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Regulatory Issues

Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

“Significant Changes to Labels and Material Safety Data Sheets”

The OSHA Hazard Communication Requirements are changing to align with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Major changes to the Hazard Communication Standard include:

- **Hazard classification:** Chemical manufacturers and importers are required to determine the hazards of the chemicals they produce or import. Hazard classification under the new standard provides specific criteria to address health and physical hazards as well as classification of chemical mixtures.
- **Labels:** Chemical manufacturers and importers must apply a label that includes a signal word, pictogram, hazard statement, and precautionary statement for each hazard class and category.
- **Safety Data Sheets:** The new format requires 16 specific sections, ensuring consistency in presentation of important protection information.
- **Information and training:** To facilitate understanding of the new system, the new standard requires that workers be trained by December 1, 2013 on the new label elements and safety data sheet format, in addition to the current training requirements.

What this means is that all labels on gas cylinders will be changing, the MSDS format is also changing and the documents will now be called just Safety Data Sheets (SDS). The law also requires every firm to train their employees by December 1, 2013, and all labels must be fully transitioned on or before June 2015.

Key Drivers for Implementation

- Improved Worker Safety – particularly in third world countries.
- Improving and providing more consistent information on chemical hazards and protective measures
- Ability to lessen the regulatory burden – It appears this benefit will accrue mostly to the regulatory agencies through harmonization of their activities, not the companies who have to implement this new initiative

Note: Industry Position: CGA has already started the revision process to the applicable publications (CGA Publication C-7) to incorporate GHS requirements. CGA believes this document gives the gases industry the tools needed to begin implementing the transition to GHS.

For more information on the issues in this newsletter, or any other medical gases compliance issue please contact B&R at (317) 297-8518, or Visit us on line at www.brcompliance.com

Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

“Resource Information”

Rollout - Compliance Schedule		
Effective Completion Date	Activity/Requirement	Applies to Whom
December 1, 2013	Train employees about the new GHS compliant chemical labels and SDSs.	All employees that use, handle, or store chemicals
June 1, 2015	Comply with all the requirements of the GHS rule, including classify chemical hazards and prepare new labels and SDSs. Distributors have until December 1, 2015 to comply with the shipping requirements for the GHS compliant label.	Chemical manufacturers, importers, or distributors
December 1, 2015	All shipments of chemical containers must include the new GHS compliant labels (signal word, pictogram, hazard statement, and precautionary statement).	Distributors
June 1, 2016	Update alternative workplace labeling and hazard communication program as necessary, and provide additional employee training for newly identified physical or health hazards.	All employees that use, handle, or store chemicals

Tele Web Training Offerings

B&R Compliance Associates and Ratermann Manufacturing would like to invite you to attend a free Tele-Web training seminar to learn the details on this new OSHA standard and the steps your company must implement to be in compliance. These trainings will also cover the OSHA training requirement.

Please join us for one of the sessions below. These seminars will be 40-45 minutes. We will also have plenty of time to answer your questions. If you have any questions about this seminar please contact B&R Compliance at (610) 868-7183. To register just click on one of the links below:

Session Offerings	
August 14, 2013 @ 1 PM EST	https://www2.gotomeeting.com/register/321849914
September 10, 2013 @ 11:30 AM EST	https://www2.gotomeeting.com/register/469681818
October 9, 2013 @ 1 PM EST	https://www2.gotomeeting.com/register/780203010
November 13, 2013 @ 1 PM EST	https://www2.gotomeeting.com/register/933819866

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OSHA Resource Materials	
A Guide to The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)	https://www.osha.gov/dsg/hazcom/ghs.html
OSHA Quick Cards	
Hazard Communication Safety Data Sheets	https://www.osha.gov/Publications/HazComm_QuickCard_SafetyData.html
Hazard Communication Standard Labels	https://www.osha.gov/Publications/HazComm_QuickCard_Labels.html
Hazard Communication Standard Pictogram	https://www.osha.gov/Publications/HazComm_QuickCard_Pictogram.html
OSHA Briefs	
Hazard Communication Standard: Safety Data Sheets	https://www.osha.gov/Publications/OSHA3514.html

Impact: Since OSHA has finalized the HAZCOM requirements the transition process will start to gain momentum from this point forward. Gases distributors need to begin planning their transition to GHS compliant labels and SDSs in the near future.

Last Month's Most Frequently Asked Question

Question	Response
During a conversation with my state agency the issues of how we assure Medical Gas Product Integrity following a natural disaster was raised. How should this be handled?	Refer to the following B&R Compliance bulletin: http://www.brcompliance.com/pdf/FAQ/ComplianceBulletinBR10-001.pdf

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This Month's Self Audit Questions

Note: This section of the newsletter will offer questions (in topic areas) you can ask each month to improve your medical gas compliance program.

Assessing FDA Compliance:

Ten Questions that every Medical Gas Manufacturer should be able to answer

1. Are your sites registered with the Food and Drug Administration and state agencies where applicable?
2. Do you provide documented annual cGMP training to all personnel, including truck drivers and distribution personnel?
3. Does the facility have a defined Quality Control Unit that is independent from Operations and Sales/Marketing?
4. Does your facility provide adequate areas, which are appropriately marked and separated for packaging, handling, and storage of full and empty cylinders?
5. Do you have written standard operating procedures (SOP's) which cover the following areas?
 - Organization & Personnel
 - Facilities, equipment, validation, & calibration
 - Filling system design & maintenance
 - Cylinder preparation, filling, and labeling
 - Label Controls
 - Quality Control Unit procedures
 - Quarantine, storage, and distribution
 - Batch and Lot Number Formulation
 - Complaints and recalls
 - Corrective & Preventative Actions (CAPA)
 - Out of Specification Investigations
6. Do you maintain Distribution records, which allow traceability by individual lot numbers?
7. Are containers and closures (cylinders, valves, and labels) inspected prior to filling according to CGA and FDA requirements?
8. Are required USP/NF tests performed at the frequency required using appropriate analytical equipment for the tests being performed?
9. Do receipts for incoming bulk products contain the required information including a "Certificate of Analysis"?
10. Do you perform an annual program review to assess the adequacy of key Quality Systems?
 - Complaint Handling
 - Resolution of deficiencies noted during audits
 - Out of Specification Test Results
 - Non-conformances
 - Other required corrective actions

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Current B&R Offerings

	<p style="text-align: center;">Tele-Web Training Seminars</p> <p>The B&R Compliance Associates highly acclaimed Tele-Web Training Programs offers industry leading training on FDA compliance and medical gas requirements. Our monthly web / teleconference seminars are an effective and efficient method to ensure your employee's training is up to date. We even provide the training documentation for your files.</p>
	<p style="text-align: center;">2013 Tune Up Special</p> <p>B&R is offering a 2013 TUNE-UP special. Save 10% off the normal B&R rate for all on-site training and audit visits.</p>
	<p style="text-align: center;">Audit Subscription Program</p> <p>Our software based audit gives you the power to identify and correct issues of non-compliance, along with the integrated tools you need to develop, implement, and track actions for continuous improvement.</p>
	<p style="text-align: center;">B&R Food & Beverage Grade Compliance Program</p> <p>A Complete System – The B&R manual is fully developed and ready to go. You do not have to assemble your SOP manual from a cut and paste library of procedures, hoping you make the right choices for your business and compliance needs. Each manual comes complete with the management systems, quality procedures, work instructions, forms, and technical data you need for compliant operations. The B&R SOP Manual allows you to select the operating procedures you need to fit your business.</p> <p>No More Tracking Regulations - At B&R we regularly monitor all FDA and industry activity related to gases. We ensure our customers are kept informed of the latest information regarding Food & Beverage grade gas compliance.</p> <p>Automatic Updates - As FDA requirements change, industry practices evolve, or enforcement trends emerge B&R Compliance Associates ensures that your SOP manual is always up to date with the latest procedures and data.</p>
<p style="text-align: center;">To Enroll or for more information on any of these programs please contact Ron Ball by telephone at (317) 297-8518 or by email at ron.ball@brcompliance.com</p>	