GAWDA
GASES AND WELDING DISTRIBUTORS ASSOCIATION

DECEMBER 2019

ENCLOSED

Safety Topic: GAWDA Sample Safety Policy: Customer Vetting Practices

Please contact Mike Dodd, GAWDA DOT, Security, OSHA & EPA Consultant for more information.

Traffic Bulletin: Drug and Alcohol Clearinghouse

Please contact Mike Dodd for more information.

Medical, Food/Beverage and Specialty Gases Bulletin

1. FAQ's: Electronic Tracking of Lot Numbers; CGA SB-26
2. Compliance To Do List: Review your Drug Listings
3. GAWDA Spring Professional Compliance Seminar 3/10-12/2020; December Medical Gas Roundtable (12/20/2019) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products; December Webinars – Specialty Gas, Food Gas Roundtable
4. Micro Audit Suggestions

Please contact Tom Badstubner, GAWDA FDA Food, Medical & Specialty Gases Consultant, 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.

GASES AND WELDING DISTRIBUTORS ASSOCIATION
One Oakwood Blvd., Suite 195, Hollywood, FL 33020 Phone (954)367-7728 Fax (954)367-7790

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 _____

The GAWDA Safety Committee has put together sample safety policies. Here a recent one that has been completed. This is an example of one of the many available off the member resources portion of the GAWDA website.

GAWDA GASES AND WELDING DISTRIBUTORS ASSOCIATION

Customer Vetting Practices

(Insert Company Name Here)

PURPOSE	Ensure Hazardous materials are purchased for legitimate purposes
RESPONSIBILITY	**Anyone with the responsibility to place orders for hazardous materials**
AUTHORITY	**Salesperson and Salesperson's Supervisor**

Key Considerations

Security of our products helps to promote the safety of our employees and the public. This document provides an example of safety and security practices for the purchase of Industrial, Medical, Food Grade, Chemical of Concern and Research grade hazardous materials to legitimate customers.

Precautionary Statements:

1. **Not all people requesting to purchase hazardous materials have legitimate intentions. Some will use it for illegal drug manufacturing, terrorism or other illegal activities.**
2. **Employees should be trained on how to record conversations regarding the purchase of hazardous materials.**
3. **Information in this document must be evaluated to suit your business needs.**

Practices:

1. Obtain information to set up Customer account:
   a. Name
   b. Address, verify address
   c. Phone number
   d. Employer Identification Code or Dun and Bradstreet number
   e. Type of business: Private, Port, Foreign trade, Research and Development

2. Legitimate Use
    a. Grade - Medical, Food, Research, Industrial.
        i. Medical - must be a legitimate Pharmacist, Physician, Medical facilities, Medical Wholesaler with current license
    b. Known application for the gas/liquid
    c. Application appropriate for the gas/liquid
3. Product needs
    a. Grade of product required
    b. Quantity of request gas/liquid appropriate for the intended use
4. Products of special concern:
    a. Products of Special Interest: Poison Inhalation gases, Liquid Nitrogen, Hazardous materials purchased by Educational Institutions, Dry Ice
    b. Nitrous Oxide
    c. Medical Drug gases
    d. Medical Device gases
    e. Food Grade gases and liquids

References:

CGA P-52-2007 Security Standard for Qualifying Customers Purchasing Compressed Gases, Second Edition. Chantilly: Compressed Gas Association, Inc., 2007. Electronic.

CGA P-53-2014 Security Code Top Screen, Second Edition. Chantilly: Compressed Gas Association, Inc., 2014. Electronic.

CGA SB-6 Nitrous Oxide Security and Control. Chantilly: Compressed Gas Association, Inc., Electronic.

Attachments:

CGA P-53 Chemicals of Concern and Chemicals of Interest

Customer Qualification – Products of Special Interest - Customer Survey

(Insert Company Name Here)

Company Name:		**Date:**
Address:	**P.O/Dept:**	
Legitimate use:	**Preferred**	**Please Explain**
1. Is the intended use of the product consistent with normal application of the product?	❑ Yes	❑ No:
2. Is the product a Zoned Product?	❑ No	❑ Yes:
General information	**Preferred**	**Please Explain**
1. Do you have an occupancy permit for the product being purchased?	❑ Yes	❑ No:
2. Have you notified to seek approvals from the local authorities with jurisdiction (fire departments, health department, and institution's EHS department)?	❑ Yes	❑ No:
3. Are you in compliance with all federal, state, and local regulations pertaining to the storage and use of the chemicals used?	❑ Yes	❑ No:
4. Does you have the correct level of security for the product type?	❑ Yes	❑ No:
5. Do you have an inventory management system?	❑ Yes	❑ No:
6. Do you have an individual that is responsible for the security of the product being purchased?	❑ Yes	❑ No:
7. Do you have a theft reporting system?	❑ Yes	❑ No:

For further information, consult:

- CGA SA-29, *Hazard of Liquid Nitrogen in Near-Consumer Applications – Attached – Provide to customer*
- CGA SP-L, *Safety Poster, Enclosed Spaces Can Be Unsafe*
- CGA P-39, *Fire Hazards of Oxygen and Oxygen-Enriched Atmospheres*
- CGA P-50-2014, *Site Security Standard*
- CGA P-76, *Hazards of Oxygen-Deficient Atmospheres*
- CGA P-52-2007, *Security Standard For Qualifying Customers Purchasing Compressed Gases*
- CGA SB-31, *Hazards of Oxygen in the Health Care Environment*

Customer Qualification - Nitrous Oxide - Customer Survey

(Insert Company Name Here)

Company Name:		**Date:**
Address:		
Legitimate use:	**Preferred**	**Please Explain**
1. For medical nitrous oxide, do you have a valid medical license from the state or federal drug manufacturing registration?	❑ Yes	❑ No:
2. For food grade nitrous oxide, are you registered with the FDA as a food manufacturer? Where required by state regulations, are you licensed by the state as a food manufacturer?	❑ Yes	❑ No:
3. For industrial or specialty gas grades of nitrous oxide, is the delivery point a lab or other legitimate nitrous oxide user?	❑ Yes	❑ No:
General information	**Preferred**	**Please Explain**
1. Do you have an occupancy permit for the product being purchased?	❑ Yes	❑ No:
2. Have you notified the local fire departments, hospitals, and other emergency services of the products you use at your facility?	❑ Yes	❑ No:
3. Are you in compliance with all federal, state, and local regulations pertaining to the storage and use of the chemicals used?	❑ Yes	❑ No:
4. Do you have a security plan in place?	❑ Yes	❑ No:
5. Do you have an inventory management system?	❑ Yes	❑ No:
6. Do you understand the need for additional security requirements for the product being purchased?	❑ Yes	❑ No:
7. Do you have an individual that is responsible for the security of the product being purchased?	❑ Yes	❑ No:
8. Do you have a security incident reporting system?	❑ Yes	❑ No:
Storage	**Preferred**	**Please Explain**
1. Is your nitrous oxide stored in a secure area?	❑ Yes	❑ No:
2. Do you control access to the nitrous oxide?	❑ Yes	❑ No:
3. Do you have an intrusion monitoring system?	❑ Yes	❑ No:

For further information, consult:

- CGA G-8.1, *Standard for Nitrous Oxide Systems at Customer Sites*
- CGA G-8.3, *Safe Practices for Storage and Handling of Nitrous Oxide*
- CGA P-50-2014, *Site Security Standard*
- CGA P-51-2014, *Transportation Security Standard for the Compressed Gas Industry*
- CGA P-52-2007, *Security Standard For Qualifying Customers Purchasing Compressed Gases*
- CGA P-53-2014, *Security Code Top Screen*

Customer Qualification – Medical Drug Gases - Customer Survey

(Insert Company Name Here)

Company Name:		**Date:**
Address:		
Legitimate use	**Preferred**	**Please Explain**
1. For medical gases (Oxygen, Nitrogen, Nitrous Oxide, Helium, Medical Air, Carbon Dioxide and mixtures), do you have a valid medical license from the state or federal drug manufacturing registration? Copy for the files.	❑ Yes	❑ No:
2. For Oxygen, USP - Do you have a valid prescription from a licensed physician or other qualified medical professional? Copy for the files.	❑ Yes	❑ No:
3. For Emergency Use Oxygen, USP without a prescription or medical license- Do you have a valid training certificate for the administration of oxygen in emergencies? Copy for the files.	❑ Yes	❑ No:
4. For Emergency Use Oxygen, USP – Are you an ambulance company, Emergency Medical Service or fire department?	❑ Yes	❑ No:
5. For Nitrogen NF to a plumber/pipefitter without a prescription or medical license - Do you have a letter specifying the hospital/medical gas piping you are repairing? Copy for the files.	❑ Yes	❑ No:
General information	**Preferred**	**Please Explain**
1. Do you have an occupancy permit for the product being purchased?	❑ Yes	❑ No:
2. Have you notified the local fire departments, hospitals, and other emergency services of the products you use at your facility?	❑ Yes	❑ No:
3. Are you in compliance with all federal, state, and local regulations pertaining to the storage and use of the chemicals used?	❑ Yes	❑ No:
4. Do you have a security plan in place?	❑ Yes	❑ No:
5. Do you have an inventory management system?	❑ Yes	❑ No:
6. Do you have an individual that is responsible for the security of the product being purchased?	❑ Yes	❑ No:
7. Do you have a theft reporting system?	❑ Yes	❑ No:

For further information, consult:

- CGA SP-L, *Safety Poster, Enclosed Spaces Can Be Unsafe*
- CGA P-39, *Fire Hazards of Oxygen and Oxygen-Enriched Atmospheres*
- CGA P-50-2014, *Site Security Standard*
- CGA P-76, *Hazards of Oxygen-Deficient Atmospheres*
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- CGA SB-31, *Hazards of Oxygen in the Health Care Environment*

Customer Qualification – Medical Device Gases - Customer Survey

(Insert Company Name Here)

Company Name:		**Date:**
Address:		
Legitimate use	**Preferred**	**Please Explain**
1. Do you have a valid medical device license from the state or federal device manufacturing registration? Copy for the files.	❑ Yes	❑ No:
2. Will this product be used under the supervision of a physician?	❑ Yes	❑ No:
3. Will this product be used by a researcher in a research lab?	❑ Yes	❑ No:
General information	**Preferred**	**Please Explain**
1. Do you have an occupancy permit for the product being purchased?	❑ Yes	❑ No:
2. Have you notified the local fire departments, hospitals, and other emergency services of the products you use at your facility?	❑ Yes	❑ No:
3. Are you in compliance with all federal, state, and local regulations pertaining to the storage and use of the chemicals used?	❑ Yes	❑ No:
4. Do you have a security plan in place?	❑ Yes	❑ No:
5. Do you have an inventory management system?	❑ Yes	❑ No:
6. Do you have an individual that is responsible for the security of the product being purchased?	❑ Yes	❑ No:
7. Do you have a theft reporting system?	❑ Yes	❑ No:

For further information, consult:

- CGA SP-L, *Safety Poster, Enclosed Spaces Can Be Unsafe*
- CGA P-39, *Fire Hazards of Oxygen and Oxygen-Enriched Atmospheres*
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- CGA P-76, *Hazards of Oxygen-Deficient Atmospheres*
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- CGA SB-31, *Hazards of Oxygen in the Health Care Environment*

Customer Qualification – Food Gases - Customer Survey

(Insert Company Name Here)

Company Name:		**Date:**
Address:		
Legitimate use	**Preferred**	**Please Explain**
1. Do you have a valid food manufacturing license from the state or federal food registration?	❑ Yes	❑ No:
2. Are you a restaurant or bar?	❑ Yes	❑ No:
3. Are you using the food gas to produce food products?	❑ Yes	❑ No:
4. For Liquid Nitrogen to near consumer applications (ice cream, cryotherapy, etc.) Will this product be used by trained personnel with proper personal protective equipment?	❑ Yes	❑ No:
5. For Liquid Nitrogen - Will this product be used in an area that could become oxygen deficient? Are oxygen alarms available?	❑ Yes	❑ No:
6. For Liquid Nitrogen - Will this product be transferred to a container with adequate pressure relief devices? See CGA SA-29	❑ Yes	❑ No:
General information	**Preferred**	**Please Explain**
1. Do you have an occupancy permit for the product being purchased?	❑ Yes	❑ No:
2. Have you notified the local fire departments, hospitals, and other emergency services of the products you use at your facility?	❑ Yes	❑ No:
3. Are you in compliance with all federal, state, and local regulations pertaining to the storage and use of the chemicals used?	❑ Yes	❑ No:
4. Do you have a security plan in place?	❑ Yes	❑ No:
5. Do you have an inventory management system?	❑ Yes	❑ No:
6. Do you have an individual that is responsible for the security of the product being purchased?	❑ Yes	❑ No:
7. Do you have a theft reporting system?	❑ Yes	❑ No:

For further information, consult:

- CGA SA-29, *Hazard of Liquid Nitrogen in Near-Consumer Applications – Attached – Provide to customer*
- CGA SP-L, *Safety Poster, Enclosed Spaces Can Be Unsafe*
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Again, the Security of our products helps to promote the safety of our employees and the public. This document provides an example of safety and security practices for the purchase of Industrial, Medical, Food Grade, Chemical of Concern and Research grade hazardous materials to legitimate customers.

Feel free to contact me if you have any questions.

Michael Dodd
GAWDA DOT, Security, OSHA, and EPA Consultant
MLD Safety Associates, LLC
P.O. Box 93
Poplar Bluff, MO 63902
(573) 718-2887
Email: MLDSafety@hotmail.com

Traffic Bulletin

December 2019

Drug and Alcohol Clearinghouse

CDL Drug and Alcohol Clearinghouse final rule becomes mandatory on January 6, 2020. FMCSA has placed new compliance resources on its website, www.clearinghouse.fmcsa.dot.gov. It is suggested that while visiting the website that you sign up for updates. Also highly suggested is to read all the FAQs. DOT has done a great job with the questions and answers found in those FAQs. Motor carriers looking to hire driver applicants must query the online database for past three years of drug and alcohol test results; current employers must upload any positive tests or refusals to test, or other D&A testing violations, into the online database

What to do to comply

- Register with Clearinghouse FMCSA web portal in Fall 2019
- Beginning January 6, 2020, run full query on all CDL drivers pre-employment
- Beginning January 6, 2020, run full or limited query on all current CDL drivers once a year (and full query if data is available)
- Upload info to database on any positive tests or refusals to take drug or alcohol tests (or other D&A testing violations) on or after January 6, 2020
- Upload info on completion of return to duty requirements for drivers who were referred to Substance Abuse Professionals

Registration

- All motor carriers must register through FMCSA portal (www.fmcsa.dot.gov) to participate in Clearinghouse
- Registration is now open
- Register by company name and USDOT number
- Company registration is effective for 5 years
- CDL drivers must register with Clearinghouse as well to provide consent for carrier database queries and to review their own records

Registration of others

- Carriers must register one company representative to be the main contact to the database; may register additional company personnel to have access to database info (“Clearinghouse Assistants”)
- Substance Abuse Professionals, Medical Review Officers (MRO), and Service Agents (Testing Consortia or Third-Party Administrators (C/TPA)) must also register with the Clearinghouse to participate

Consent for Queries

- Drivers must give written or electronic consent for carriers to access the driver’s info in Clearinghouse database
- Written (general) consent acceptable for limited queries; may be for indefinite period, such as duration of employment; no specific form required
- Electronic (specific) consent through the FMCSA portal is necessary for full queries—requires driver to register with Clearinghouse
- Consent is a condition of employment—companies may not allow drivers who have refused consent to perform any safety sensitive functions

Traffic Bulletin

Pre-Employment Queries

- Company (or C/TPA) must conduct full query of driver's record in Clearinghouse database before allowing new hire CDL driver to perform safety sensitive functions (SSF)
- Driver must provide electronic consent for query (requires driver to register with Clearinghouse)
- If driver's record in Clearinghouse database shows positive drug or alcohol tests, refusal to take a test, or other D&A violations, without completing return to duty process, company may not allow driver to perform SSF

Annual Queries

- Company (or C/TPA) must conduct annual query for all CDL drivers to determine if there are violations in the database (might be working for other carriers)
- Annual queries may be limited queries—Is there info in the database on this driver? If no, the query stops. If yes, then conduct a full query to access the driver's violation history
- All queries cost $1.25 per transaction; companies may purchase queries in bulk

Full Query Report

- Driver details, including name, date of birth, contact information, CLP/CDL information, and eligibility status
- Information about the driver's employer who ordered the test or reported a violation to the Clearinghouse
- Test details, including the type of test, violation details, and test result
- Information about who entered the test result
- Return to Duty (RTD) activity information

Reporting Info to Database

- Information must be reported to Clearinghouse database on a CDL driver's positive drug or alcohol test, refusal to take a test, or other D&A violations
- Within 2 business days of determination, MRO must report a verified positive, adulterated, or substituted controlled substances test result, or refusal-to-test determination by the MRO

MRO Reporting Data

- Reason for the test;
- Federal Drug Testing Custody and Control Form specimen ID number;
- Driver's name, date of birth, and CDL number and State of issuance;
- Employer's name, address, and USDOT number, if applicable;
- Date of the test;
- Date of the verified result; and
- Test result. The test result must be one of the following:
  - (A) Positive (including the controlled substance(s) identified);
  - (B) Refusal to test: Adulterated;
  - (C) Refusal to test: Substituted; or
  - (D) Refusal to provide a sufficient specimen

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Employer Reporting to Database

- Within 3 business days following the date on which it obtained that information, employer or C/TPA must report to database:
  (i) An alcohol confirmation test result with an alcohol concentration of 0.04 or greater;
  (ii) A negative return-to-duty test result;
  (iii) A refusal to take an alcohol test;
  (iv) A refusal to test determination; and
  (v) A report that the driver has successfully completed all follow-up tests as prescribed in the SAP report

Other Violation Reports

- For each violation, the employer must report the following information:
  (i) Driver's name, date of birth, CDL number and State of issuance;
  (ii) Employer name, address, and USDOT number, if applicable;
  (iii) Date the employer obtained actual knowledge of the violation;
  (iv) Witnesses to the violation, if any, including contact information;
  (v) Description of the violation;
  (vi) Evidence supporting each fact alleged in the description of the violation, including but not limited to, affidavits, photographs, video or audio recordings, employee statements, correspondence, or other documentation; and
  (vii) A certificate of service or other evidence showing that the employer provided the driver with all information reported

Substance Abuse Professional (SAP) Reporting

- SAPs must report to the Clearinghouse, for each driver who has completed the return-to-duty process, the following information:
  (i) SAPs name, address, and telephone number;
  (ii) Driver's name, date of birth, and CDL number and State of issuance;
  (iii) Date of the initial substance-abuse-professional assessment; and
  (iv) Date the SAP determined that the driver demonstrated successful compliance and was eligible for return-to-duty testing

Additional Clearinghouse Info

- After 3 years, this process will eliminate need to request drug and alcohol test history directly from prior employers; in the meantime, must complete both procedures
- Violations prior to January 6, 2020 are not reportable to the database
- Non-DOT test results are not reportable, either
- FMCSA proposed 3-year extension of State queries to Clearinghouse before issuing, renewing, upgrading or transferring a CDL; States may voluntarily query the database during that period

Traffic Bulletin

I want to say a special thank you to Rick Schweitzer, GAWDA General Counsel, for providing the above information.

Feel free to contact me if you have questions.

Michael Dodd
GAWDA DOT, Security, OSHA, and EPA Consultant
P.O. Box 93
Poplar Bluff, MO 63902
(573) 718-2887
Email: MLDSafety@hotmail.com

Medical, Food/Beverage and Specialty Gases Bulletin

12/01/2019

Frequently Asked Questions – Electronic Tracking of Lot Numbers

Q – I input the medical and food gas lot numbers into my accounting software. Do I also need to have a paper record of the lot number distribution?

A – Not necessarily. If you intend to use your accounting/cylinder tracking software to manage your medical/food gas lot number distribution, you need to validate that software. If your software vendor does not have a validation package, contact tom@asteriskllc.com. We have sample procedures that may be able to help.

Frequently Asked Questions – CGA SB-26

Q – Is CGA SB-26, *Cylinder Connections on Portable Liquid Cryogenic Cylinders*, still in effect since the FDA adopted the new container and closure rules?

A – Yes. The relevant portion of the new FDA regulations specify:

Portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (e.g., those that have been silver- brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the containers' use) except by the manufacturer.

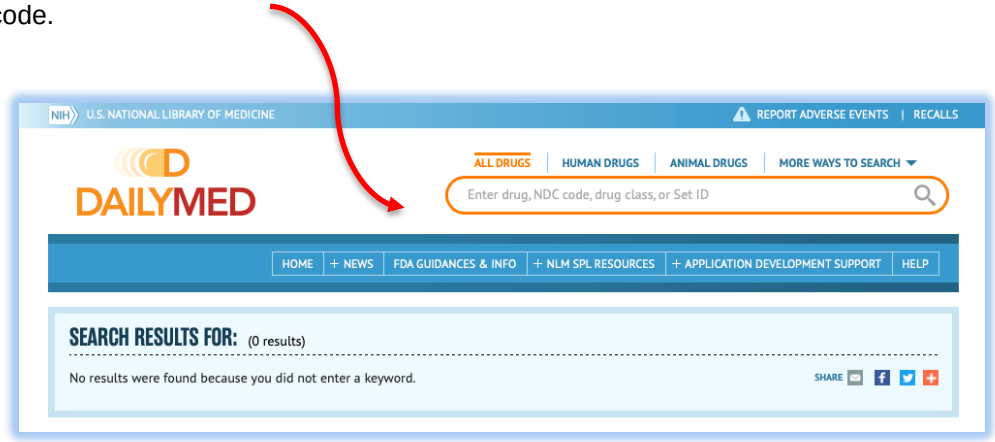
CGA SB-26 was developed in 2000 following several tragic incidents where cryogenic container outlet connections had been switched to connect the wrong gas to a customer's distribution system. Using different words, the FDA has adopted the principles behind CGA SB-26.

We strongly encourage you to get your own copy of CGA SB-26 and follow its guidance. This publication is available for free to GAWDA members who participate in the CGA safety program (www.cganet.com). If you are not a part of the CGA safety program, this would be a good time to join. Otherwise, the publication's cost is only $5.00.

Compliance To Do List – Review your Drug Listings

The FDA drug registration and listing regulations (21 CFR 207) require drug manufacturers to review their online drug labels in June and December each year. Look for obsolete labels, "unapproved medical gas" statements, or errors in the submission.

To verify your Drug Listing log on to: http://dailymed.nlm.nih.gov/dailymed/search.cfm. Enter your NDC Code (Labeler Code). Let jodie@asteriskllc.com know if you would like to know your labeler code.



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One Oakwood Blvd., Suite 195, Hollywood, FL 33020 Phone (954)367-7728 Fax (954)367-7790

Medical, Food/Beverage and Specialty Gases Bulletin

Hold the Date! – Spring GAWDA Professional Compliance Seminar

At Chart Industries, Ball Ground GA

March 10-12 and 17-19, 2020

December Medical Gas Roundtable (12/20/2019) – Subparts J & K – Records and Reports/ Returned and Salvaged Drug Products.

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In December, we will be discussing the various records required by the FDA. In addition, we will have an easy to use handout about how to document your Annual Records Review.

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

- ***Specialty Gas*** - Gas Chromatography Fundamentals
- **Food Gas Roundtable** – 21 CFR Part 117 - Subpart G - Supply-Chain Program

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 jodie@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 this month, simply do these items:

1. **Complaints -** Verify that your complaint file has any instances of customers asking for credit because they thought the cylinder was not full. (Even if the complaint was found to be without merit).
2. **QCU Review -** Verify that your QCU reviews all complaints.
3. **Other Lots? –** Be sure your complaint investigations consider whether any other cylinders from the same or different lots should be investigated. Document your decision to not investigate other cylinders/batches on the complaint record.

Tom Badstubner
GAWDA Medical Gas Consultant
Telephone: 508-883-0927
Fax: 508-883-3558
Email: tom@asteriskllc.com