.

Traffic Bulletin: “Hazmat Security Program Update”
Please contact GAWDA's DOT and Security Consultant, Mike Dodd for more information.

Medical Gas Bulletin: “Heads Up - SNI (Standardized Numerical Identification)”
Please contact GAWDA Medical Gas Consultant, Tom Badstubner for more information.

Human Resources - HR Manager's Legal Reporter: A Newsletter for the HR Professional - Available only at www.gawda.org. Click on Safety Organizer under Members Only.

May 2010

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

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.

May 2010 – Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

On Sept. 30, 2009, OSHA has issued a proposed rule to modify the Hazard Communication regulations. OSHA is proposing to modify the hazcom standard (HCS) to align with the provisions of the GHS.

A side by side comparison of the current hazcom regulations and the proposed wording changes can be found here: http://www.osha.gov/dsg/hazcom/hcs_side_by_side_draft_100109.pdf

A Guide to “*The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*” is available on the OSHA website at this link: <http://www.osha.gov/dsg/hazcom/ghs.html>.

Here are some highlights from the guide but please refer to the guide for more details and links to the actual guideline.

Proposal to align HazCom with the GHS

The primary benefit of the GHS is to increase the quality and consistency of information provided to workers, employers and chemical users by adopting a standardized approach to hazard classification, labels and safety data. The GHS provides a single set of harmonized criteria for classifying chemicals according to their health and physical hazards and specifies hazard communication elements for labeling and safety data sheets. Under the GHS, labels would include signal words, pictograms, and hazard and precautionary statements and safety data sheets would have standardized format.

OSHA's proposal to adopt the GHS will not change the framework and scope of the current HCS but will help ensure improved quality and more consistency in the classification and labeling of all chemicals. OSHA believes that this will enhance worker comprehension, resulting in appropriate handling and use of chemicals. The harmonized format of the safety data sheets will enable workers to access the information more efficiently. In addition, currently multiple labels and safety data sheets must often be developed for the same product when shipped to different countries. This creates a major compliance burden for chemical manufacturers and those involved in international trade, increasing the cost of providing hazard information. The adoption of GHS will minimize this burden.

Major proposed changes to the HCS:

Hazard classification: Provides specific criteria for classification of health and physical hazards, as well as classification of mixtures.

Labels: Chemical manufacturers and importers will be required to provide a label that includes a harmonized signal word, pictogram, and hazard statement for each hazard class and category. Precautionary statements must also be provided.

Safety Data Sheets: Will now have a specified 16-section format.

Information and training: The GHS does not address training. However, the proposed HCS will require that workers are trained within two years of the publication of the final rule to facilitate recognition and understanding of the new labels and safety data sheets.

This is only a proposed rule and if and when it becomes final, there will be a 2-3 year phase in period for compliance.

As always, if there are questions or items that I can help you with, please don't hesitate to contact me.

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Traffic Bulletin

May 2010

Hazmat Security Program Update

PHMSA Publishes Final Rule Limiting Security Plans. The Pipeline and Hazardous Materials Safety Administration has published a final rule in HM-232F narrowing the list of materials subject to the security plan requirements and reducing the regulatory costs and paperwork burden. [75 Federal Register 10974](#) (March 9, 2010). The final rule, issued in consultation with the Transportation Security Administration, was developed in response to petitions from industry groups arguing that not all placardable amounts of hazardous materials were capable of being used as weapons and thus did not require security plans.

PHMSA published its final rule so that the list of materials requiring a security plan corresponds with the United Nations Model Regulations for the Transport of Dangerous Goods and the TSA's list of Highly Security Sensitive Hazardous Materials. Here are some selected changes in the final rules. A variety of changes have been made to the requirements for various other classes of hazardous materials as well. Please refer to the actual final rule (use the above link) to see all the changes.

Class	Current threshold	Proposed threshold	Change
2.1	A quantity requiring placarding	>3,000 L in a single packaging	Security plan not required for 3,000 L (793 gallons) or less.
2.2	A quantity requiring placarding	Not subject except for oxygen and gases with a subsidiary 5.1 hazard (<3,000 L (793 gallons) in a single packaging).	Security plan not required for most non- flammable, non-poisonous compressed gas shipments.
2.3	Any quantity	Any quantity	None.
3	A quantity requiring placarding	>3,000 L (793 gallons) in a single packaging and any quantity of Class 3 desensitized explosives.	Security plan not required for 3,000 L (793 gallons) or less except for desensitized explosives.
5.1	A quantity requiring placarding	PG I and II liquids, perchlorates, ammonium nitrate (including fertilizers) in quantities >3,000 L (793 gallons) in a single packaging.	Security plan not required for PG III liquids or unlisted solids.
6.1	A quantity requiring placarding; any quantity of PIH material.	Any quantity of PG I; >3,000 L (793 gallons) for PG II and III.	Security plan not required for 3,000 L (793 gallons) or less of PG II and III.

Here is the list of gases in the final rule that have a subsidiary hazard of 5.1 and still require the security plan.

Proper shipping name	Hazard class	Identification Nos.	Label code
Air, refrigerated liquid, (cryogenic liquid)	2.2	UN1003	2.2, 5.1
Air, refrigerated liquid, (cryogenic liquid) non-pressurized	2.2	UN1003	2.2, 5.1
Compressed gas, oxidizing, n.o.s.	2.2	UN3156	2.2, 5.1
Gas, refrigerated liquid, oxidizing, n.o.s. (cryogenic liquid)	2.2	UN3311	2.2, 5.1
Liquefied gas, oxidizing, n.o.s.	2.2	UN3157	2.2, 5.1
Nitrous oxide	2.2	UN1070	2.2, 5.1
Nitrous oxide, refrigerated liquid	2.2	UN2201	2.2, 5.1
Oxygen, compressed	2.2	UN1072	2.2, 5.1
Oxygen, refrigerated liquid (cryogenic liquid)	2.2	UN1073	2.2, 5.1

The final rule is effective as of October 1, 2010, but voluntary compliance is authorized as of April 8, 2010. **This means that many of the GAWDA members are no longer required to have the hazmat security plan as of 4-8-2010.**

For those still required to have a security plan, there are some new changes required in the written plan. Please read the last two pages of the final rule for all the changes. Here is a sample of the changes:

172.802 (b) The security plan must also include the following:

(1) Identification by job title of the senior management official responsible for overall development and implementation of the security plan;

(2) Security duties for each position or department that is responsible for implementing the plan or a portion of the plan and the process of notifying employees when specific elements of the security plan must be implemented; and

(3) A plan for training hazmat employees in accordance with § 172.704 (a)(4) and (a)(5) of this part.

If you have any questions about whether you are still in the program or not, please contact:

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Medical Gas Bulletin

May 2010

Heads Up - SNI (Standardized Numerical Identification)

May Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In April we covered Subparts A & B - Organization and Personnel. On May 7, 2010, we will cover Subpart C – Buildings and Facilities.

For your information, we are also conducting the following webinars on May 7:

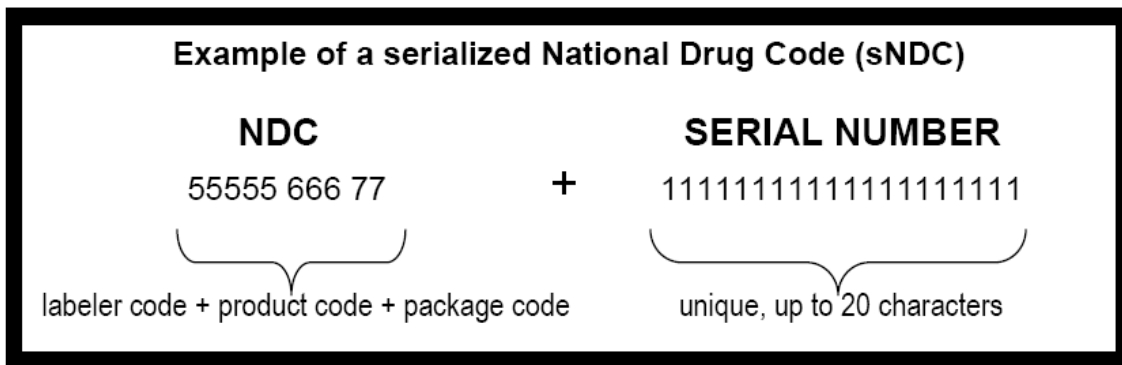
- Process validation for Cylinder Fill Plants
- ISO 17025 - Measurement Uncertainty

If you are not already receiving invitations to the training webinars, just send an email to tom@asteriskllc.com.

FYI – we also conduct monthly online webinars covering FDA Device Compliance, Specialty

Heads Up - SNI (Standardized Numerical Identification)

In March 2010, the FDA released a new guidance document: *Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages*. This guidance addresses the development of new unique labeling for each cylinder. The labeling would numerically identify the manufacturer, the product code, the package code and a unique serial number.



The guidance clearly focuses on traditional prescription drugs and is incomplete/not appropriate for refillable medical gas cylinders. GAWDA and CGA have submitted comments/questions to the FDA on at least four occasions over the past three years. We are working on procedures to comply.

Recommendation – No Action Yet

We do not have enough information to implement the guidance. GAWDA and CGA will be developing a consistent position about how to apply the guidance/regulation to our industry. In the meantime, we recommend not making any changes to your labels. When we know how to apply SNI to refillable medical gas cylinders, we will let you know. If you are interested in reading the entire guidance document, send a message to tom@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 May, simply do these items:

1. **Cryogenic Hoses** - Be sure that your cryogenic hoses are capped when not in use.
(Homecare vans and large cryogenic containers)
2. **Nitrous Oxide** – Be sure that your nitrous oxide is secure.

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