



Food Safety Modernization Act

The new regulations for the Food Safety Modernization Act (21 CFR Part 117) are now effective.

- The old Food regulations, 21 CFR Part 110, are obsolete
- Many of the requirements as specified in 21 CFR Part 110 have simply been restated in 21 CFR Part 117, but there are also some significant changes.

What is required to comply with the federal regulations?

We can send you a full text copy of the regulations (with annotations) in Word format along with the sample procedures you need to comply with the new regulations. Here are the highlights:

- **Registration** – The FDA requires registration of all food/beverage gas production and warehousing facilities. This includes food and beverage gases. Food facility registrations occur from October 1 thru December 31 during even-numbered years. We have a registration white paper that explains the process of creating an account and registering your facility.
- **Raw material qualification** - You can qualify your incoming raw material by annually requesting a certificates of conformance from your food gas suppliers. A more comprehensive supplier and product qualification program will be available when the Compressed Gas Association completes the development of industry guidance.
- **SOPs/Lot Numbers** – Your food/beverage gas cylinders are filled using written procedures. The SOP's will detail the lot number system, including the placement of lot labels on cylinders and containers. Lot numbers for micro-bulk products can be applied to the delivery ticket or other document as described in the procedures.
- **Tracking Lot Numbers** – Keep track of the distribution of the food/beverage gas product lot numbers to your customers. This can be done with cylinder tracking, a lot number log, recording on the delivery ticket, etc.
- **Housekeeping/Pest Control** – Periodically use the checklist in the sample SOPs to do a physical inspection for cleanliness and for evidence of pests (spider webs, rodent droppings, etc.). We recommend that you engage a pest control contractor to manage the pest bait, traps, etc.
- **Training** – In addition to routine training requirements describing how to process and fill cylinders, labeling, testing finished product, current good manufacturing practices, etc., the new regulations also require allergen awareness and sanitation training. Fortunately for food gas manufacturers and distributors, this training is simple and fairly brief. Asterisk conducts this training monthly at Food Gas Roundtables at no cost.
- **Recall Plan** – A written procedure describing how adulterated products would be recalled and recovered from the marketplace is required by the regulations even though you are unlikely to ever need to use it.
- **Risk Assessments - Supplier** – The regulations require that you perform a thorough risk assessment for each process to assure that the food/beverage gases are safe for human consumption. This can be conducted as a formal HAPRC or depending on the risk and the size of your food gas business, a less formal review of the process may be acceptable. As part of the new "Supply-Chain Program" requirements, the process would begin with the bulk supplier to determine how well they control their food safety risks.
- **Risk Assessments – Your Process** – In addition the risk assessment of your supplier, an assessment of risk must also be conducted on your own manufacturing processes. Historically, the greatest risk for a cylinder filling operation has been internal cylinder contamination from the prior customer. There have been incidents where customers have allowed water, syrup or other chemicals to back up into an empty cylinder creating a high potential for a food safety hazard, Both



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Food Safety Modernization Act – Key Provisions

CGA G-6.3 and the ISBT Fountain CO2 Guidelines address these internal cylinder contamination hazards and make recommendations about how to mitigate these hazards. You would consider your risk assessment and the Food Safety Plan in the sample procedures and mitigate the risks as necessary.

- **Product Testing** – Your risk assessment will help determine product testing requirements for incoming bulk products as well as finished product testing of cylinder batches, refrigerated liquid containers and micro-bulk. Testing could be reduced or eliminated if all potential risk is mitigated. The regulations do not specifically require testing unless a food safety risk has been identified and cannot be mitigated. Keep in mind however that the product must be tested to meet Food Chemical Codex (FCC), ISBT or CGA specifications at the original manufacturer's production facility. If the product is safeguarded during transportation and transfer, additional testing at the packaging facility may not be necessary as determined by the risk assessment.

How can we help?

Asterisk has developed a sample Food Safety Compliance Program. The program includes sample procedures in Word format that are easily editable to match your specific needs. As procedures are updated with new features, training material and regulatory interpretations, the revisions are automatically available to you through our Dropbox.

- **FDA Compliance** - The basic sample procedures are designed to comply with the Federal Food Safety regulations (21 CFR Part 117) and cover food and beverage gas applications.
 - **ISBT** - If you choose to fill cylinders in compliance with ISBT because of specific customer needs, an optional appendix is available as a supplement to the standard procedures. The ISBT appendix contains the necessary procedures, over and above the basic federal requirements.
 - **Fast Food Quality Management Systems** - If you desire to comply with a major fast food restaurant and beverage quality management systems, there is a second appendix you can add on to your procedures with specific customer QSM requirements.
 - **FSSC/ISO 22000** – If you need certification to ISO Food Safety Management Systems, we can provide the additional procedures you need.
- **HARPC** - We have developed sample HARPC templates you may decide to customize to your Food/BevGas production requirements. These HARPCs are in Excel format and can be revised to address your specific operational needs.

Please direct questions or requests for sample procedures/white papers to:

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