



SAFETY & TECHNOLOGY ORGANIZER

JULY 2013

ENCLOSED

Safety Topic: “Under the Blazing Heat of the Sun, Heat Stress”

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

Traffic Bulletin: “Chemical Facility Anti-Terrorism Standards (CFATS)”

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 _____

UNDER THE BLAZING HEAT OF THE SUN / HEAT STRESS

OSHA reminds outdoor workers of vital safety procedures.

The heat is on this summer, and for outdoor workers, rising temperatures are not the only danger. Workers must also beware of heat-related injuries, poison ivy and fatal diseases.

The OSHA website features a Fact Sheet that provides workers with safety tips. (See the link below). Here is a short recap of the Fact Sheet.

For UV-ray protection:

- Wear long-sleeved shirts and pants, but make sure they're loose enough to allow air circulation
- Use sunscreen with SPF of at least 30
- Put on a wide-brimmed hat to shield ears, eyes, scalp, forehead and nose
- Wear UV-absorbent sunglasses
- Be aware that UV rays are most powerful between 10 a.m. and 4 p.m.

To prevent heat-related injuries:

- Drink water frequently
- Wear cotton-made, light-colored and loose clothing
- Eat light before working
- Avoid intakes of caffeine, alcohol and sugar-heavy foods before working.

To prevent Lymes and other tick-borne diseases:

- Wear light-colored shirts to spot ticks easily
- Wear long-sleeves
- Tuck pant legs into socks or boots
- Wear boots/closed shoes that completely shield the feet
- Apply tick repellants
- Check for and remove ticks on the body after working (using fine-tipped tweezers).



To prevent West Nile Virus:

- Use insect repellents with DEET
- Take extra care during dusk and dawn (active time for mosquitoes)
- Reduce mosquitoes' breeding areas (areas where water may stagnate - tires, ditches, drums, etc.)

To avoid poison oak injuries/illnesses:

- Increase employee awareness of poison oak (symptoms, etc.)
- Tuck pants into boots
- Wear gloves
- Keep rubbing alcohol handy.

Here is the website for additional tips and more detail on this subject:

http://www.osha.gov/OshDoc/data_Hurricane_Facts/working_outdoors.pdf

Heat Stress

Here is an excellent link on the OSHA website that you get when you enter "heat stress" into the search bar on the OSHA website:

http://www.osha.gov/pls/oshaweb/searchresults.category?p_text=heat%20stress&p_title=&p_status=CURRENT

Be sure to check out the links under the "Top Links" section. There is even a link for printing out a Heat Stress employee card in Spanish if needed.

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

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TRAFFIC BULLETIN

July 2013

Chemical Facility Anti-Terrorism Standards (CFATS)

This is a follow-up Bulletin to remind people that they may need to get into the CFATS program if they have any of the chemicals listed in the Appendix A discussed below on their property for any amount of time and exceed any of the weights shown in the Appendix A.

What is this? Department of Homeland Security (DHS) Chemical Facility Anti-Terrorism Standards, final updated Appendix A, published on Nov. 20, 2007.

Does this apply to me? You must look at the Appendix A (click on this link to download Appendix A; http://www.dhs.gov/xlibrary/assets/chemsec_appendixa-chemicalofinterestlist.pdf) and if you have any of the chemicals of concern on your property at any time in quantities at or above any of the Screening Threshold Quantities, then you are in this program. Most of the GAWDA members will not be in this program, but many of you will. Several of the gases we sell are on the list, such as poison gases or flammable gases like acetylene, propane, and propylene for examples.

If I'm in the program, what do I do? You must first register with DHS to receive your ID and passwords in order to have access to the Chemical Security Assessment Tool (CSAT). You register by going clicking on the register link found on the CSAT webpage; <http://www.dhs.gov/register-access-csat>

Next, you must take the Chemical-Terrorism Vulnerability Information (CVI) authorized user training on line at this link:

<http://www.dhs.gov/training-chemical-terrorism-vulnerability-information>

<https://csat.dhs.gov/dana/home/index.cgi>

The CVI training will take about 30 minutes to an hour to complete the reading, 6 question test, and submission of information. This training and certification must be done prior to working on and submitting the Top Screen information.

After registration, you will be notified of your ID and password and then you will have access to and must complete the on-line Top Screen found in the Chemical Security Assessment Tool (CSAT).

Helpful hint: You should print the CSAT Top Screen questions (the November 2007 version is 111 pages), the Top Screen User Manual, then gather the required information, and complete the question sheets manually first. After you have completed the questions on paper, it will be much easier to complete the on-line submission.





TRAFFIC BULLETIN

When must I do this? If you are a part of the program (you have chemicals of concern that meet or exceed the screening threshold quantities), then you must complete the Top Screen in the CSAT with 60 days. The 60 calendar day deadline starts with either Nov. 22, 2007 if you already have any of the chemicals of concern on your location at or above the screening threshold quantities or within 60 calendar days if you have them in the future.

How do I get out of this? You don't unless you are either below or get below the screening threshold quantities shown in Appendix A.

For propane only, facilities need not include propane in tanks of 10,000 pounds or less when calculating whether a facility has a total inventory of 60,000 pounds.

What happens next? DHS will review the submitted Top Screen and then make a determination of whether you are exempted from the program (no further action necessary on your part) or if you are deemed a high risk facility and which of the 4 risk tiers you are assigned. You may then be notified that you need to complete a Security Vulnerability Assessment (SVA), (an on-line tool). You may also be notified at this time that you need to develop a Site Security Plan (SSP) along with guidance and time lines. The SSP will need to address 19 risk based performance standards that DHS has set up. The 4 risk tiers will have different levels of site security protection requirements. DHS at this time has not released any information on exactly what the protection requirements will be for each of the 4 tiers. This is a work in progress.

Important Notes: The weights are only for the product and not the package. The weights are only what are in your inventory and not based on the capacity of the storage container.

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

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MEDICAL GAS BULLETIN

07/01/2013

Frequently Asked Questions

Q – What do I need to document if a batch fails to meet the purity specifications?

A – First, you report exactly what you observe – even if this means that the product fails to meet the specifications. This specification failure may be a result of low purity, detectable odor in full cylinders, improper lot number, incorrect cylinder color in the full pile, etc.

Next, the operator and QCU invoke your written Out of Specification (OOS) procedures. OOS may involve:

- Retesting in certain circumstances
- Recalibration of test equipment
- Quarantine of affected lots and other suspect lots
- Written investigation
- Temporary corrective actions
- Formal review by the QCU

FYI – Members of the GAWDA Medical Gas SOP Program should follow J500, Investigation of Out Of Specification Results.

The written report may be documented on special forms, complaint forms, or in some cases, right on the test/fill log.

It is very important to consider whether the specification failure could apply to other cylinders in the lot, other lots or other products. Document your decision about the applicability of the OOS to other lots, etc.

July Medical Gas Roundtable (07/12/2013) – CGMP - Subpart F – Production and Process Controls

Note --- this training is scheduled in the second week of the month due to the Independence Day holiday.

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 July, we will cover Subpart F – Production and Process Controls --- SOPs, filling cylinders, equipment identification, reprocessing, etc.

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

- **Medical Device Gases** - QSR Subparts K, L & M - Handling, Storage, Distribution, Installation, Packaging and Labeling Control, Records
- **Specialty Gas** - Making Highly Reliable Gravimetric Mixtures

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. **Authorized Procedures** – Verify that your SOPs have been authorized in writing by your Quality Control Unit.
2. **Following SOPs** – Be sure that your cylinder filling personnel are strictly following the authorized procedures. This is easily accomplished by taking a copy of the cylinder fill procedure to the manifold and watching the operator fill the cylinders.

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