

Accredited Third-Party Certification Program: Voluntary Audit Templates

Under the FSMA Accredited Third-Party Certification (Third-Party Program) regulation ([21 CFR part 1 subpart M \(https://www.ecfr.gov/cgi-bin/text-idx?SID=3c87fc60eecf6fa8b348f815348bd5ed&mc=true&node=sp21.1.1.m&rgn=div6\)\)](https://www.ecfr.gov/cgi-bin/text-idx?SID=3c87fc60eecf6fa8b348f815348bd5ed&mc=true&node=sp21.1.1.m&rgn=div6)), accreditation bodies (ABs) are recognized for designated scopes for evaluating third-party certification bodies (CBs) seeking accreditation for scopes of accreditation under the Third-Party Program. A recognized AB must ensure that CBs can adequately evaluate compliance with applicable food safety requirements of the FD&C Act and FDA regulations.

We are providing templates that may be used to help ABs develop evaluation criteria for food safety requirements of certain FDA regulations to ensure that CBs will conduct audits to adequately evaluate the food safety requirements. Under the Third-Party Program, the food safety audits conducted by accredited CBs are conducted to determine if facilities are complying with the applicable food safety requirements of the FD&C Act and FDA regulations, such that CBs may consider additional food safety requirements beyond those for which FDA has developed templates as appropriate. These templates present certain food safety requirements in a table format, which can be used to more easily compare third-party food safety audit standards to these food safety requirements. These templates are not required to be used. ABs and CBs may use other means to determine that audits meet the requirements of the FDA Third-Party Program.

Audit Templates

Title	File type/Size
Audit Standards Comparison to the FDA Hazard Analysis and Critical Control Point (Seafood HACCP) Systems Regulation (/media/115095/download?attachment)	PDF (301KB)
Audit Standards Comparison to the FDA Hazard Analysis and Critical Control Point (Juice HACCP) Systems Regulation (/media/115105/download?attachment)	PDF (309KB)
Audit Standards Comparison to the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation (/media/115130/download?attachment)	PDF (1MB)
Audit Standards Comparison to the FDA Acidified Foods Regulation (/media/115114/download?attachment)	PDF (311KB)

Title	File type/Size
Audit Standards Comparison to the FDA Preventive Controls for Human Food Rule (/media/111837/download?attachment)	PDF (667KB)
Audit Standards Comparison to the FDA Preventive Controls for Food for Animals Rule (/media/118088/download?attachment)	PDF (667KB)
Audit Standards Comparison to the FDA Produce Safety Rule (/media/111822/download?attachment)	PDF (594KB)
Audit Standards Comparison to the Infant Formula Regulations (/media/133211/download?attachment)	PDF (952KB)
Audit Standards Comparison to the FDA Shell Eggs Safety Regulations (/media/133208/download?attachment)	PDF (248KB)
Audit Standards Comparison to the Current Good Manufacturing Practices (CGMPs) for Dietary Supplements Regulation (/media/133209/download?attachment)	PDF (839KB)
Audit Standards Comparison to the Current Good Manufacturing Practice for Medicated Feeds Regulation (/media/133206/download?attachment)	PDF (215KB)

Was this helpful?

Yes

No