



SAFETY & TECHNOLOGY ORGANIZER

NOVEMBER 2011

ENCLOSED

Safety Topic: "OSHA Audits Part 2"

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

Traffic Bulletin: "Drug and Alcohol Policy"

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

Medical Gas Bulletin: Upcoming Roundtables, FDA Audit Activity 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 _____

OSHA Audits Part 2

This is a second installment of “Would you be ready to handle an OSHA audit?” Last month I talked about what triggers an audit and how to handle the audit process. This month I’ll give you some suggestions for quick fixes and longer term fixes.

Quick Fixes

These are some items that you can do fairly quickly and check on pretty quickly should an inspector show up.

- Recordkeeping
 - Make sure that you have your OSHA 300 forms up to date and on file for 5 years
- Electrical Fuse Boxes
 - Make sure that you don’t have these blocked, the breakers marked, and the doors closed
- Isles
 - if marked out, then nothing inside them and not blocked
- Exits
 - Properly marked, not blocked, proper lighting if needed, and not chained and locked
- Fire Extinguishers
 - Visible or marked on walls, not blocked, properly charged, and doing the monthly and annual inspections
- Electrical extension cords
 - Not using them as permanent wiring and not tripping hazards
- Grinders tool rests / tongue guards
 - Tool rest adjusted to within 1/8” of the wheel and tongue guards adjusted to within 1/4” of the wheel
- Guards
 - Make sure all required machine guarding is in place and fastened
- Housekeeping
 - The cleaner and more organized the workplace, the more comfortable the inspector will feel.

Long Term Fixes

These are some items that are always on the 10 most cited items list each year. These take more time and effort to get into place and maintain, but definitely should be done if they apply to your location.



Long Term Fixes (cont.)

- Hazard Communication Program
- Lockout / Tagout
- Confined Space
- Hearing Conservation
- Personal Protective Equipment
- Respiratory Protection

Feel free to contact me if you have questions.

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TRAFFIC BULLETIN

November 2011

Drug and Alcohol Policy

Motor carriers are required to have written materials and a policy outlining their alcohol and drug program. These materials must be provided to each driver and written notice of the availability of these materials must be provided to union representatives. These materials must be distributed **prior** to the start of alcohol and drug testing. The regulations found in section **382.601** outline the eleven areas that **must** be covered in the education materials.

1. The name of the person designated by the employer to answer driver questions about the materials;
2. The categories of drivers who are subject to the provisions of Part 382;
3. Sufficient information about the safety-sensitive functions performed by those drivers to make clear what period of the work day the driver is required to be in compliance with Part 382;
4. Specific information concerning driver conduct that is prohibited;
5. The circumstances under which a driver will be tested for alcohol and/or drugs under Part 382;
6. The procedures that will be used to test for the presence of alcohol and drugs, protect the driver and the integrity of the testing processes, safeguard the validity of the test results, and ensure that those results are attributed to the correct driver;
7. The requirement that a driver submit to alcohol and drug tests administered in accordance with Part 382;
8. An explanation of what constitutes a refusal to submit to an alcohol or controlled substances test and the attendant consequences;
9. The consequences for drivers found to have violated Subpart B, including the requirement that the driver be removed immediately from safety-sensitive functions, and the procedures under Sec. 382.605;
10. The consequences for drivers found to have an alcohol concentration of 0.02 or greater but less than 0.04;





TRAFFIC BULLETIN

11. Information concerning:

1. The effects of alcohol and drug use on an individual's health, work, and personal life;
2. Signs and symptoms of an alcohol or drug problem (the driver's or a co-worker's); and
3. Available methods of intervening when an alcohol or drug problem is suspected, including confrontation, referral to any employee assistance program and or referral to management.

Optional Provision — The materials may also include information on additional employer policies with respect to the use or possession of alcohol or drugs, including any consequences for an employee found violating the company policies. These additional policies must be clearly identified as based on the employer's independent authority.

Again, these materials must be provided to each driver and written notice of the availability of these materials must be provided to union representatives. These materials must be distributed **prior** to the start of alcohol and drug testing. **Each driver must sign a receipt that he/she has received a copy of the materials.**

During audits of our members, if the member has written their own materials, I consistently find at least one if not many of these elements missing from their written policy. Please take some time to review your current written program to verify that the above items are covered.

A very easy way to comply with this requirement is to purchase a pamphlet from JJ Keller (532-H), *Alcohol & Drug Testing, Driver Awareness Training*. You simply write in a contact name and phone number on the last page of the pamphlet and then tear out and complete the first page, which is the required signed receipt. You do this for every CDL driver. I always suggest that this receipt be kept in the driver's drug and alcohol file. I also suggest that the receipt be stapled to the inside cover of the file so that it will never be tossed or misplaced by mistake.

Feel free to contact me if you have questions.

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MEDICAL GAS BULLETIN

11/01/2011

November Medical Gas Roundtable

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In October we covered 21 CFR 211 Subparts H & I – Holding and Distribution, Laboratory Controls. On November 4, we will cover the present and proposed revisions to the **USP Medical Gas Monographs and “OOS” - Out of Specification Procedures/Guidance**. In addition a Certificate of Analysis checklist will be distributed at the webinar.

Mark your calendar – here is the training schedule for the next three months:

Medical Gas CGMP

- 11/4/2011 CGMP - USP SOPs/OOS - Out of Specification Procedures/Guidance
- 12/2/2011 Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products
- 1/6/2012 Subpart A & B – Personnel Qualifications

Specialty Gas

- 11/4/2011 Gas Chromatography Fundamentals
- 12/2/2011 Gas Chromatography Column & Detector Selection / Troubleshooting
- 1/6/2012 Gas Chromatograph Method Development

ISO Quality Systems/Device Gases

- 11/4/2011 ISO 17025 - Internal Audits and Management Reviews
- 12/2/2011 ISO 17025 - Propagation of Errors
- 1/6/2012 Device QSR Subparts A & B – Quality Systems Requirements

These and other webinars are also available as a streaming recording. 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 are not already receiving invitations to the training webinars, just send an email to tom@asteriskllc.com.

FDA Audit Activity

In some areas, the FDA has become much more active with inspections. We have seen an emphasis on training records, gauge/thermometer calibrations and QCU responsibilities. Please look at your training and calibration records to be sure you are compliant.

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.





MEDICAL GAS BULLETIN

For this month, simply do these items:

1. **Driver CGMP Training** - Verify that your drivers have had CGMP training within the last twelve months. Assure that you document this training.
2. **QCU and Operator CGMP Training** - Verify that your QCU and operators have documented CGMP training within the last twelve months.
3. **Calibrations** - Verify that your high pressure gauges, vacuum gauges and thermometers have been calibrated within the last year, or according to your SOP.

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