



SAFETY & TECHNOLOGY ORGANIZER

AUGUST 2012

ENCLOSED

Safety Topic: "Accident Investigation"

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

Traffic Bulletin: "Driver Supervisor Drug and Alcohol Awareness Training"

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.

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



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 _____

Accident Investigation

OK, you had an accident. Now what are you going to do about it? Are you just addressing that accident putting a band aid on it and moving on only to have it happen again at a later date? Or, will you investigate it more thoroughly looking for the underlying causes and putting steps in place to eliminate the causes so that the chances of it happening at a later date are reduced. Even better, are you going through the workplace looking for accident potentials and eliminating those before they even cause the accident?

An effective safety and health program depends on the credibility of management's involvement in the program, inclusion of employees in safety and health decisions, rigorous worksite analysis to identify hazards and potential hazards, including those which could result from a change in worksite conditions or practices, stringent prevention and control measures, and thorough training. It addresses hazards whether or not they are regulated by government standards.

The OSHA website has excellent links to help you with accident investigation. Here is the main link:

<http://www.osha.gov/SLTC/accidentinvestigation/index.html>

The OSHA Small Business Handbook gives a great overview and helpful suggestions regarding the entire safety program.

<http://www.osha.gov/Publications/smallbusiness/small-business.html>

OSHA Publication 3071, (2002) explains what a job hazard analysis is and offers guidelines to help employers conduct their own step-by-step analysis.

<http://www.osha.gov/Publications/osh3071.pdf>

OSHA eTool. There are four crucial questions you should be asking when it comes to safety and health programs. The detailed answers are found in the four modules of this eTool.

<http://www.osha.gov/SLTC/etools/safetyhealth/index.html>



Here is a link to a PowerPoint program (20 slides) summarizing voluntary safety and health program management guidelines.

[http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL REGISTER&p_id=12909](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=12909)

OSHA's "\$afety Pays" program is an interactive expert system to assist employers in estimating the costs of occupational injuries and illnesses and the impact on a company's profitability. This system uses a company's profit margin, the AVERAGE costs of an injury or illness, and an indirect cost multiplier to project the amount of sales a company would need to generate in order to cover those costs. Businesses can use this information to predict the direct and indirect impact of injuries and illnesses and the estimated sales needed to compensate for these losses. The "\$afety Pays" program will:

- Offer choices from a set of Lost Work Day injuries and illnesses
- Prompt users for information to do the analysis
- Allow users to input the actual loss figures or workers' compensation costs
- Generate a report of the costs and the sales needed to cover those costs

<http://www.osha.gov/dcsp/smallbusiness/safetypays/index.html>

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

August 2012

Driver Supervisor Drug and Alcohol Awareness Training

49 CR 382.603 requires an employer to ensure all persons designated to supervise drivers receive the following:

- 60 minutes of training on alcohol misuse, and
- 60 minutes of training on drug use.

Supervisors will use the training to determine whether reasonable suspicion exists to require a driver to undergo testing. The key point is that in order to send someone for reasonable suspicion testing, you must have been properly trained. The training must cover the physical, behavioral, speech, and performance indicators of probable alcohol misuse and use of drugs. Recurrent training is not required. There are some good programs sold to help you with this training. JJ Keller sells a training program for this. The drug and alcohol testing company that you have contracted with might be able to provide this training. In larger cities, there are organizations that conduct this training as well.

Please read 49 CFR 382.307 for all the details and requirements for reasonable suspicion testing. Here are a few of the key points found in 382.307:

- An employer shall require a driver to submit to an alcohol test when the employer has reasonable suspicion to believe that the driver has violated the prohibitions of 382.201- 382.215 concerning alcohol or controlled substances.
- The employer's determination that reasonable suspicion exists to require the driver to undergo an alcohol or controlled substances test must be based on specific, contemporaneous, articulable observations concerning the appearance, behavior, speech or body odors of the driver. The observations may include indications of the chronic and withdrawal effects of controlled substances. (The mere possession of alcohol does not constitute a need for reasonable suspicion testing, which must be based on observations concerning the driver's appearance, behavior, speech, or body odor.)





TRAFFIC BULLETIN

- The required observations for alcohol and/or controlled substances reasonable suspicion testing shall be made by a supervisor or company official who is trained in accordance with §382.603. The person who makes the determination that reasonable suspicion exists to conduct an alcohol test shall not conduct the alcohol test of the driver. (Under the Part 382 rules, only one supervisor or company official is required to make the observations necessary to require a test. The FHWA believes requiring only one supervisor or company official to make a reasonable suspicion determination responds to the operational realities of motor carrier operations.)
- A driver may be directed by the employer to only undergo reasonable suspicion testing while the driver is performing safety-sensitive functions, just before the driver is to perform safety-sensitive functions, or just after the driver has ceased performing such functions. (This is why you are required to define “safety-sensitive work” in your company written drug and alcohol program.)
- If a reasonable suspicion alcohol test is not administered within two hours following the observations, the employer shall prepare and maintain on file a record stating the reasons the alcohol test was not administered promptly. If the test was not administered within eight hours, the employer shall cease attempts to administer the test, and shall prepare and maintain the record listed above.
- If reasonable suspicion is observed but a reasonable suspicion test has not yet been administered, a driver shall not perform safety-sensitive functions until: an alcohol test is administered and the driver's alcohol concentration measures less than 0.02; or twenty four hours have elapsed following the determination that there is reasonable suspicion to believe that the driver has violated the prohibitions in this part concerning the use of alcohol.
- A written record shall be made of the observations leading to an alcohol or controlled substances reasonable suspicion test, and signed by the supervisor or company official who made the observations, within 24 hours of the observed behavior or before the results of the alcohol or controlled substances tests are released, whichever is earlier.

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

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MEDICAL GAS BULLETIN

8/01/2012

Frequently Asked Questions

Q – Since the FDA has been issuing violations for using expiration dates on medical gases, we intend to discontinue using expiration dates. We have some high-profile customers who expect expiration dates on their medical gases. How can we communicate the FDA's position on expiration dates for medical gases?

A - Not only are some medical gas customers accustomed to seeing expiration dates, but some accreditation bodies and boards of pharmacy also misunderstand the FDA's current position and enforcement. If you need a sample letter of explanation about expiration dates for medical gases, contact juliet@asteriskllc.com.

August Medical Gas Roundtable (08/03/2012) – 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 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 Safety Act

The Medical Gas Safety Act was incorporated into "The Food and Drug Administration Safety and Innovation Act" (FDASIA). The President signed FDASIA into law on July 9, 2012 and it gives the FDA continuing authority to collect user fees from industry, to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biologics. It also reauthorizes programs that encourage pediatric drug development.

Only a small portion of FDASIA applies to medical gases. Contact juliet@asteriskllc.com for a white paper with the full text of the medical gas portion of the new law along with annotations explaining the key provisions.

FDASIA is the result of years of work from Mike Tiller, CGA President, and CGA's Medical Gas and Regulatory Policy Committee (MGRP). GAWDA is a member of MGRP. Well over a hundred GAWDA members contributed to FDASIA's passage by writing their Congressman at a critical time of it's deliberation.





MEDICAL GAS BULLETIN

Executive Summary:

Passage of the Food and Drug Administration Safety and Innovation Act accomplishes the following major goals for our industry:

1. Medical Gas “Approval”

- a. Establishes “Designated Medical Gases” with the protection of “approved drug” status for the common pure medical gases and mixtures.
- b. Provides for intellectual property protection if a company develops a new medical gas.
- c. Establishes a certification process for the designated medical gases to be produced.

2. Regulations - Requires the FDA to consult with the medical gas industry about the need for medical gas regulations. Provides a framework to develop/revise medical gas regulations.

3. Fees - Assures Drug User Fees are NOT applied to medical gases.

Contact tom@asteriskllc.com with questions and comments.

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.).

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