AUDIT STANDARDS COMPARISON TO THE THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF) REGULATION

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
Subpart A—General Provisions				
§113.5 Current good manufacturing practice.				
Thecriteria in 21 CFR §§113.10, 113.40, 113.60, 113.81, 113.83, 113.87, 113.89, and 113.100 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.				21 CFR 117.5(d) exempts the processing activities of processors of low-acid canned foods from the requirements of 21 CFR part 117 subpart C (concerning Hazard Analysis and Risk-Based Preventive Controls) and 21 CFR part 117 subpart G (concerning Supply-Chain Program) for biological hazards and their controls, if the processor of low-acid canned foods is in compliance with 21 CFR part 113. The exemption

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				in 21 CFR 117.5(d) applies to the activities that are subject to 21 CFR part 113. Low-acid canned food processors still must meet the requirements of 21 CFR part 117 subparts A, B, and F (for the records required by subpart A).
§113.10 Personnel.				
The operators of processing systems, retorts, aseptic processing and packaging systems and product formulating systems (including systems wherein water activity is used in conjunction with thermal processing) and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction appropriate to the preservation technology involved and who has been identified by that school as having satisfactorily completed the				

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prescribed course of instruction. This person shall supervise only in those areas for which a school approved by the Commissioner identifies the person as having satisfactorily completed training.				
Subpart C—Equipment				
§113.40 Equipment and procedures.				
(a) *Equipment and procedures for pressure processing in steam in still retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year				

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thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.				
(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.				
(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with §113.100(c) and (d).				
(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.				
(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-				

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in-glass thermometer that has a divided mercury column shall be considered defective.				
(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a $^{3}/_{4}$ -inch (2 centimeters) diameter opening and equipped with a $^{1}/_{16}$ -inch (1.5 millimeters) or larger bleeder opening so located as to provide a full flow of steam past the length of the temperature-indicating device sensor. The bleeders for external wells shall emit steam continuously during the entire processing period. The temperature-indicating device—not the temperature recording device—shall be the reference instrument for indicating the processing temperature.				
(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and				

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a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recording device sensor well shall have a $^{1}/_{16}$ -inch (1.5 millimeters) or larger bleeder that emits steam continuously during the processing period.				
(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals				

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that will assure that the parameters of the process time and process temperature have been met.				
(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				

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(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller.				
(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.				
(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. The steam controller may be air-operated and actuated by a temperature sensor positioned near the temperature-indicating device in the retort. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily.				

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(5) *Steam inlet.* The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.				
(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of still retorts.				
(7) *Steam spreaders.* Steam spreaders are continuations of the steam inlet line inside the retort. Horizontal still retorts shall be equipped with steam spreaders that extend the length of the retort. For steam spreaders along the bottom of the retort, the perforations should be along the top 90° of the pipe, that is, within 45° on either side of the top center. Horizontal still retorts over 30 feet (9.1 meters) long should have two steam inlets connected to the spreader. In vertical still retorts, the steam spreaders, if used, should be perforated along the center line of				

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the pipe facing the interior of the retort or along the sides of the pipe. The number of perforations should be such that the total cross-sectional area of the perforations is equal to 1.5 to 2 times the cross-sectional area of the smallest restriction in the steam inlet line.				
(8) *Bleeders.* Bleeders, except those for temperature-indicating device wells, shall be 1/8-inch (3 millimeters) or larger and shall be wide open during the entire process, including the come-up time. For horizontal still retorts, bleeders shall be located within approximately 1 foot (30.5 centimeters) of the outermost locations of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 meters) apart along the top. Bleeders may be installed at positions other than those specified in this paragraph, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of steam within the retort. Vertical retorts shall have at least one bleeder opening located in				

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that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged so that the operator can observe that they are functioning properly.				
(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, *etc.,* for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch (2.5 centimeters) holes on 2-inch (5.1 centimeters) centers. If dividers are used between the layers of containers, they should be perforated as stated in this paragraph. The positioning of containers in the retort, when specified in the scheduled process, shall be in accordance with that process.				

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(10) *Air valves.* Retorts using air for pressure cooling shall be equipped with a suitable valve to prevent air leakage into the retort during processing.				
(11) *Water valves.* Retorts using water for cooling shall be equipped with a suitable valve to prevent leakage of water into the retort during processing.				
(12) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or other adequate				

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type of valve. The retort manifold shall be of a size that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached. Some typical installations and operating procedures reflecting the requirements of 21 CFR 113.40 for venting still retorts without divider plates are given in paragraphs (a)(12)(i)(A) through (a)(12)(i)(D) and (a)(12)(ii)(A) and (a)(12)(ii)(B) of 21 CFR 113.40.				

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(i) *Venting horizontal retorts.* (A) Venting through multiple 1-inch (2.5 centimeters) vents discharging directly to atmosphere. [Diagram View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(i)(A)
(*1*) *Specifications.* One 1-inch (2.5 centimeters) vent for every 5 feet (1.5 meters) of retort length equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than 2.5 feet (76 centimeters) from ends of retort. . [Diagram View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(i)(A)
(*2*) *Venting method.* Vent valves should be wide open for at least 5 minutes and to at least 225 °F (107 °C), or at least 7 minutes and to at least 220 °F (104.5 °C).				For a Diagram see 21 CFR 113.40(a)(12)(i)(A)
(B) Venting through multiple 1-inch (2.5 centimeters) vents discharging through a manifold to atmosphere. [Diagram View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(i)(B)
1) *Specifications.* One 1-inch (2.5 centimeters) vent for every 5 feet (1.5 meters) of retort length; and vents not over 2.5 feet (76 centimeters) from ends of retort. Size of manifold—for retorts less than 15 feet (4.6 meters) in length, 2.5 inches (6.4 centimeters);				For a Diagram see 21 CFR 113.40(a)(12)(i)(B)

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for retorts 15 feet (4.6 meters) and over in length, 3 inches (7.6 centimeters). [Diagram View or download PDF]				
(*2*) *Venting method.* Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225 °F (107 °C), or for at least 8 minutes and to at least 220 °F (104.5 °C). [Diagram View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(i)(B)
(C) Venting through water spreaders. [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(i)(C)
(*1*) *Size of vent and vent valve.* For retorts less than 15 feet (4.6 meters) in length, 2 inches (5.1 centimeters); for retorts 15 feet (4.6 meters) and over in length, 2.5 inches (6.4 centimeters). [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(i)(C)
(*2*) *Size of water spreader.* For retorts less than 15 feet (4.6 meters) in length, 1.5 inches (3.8 centimeters); for retorts 15 feet (4.6 meters) and over in length, 2 inches (5.1 centimeters). The number of holes should be such that their total cross-sectional area is approximately equal to the cross-				For a Diagram see 21 CFR 113.40(a)(12)(i)(C)

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sectional area of the vent pipe inlet. [Diagram: View or download PDF]				
(*3*) *Venting method.* Water spreader vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 225 °F (107 °C), or for at least 7 minutes and to at least 220 °F (104.5 °C). [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(i)(C)
(D) Venting through a single 2.5-inch (6.4 centimeters) top vent (for retorts not exceeding 15 feet (4.6 meters) in length). [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(i)(D)
(*1*) *Specifications.* A 2.5-inch (6.4 centimeters) vent equipped with a 2.5-inch (6.4 centimeters) gate or plug cock valve and located within 2 feet (61 centimeters) of the center of the retort. [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(i)(D)
(*2*) *Venting method.* Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220 °F (104.5 °C).				For a Diagram see 21 CFR 113.40(a)(12)(i)(D)

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(ii) *Venting vertical retorts.* (A) Venting through a 1.5-inch (3.8 centimeters) overflow. [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(ii)(A)
(*1*) *Specifications.* A 1.5-inch (3.8 centimeters) overflow pipe equipped with a 1.5-inch (3.8 centimeters) gate or plug cock valve and with not more than 6 feet (1.8 meters) of 1.5-inch (3.8 centimeters) pipe beyond the valve before break to the atmosphere or to a manifold header. [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(ii)(A)
(*2*) *Venting method.* Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218 °F (103.5 °C), or for at least 5 minutes and to at least 215 °F (102 °C). [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(ii)(A)
(B) Venting through a single 1-inch (2.5 centimeters) side or top vent. [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(ii)(B)
(*1*) *Specifications.* A 1-inch (2.5 centimeters) vent in lid or top side, equipped with a 1-inch (2.5 centimeters) gate or plug cock valve and discharging				For a Diagram see 21 CFR 113.40(a)(12)(ii)(B)

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
directly into the atmosphere or to a manifold header. [Diagram: View or download PDF]				
(*2*) *Venting method.* Vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 230 °F (110 °C), or for at least 7 minutes and to at least 220 °F (104.5 °C). [Diagram: View or download PDF]				For a Diagram see 21 CFR 113.40(a)(12)(ii)(B)
(iii) *Other procedures.* Other installations and operating procedures that deviate from the requirements in paragraph (a)(12) of 21 CFR 113.40 may be used if there is evidence in the form of heat distribution data, which shall be kept on file, that they accomplish adequate venting of air.				
(13) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.				
(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient				

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frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.				
(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.				
(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.				
(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.				
(b) *Equipment and procedures for pressure processing in water in still retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

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processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.				
(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.				
(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with §113.100(c) and (d).				

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(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.				
(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.				
(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. In both horizontal and vertical retorts, the temperature-indicating device sensor shall be inserted directly into the retort shell or in a separate well or sleeve attached to the retort. The temperature-indicating device sensor shall be located so that it is beneath the surface of the water throughout the process and where there is adequate circulation to ensure accurate temperature measurement. On horizontal retorts, the				

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temperature-indicating device sensor should be located in the side at the center of the retort. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.				
(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart.				
(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices				

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that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				

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(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a combination recorder-controller. For a vertical retort equipped with a combination recorder-controller, the temperature recorder-controller sensor shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. For a horizontal retort equipped with a combination recorder-controller, the temperature recorder-controller sensor shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the sensor. For all still retort systems that pressure process in water and are equipped with combination recorder-controllers, the temperature recorder-controller sensors shall be located where the recorded temperature is an accurate measurement of the scheduled process temperature and is not affected by the heating media.				

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(3) *Pressure gages.* (i) Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.				
(ii) Each retort should have an adjustable pressure relief or control valve of a capacity sufficient to prevent an undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.				
(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. The steam controller may be combined with a temperature-recording device and, thus, may be a combination recorder-controller. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.				
(5) *Steam introduction.* Steam shall be distributed in the bottom of the retort in a manner adequate to provide uniform heat distribution throughout the retort. In vertical retorts, uniform steam distribution can be achieved by any of several methods. In				

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horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.				
(6) *Crate supports.* A bottom crate support shall be used in vertical still retorts. Baffle plates shall not be used in the bottom of the retort. Centering guides should be installed so as to ensure that there is about a 1.5-inch (3.8 centimeters) clearance between the side wall of the crate and the retort wall.				
(7) *Stacking equipment and position of containers.* Crates, trays, gondolas, *etc.,* for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch (2.5 centimeters) holes on 2-inch (5.1 centimeters) centers. If divider plates are used between the layers of containers, they should be perforated as stated in this paragraph. The positioning of containers in the retort, when specified				

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in the scheduled process, shall be in accordance with that process. Dividers, racks, trays, or other means of positioning of flexible containers shall be designed and employed to ensure even circulation of heating medium around all containers in the retort.				
(8) *Drain valve.* A nonclogging, water-tight valve shall be used. A screen shall be installed or other suitable means shall be used on all drain openings to prevent clogging.				
(9) *Air supply and controls.* In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system. Air or water circulation shall be maintained continuously during the come-up time and during processing and cooling periods. The adequacy of the air or water circulation for uniform heat distribution within the retort shall be established in accordance				

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with procedures recognized by a competent processing authority and records shall be kept on file. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.				
(10) *Water level indicator.* There shall be a means of determining the water level in the retort during operation, e.g., by using a sensor, gage, water glass, or petcock(s). Water shall cover the top layer of containers during the entire come-up time and processing periods and should cover the top layer of containers during the cooling periods. The operator shall check and record the water level at intervals sufficient to ensure its adequacy.				
(11) *Water circulation.* When a water circulating system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes				

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in the water spreader shall be uniformly distributed and should have an aggregate area not greater than the cross-sectional area of the outlet line from the pump. The suction outlets shall be protected with nonclogging screens or other suitable means shall be used to keep debris from entering the circulating system. The pump shall be designed to provide proper flow on startup and during operation, such as with a bleeder or other suitable means to remove air during startup and with an appropriate device or design to prevent pump cavitation during operation. The pump shall be equipped with a signaling device to warn the operator when it is not running. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.				
(12) *Cooling water supply.* In vertical retorts, the cooling water should be introduced at the top of the retort between the water and container levels. In horizontal retorts the cooling water should be				

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introduced into the suction side of the pump. A check valve should be included in the cooling water line.				
(13) *Retort headspace.* The headspace necessary to control the air pressure should be maintained between the water level and the top of the retort shell.				
(14) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the diagrams in this paragraph. Other installation and operating procedures that deviate from these arrangements may be used, as long as there is evidence in the form of heat distribution data or other suitable information, which shall be kept on file, which demonstrates that the heat distribution is adequate. [Diagram: View or download PDF] LEGEND FOR VERTICAL AND HORIZONTAL STILL RETORTS [FOR DIAGRAM] A—Water line.				For a Diagram see 21 CFR 113.40(b)(14)

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B—Steam line. C—Temperature control. D—Overflow line. E_1—Drain line. E_2—Screens. F—Check valves. G—Line from hot water storage. H—Suction line and manifold. I—Circulating pump. J—Petcocks. K—Recirculating line. L—Steam distributor.				

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M—Temperature-controller sensor. N—Temperature-indicating device sensor. O—Water spreader. P—Safety valve. Q—Vent valve for steam processing. R—Pressure gage. S—Inlet air control. T—Pressure control. U—Air line. V—To pressure control instrument. W—To temperature control instrument. X—Wing nuts.				

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Y_1—Crate support. Y_2—Crate guides. Z—Constant flow orifice valve. Z_1—Constant flow orifice valve used during come-up. Z_2—Constant flow orifice valve used during cook.				
(15) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.				
(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.				
(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals				

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of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.				
(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.				
(iv) When the product style results in stratification or layering of the primary product in the containers, the positioning of containers in the retort shall be according to the scheduled process.				
(c) *Equipment and procedures for pressure processing in steam in continuous agitating retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.				
(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.				
(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with §113.100(c) and (d).				
(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.				
(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.				
(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a $^{3}/_{4}$ -inch (2 centimeters) diameter opening and equipped with a $^{1}/_{16}$ -inch (1.5 millimeters) or larger bleeder opening so located as to provide a full flow of steam past the length of the temperature-indicating device sensor. The bleeders for external wells shall emit steam continuously during the entire processing period. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recording device sensor well shall have a $^{1}/_{16}$ -inch (1.5 millimeters) or larger bleeder that emits steam continuously during the processing period.				
(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller.				
(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.				
(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully maintained mechanically so that it operates satisfactorily. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.				
(5) *Bleeders.* Bleeders, except those for temperature-indicating device wells, shall be $\frac{1}{8}$ -inch (3 millimeters) or larger and shall be wide open during the entire process, including the come-up time. Bleeders shall be located within approximately 1 foot				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(30.5 centimeters) of the outermost location of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 meters) apart along the top of the retort. All bleeders shall be arranged so that the operator can observe that they are functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate or shall be equipped with an automatic alarm system(s) that would serve as a continuous monitor of condensate-bleeder functioning. Visual checks should be done at intervals of not more than 15 minutes. A record of such checks should be kept to show that the bleeder is functioning properly.				
(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort, and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.				
(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time a speed change is made, and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				
(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall be operated in such a way that ensures that the product is commercially sterile, or the retort is to be cooled promptly and all containers either reprocessed, repacked and reprocessed, or discarded. When operated as a still retort, all containers shall be given a full still retort process before the retort is cooled. If, in such an emergency, a scheduled still process or another process established to ensure commercial sterility is to be used, it shall be made readily available to the retort operator.				
(i) Any containers in the retort intake valve or in transfer valves between cooker shells of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be indicated on the temperature-recording device record and entered on the other production records required in 21 CFR 113. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort at the time of stopping and cooling shall be entered on the production records.				
(9) *Temperature drop.* If the temperature of the continuous retort drops below the temperature specified in the scheduled process while containers are in the retort, the retort reel shall be stopped promptly. An automatic device should be used to stop the reel when the temperature drops below the specified process temperature. Before the reel is restarted, all containers in the retort shall be given a complete scheduled still retort process if the temperature drop was 10 °F (5 °C) or more below the specified temperature, or alternatively, container entry to the retort shall be stopped and the reel				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or discarded. Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be indicated on the temperature-recording device record and entered on the other production records required in 21 CFR 113. If the alternative procedure of emptying the retort is followed, the subsequent handling methods used for the containers in the retort at the time of the temperature drop shall be entered on the production records. If the temperature drop was less than 10 °F (5 °C), a scheduled authorized emergency still process approved by a qualified person(s) having expert knowledge of thermal processing requirements may be used before restarting the retort reel. Alternatively, container entry to the retort shall be stopped and an authorized emergency agitating process may be used before container entry to the retort is restarted. When emergency procedures are used, no containers may enter the				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
retort and the process and procedures used shall be noted on the production records.				
(10) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lapseam (vent hole) cans may be measured by net weight determinations. The headspace of double seamed cans may also be measured by net weight determinations for homogenous liquids, taking into account the specific can end profile and other factors which affect the headspace, if proof of the accuracy of such measurements is maintained and the procedure and resultant headspace is in accordance with the scheduled process. When the product consistency is				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.				
(d) *Equipment and procedures for pressure processing in steam in discontinuous agitating retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.				
(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.				
(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with §113.100(c) and (d).				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.				
(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.				
(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a $^{3}/_{4}$ -inch (2 centimeters) diameter opening and equipped with a $^{1}/_{16}$ -inch (1.5 millimeters) or larger bleeder opening so located as to provide a full flow of steam past the length of the temperature-indicating device sensor. The bleeders for external wells shall emit				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
steam continuously during the entire processing period. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.				
(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recording device sensor well shall have a $^{1}/_{16}$ -inch (1.5 millimeters) or larger bleeder that emits steam continuously during the processing period.				
(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				
(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller.				
(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.				
(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. A steam controller activated by the steam pressure of the retort is acceptable if it is mechanically maintained so that it operates satisfactorily. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(5) *Bleeders.* Bleeders, except those for temperature-indicating device wells, shall be 1⁄8 -inch (3 millimeters) or larger and shall be wide open during the entire process, including the come-up time. Bleeders shall be located within approximately 1 foot (30.5 centimeters) of the outermost location of containers, at each end along the top of the retort; additional bleeders shall be located not more than 8 feet (2.4 meters) apart along the top. Bleeders may be installed at positions other than those specified in this paragraph, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of heat within the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to remove condensate. All bleeders shall be arranged in a way that enables the operator to observe that they are functioning properly.				
(6) *Venting and condensate removal.* The air in each retort shall be removed before processing is started.				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
Heat distribution data or documentary proof from the manufacturer or from a competent processing authority, demonstrating that adequate venting is achieved, shall be kept on file. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for continuing drainage of condensate during the retort operation.				
(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided. A lock or a notice from management posted at or near the speed-adjustment device that provides a warning that only authorized persons are permitted to make adjustments is a				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
satisfactory means of preventing unauthorized changes.				
(8) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products for which deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.				
(e) *Equipment and procedures for pressure processing in water in discontinuous agitating retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.				
(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.				
(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with §113.100(c) and (d).				
(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.				
(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.				
(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. In both horizontal and vertical retorts, the temperature-indicating device sensor shall be inserted directly into the retort shell or in a separate well or sleeve attached to the retort. The temperature-indicating device sensor shall be located so that it is beneath the surface of the water throughout the process and where there is adequate circulation to ensure accurate temperature measurement. On horizontal retorts, the temperature-indicating device sensor should be located in the side at the center of the retort. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the retort shell or in a well attached to the shell.				
(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
that will assure that the parameters of the process time and process temperature have been met.				
(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital records may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				
(iv) *Temperature controller.* The temperature-recording device may be combined with the steam				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
controller and may be a recorder-controller. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.				
(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.				
(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.				
(5) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided. A lock or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustment is a satisfactory means of preventing unauthorized changes.				
(6) *Air supply and controls.* When air is used to provide overpressure:				
(i) A means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.				
(ii) A water level indicator, e.g., sensor, gage, water glass, or petcock(s), shall be used for determining the water level in the retort during operation. Water shall cover the top layer of containers during the entire come-up time and processing periods and should also cover the top layer of containers during the cooling				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
periods. The operator shall check and record the water level at intervals sufficient to ensure its adequacy.				
(7) *Water circulation.* When a water circulating system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed and should have an aggregate area not greater than the cross-sectional area of the outlet line from the pump. The suction outlets shall be protected with nonclogging screens or other suitable means shall be used to keep debris from entering the circulating system. The pump shall be designed to provide proper flow on startup and during operation, such as with a bleeder or other suitable means to remove air during startup and with an appropriate device or design to prevent pump cavitation during operation. The pump shall be equipped with a signaling device				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
to warn the operator when it is not running. Alternative methods for circulation of water in the retort may be used when established by a competent authority as adequate for even heat distribution.				
(8) *Drain valve.* A nonclogging, water-tight valve shall be used. A screen shall be installed or other suitable means shall be used on all drain openings to prevent clogging.				
(9) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to ensure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. When the product consistency is specified in the scheduled process, the consistency of the product				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to ensure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products when deviations from such specifications may affect the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.				
(f) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—(1) *Temperature-indicating device.* Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is				

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maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.				
(i) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.				
(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with §113.100(c) and (d).				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

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(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.				
(iv) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.				
(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be located in the steam dome near the steam-water interface. When the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a temperature-indicating device sensor shall be located in each hydrostatic water leg in a position near the bottom temperature-recording device sensor. The temperature-indicating device—not the temperature-recording device—shall				

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be the reference instrument for indicating the processing temperature.				
(2) *Temperature-recording device.* Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the steam dome or in a well attached to the dome. Each temperature-recording device sensor well shall have a $^{1}/_{16}$ -inch (1.5 millimeters) or larger bleeder that emits steam continuously during the processing period. Additional temperature-recording device sensors shall be installed in the hydrostatic water legs in situations where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs.				
(i) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording				

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devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(ii) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital recordings may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(iii) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device				

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during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				
(iv) *Temperature controller.* The temperature-recording device may be combined with the steam controller and may be a recorder-controller.				
(3) *Pressure gages.* Each retort should be equipped with a pressure gage that is accurate to 2 pounds per square inch (13.8 kilopascals) or less.				
(4) *Recording of temperatures.* Temperatures indicated by the temperature-indicating device or devices shall be entered on a suitable form during processing operations. Temperatures shall be recorded by an accurate temperature-recording device or devices at the following points: (i) In the steam chamber between the steam-water interface and the lowest container position. (ii) Near the top				

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and the bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the legs.				
(5) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recorder-controller when combined with a temperature-recording device. A steam controller activated by the steam pressure of the retort is acceptable if it is carefully mechanically maintained so that it operates satisfactorily. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.				
(6) *Venting.* Before the start of processing operations, the retort steam chamber or chambers shall be vented to ensure removal of air.				
(7) *Bleeders.* Bleeder openings ¼ -inch (6 millimeters) or larger shall be located at the top of the steam chamber or chambers opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process,				

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including the come-up time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.				
(8) *Retort speed.* The speed of the container-conveyor chain shall be specified in the scheduled process and shall be determined and recorded at the start of processing and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified. The speed should be determined and recorded every 4 hours. An automatic device should be used to stop the chain when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided. A lock or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				
(9) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded				

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on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.				
(i) When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.				
(ii) Closing machine vacuum in vacuum-packed products shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.				
(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.				
(g) *Aseptic processing and packaging systems*—(1) *Product sterilizer*—(i) *Equipment*—(A) *Temperature-indicating device.* Each product sterilizer shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating				

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device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures, upon installation and at least once a year thereafter, or more frequently if necessary, to ensure accuracy during processing. Each temperature-indicating device and each reference device that is maintained by the processor shall have a tag, seal, or other means of identity.				
(*1*) The design of the temperature-indicating device shall ensure that the accuracy of the device is not affected by electromagnetic interference and environmental conditions.				
(*2*) Records of the accuracy of the temperature-indicating device and of a reference device that is				

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maintained by the processor shall be established and maintained in accordance with §113.100(c) and (d).				
(*3*) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.				
(*4*) A temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.				
(*5*) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.				
(B) *Temperature-recording device.* Each product sterilizer shall have an accurate temperature-recording device. Each temperature-recording device				

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shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. A temperature-recording device sensor shall be installed in the product at the holding-tube outlet between the holding tube and the inlet to the cooler. Additional temperature-recording device sensors shall be located at each point where temperature is specified as a critical factor in the scheduled process.				
(*1*) *Analog or graphical recordings.* Temperature-recording devices that create analog or graphical recordings may be used. Temperature-recording devices that record to charts shall be used only with the appropriate chart. Each chart shall have a working scale of not more than 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the desired product sterilization temperature. Chart graduations shall not exceed 2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature. Temperature-recording devices that create multipoint plottings of temperature readings shall				

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record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(*2*) *Digital recordings.* Temperature-recording devices, such as data loggers, that record numbers or create other digital recordings may be used. Such a device shall record the temperature at intervals that will assure that the parameters of the process time and process temperature have been met.				
(*3*) *Adjustments.* The temperature-recording device shall be adjusted with sufficient frequency to ensure agreement as nearly as possible with, but to be in no event higher than, the temperature-indicating device during processing. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the temperature-recording device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				

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(C) *Temperature controller.* An accurate temperature controller shall be installed and capable of ensuring that the desired product sterilization temperature is maintained. Air-operated temperature controllers should have adequate filter systems to ensure a supply of clean, dry air.				
(D) *Product-to-product regenerators.* When a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to ensure that any leakage in the regenerator is from the sterilized product into the unsterilized product.				
(E) *Differential pressure recorder-controller.* When a product-to-product regenerator is used, it shall be equipped with an accurate differential pressure recorder-controller. The differential pressure recorder-controller shall be accurate to within 2				

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pounds per square inch (13.8 kilopascals). One pressure sensor shall be installed at the sterilized product regenerator outlet and the other pressure sensor shall be installed at the unsterilized product regenerator inlet. The sensor and recorder of the differential pressure recorder-controller shall be tested for accuracy against an accurate reference device upon installation and at least once every 3 months of operation thereafter, or more frequently if necessary, to ensure its accuracy.				
(*1*) *Analog or graphical recordings.* Differential pressure recorder-controllers that create analog or graphical recordings may be used. Differential pressure recorder-controllers that record to charts shall be used only with the appropriate chart. The scale divisions of the chart shall not exceed 2 pounds per square inch (13.8 kilopascals) on a working scale of not more than 20 pounds per square inch per inch of scale (55 kilopascals per centimeter).				
(*2*) *Digital recordings.* Differential pressure recorder-controllers, such as data loggers, that record numbers				

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or create other digital recordings may be used. Such differential pressure recorder-controllers shall record the differential pressure at intervals that will assure that the minimum differential pressure is maintained.				
(F) *Flow control.* A flow control device shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized flow adjustments shall be provided. A lock or a notice from management posted at or near the flow controlling device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				
(G) *Product holding tube.* The product-sterilizing holding tube shall be designed to give continuous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it must be				

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sloped upward at least ¼ -inch per foot (2.1 centimeters per meter).				
(H) *Flow-diversion systems.* If a processor elects to install a flow-diversion system, it should be installed in the product piping located between the product cooler and the product filler or aseptic surge tank and should be designed to divert flow away from the filler or aseptic surge tank automatically. Controls and/or warning systems should be designed and installed with necessary sensors and actuators to operate whenever the sterilizing temperature in the holding tube or pressure differential in the product regenerator drops below specified limits. Flow-diversion systems should be designed and operated in accordance with recommendations of an aseptic processing and packaging authority.				
(I) *Equipment downstream from the holding tube.* Product coolers, aseptic surge tanks, or any other equipment downstream from the holding tube, with rotating or reciprocating shafts, valve stems, instrument connections, or other such points, are				

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subject to potential entry of microorganisms into the product. Such locations in the system should be equipped with steam seals or other effective barriers at the potential access points. Appropriate means should be provided to permit the operator to monitor the performance of the seals or barriers during operations.				
(ii) *Operation*—(A) *Startup.* Before the start of aseptic processing operations the product sterilizer and all product-contact surfaces downstream shall be brought to a condition of commercial sterility.				
(B) *Temperature drop in product-sterilizing holding tube.* When product temperature in the holding tube drops below the temperature specified in the scheduled process, product flow should be diverted away from the filler or aseptic surge tank by means of a flow-diversion system. If for any reason product subjected to a temperature drop below the scheduled process is filled into containers, the product shall be segregated from product that received the scheduled process. The processing				

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deviation shall be handled in accordance with §113.89. The product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before product flow is resumed to the filler or to the aseptic surge tank.				
(C) *Loss of proper pressures in the regenerator.* When a regenerator is used, the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 1 pound per square inch (6.9 kilopascals) greater than the pressure of unsterilized product in the regenerator. In this case, product flow should be diverted away from the filler or aseptic surge tank by means of the flow-diversion system. If for any reason the product is filled into containers, the product shall be segregated from product that received the scheduled process. The processing deviation shall be handled in accordance with §113.89. Product flow to the filler or to the aseptic surge tank shall not be resumed until the cause of the improper pressure relationships in the regenerator				

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has been corrected and the affected system(s) has been returned to a condition of commercial sterility.				
(D) *Loss of sterile air pressure or other protection level in the aseptic surge tank.* When an aseptic surge tank is used, conditions of commercial sterility may be lost when the sterile air overpressure or other means of protection drops below the scheduled process value. Product flow to and/or from the aseptic surge tank shall not be resumed until the potentially contaminated product in the tank is removed, and the aseptic surge tank has been returned to a condition of commercial sterility.				
(E) *Records.* Readings at the following points shall be observed and recorded at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process: Temperature-indicating device in holding tube outlet; temperature-recording device in holding tube outlet; differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate as established				

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by the flow control device or as determined by filling and closing rates and, if an aseptic surge tank is used, sterile air pressure or other protection means; and proper performance of steam seals or other similar devices. The measurements and recordings should be made at intervals not to exceed 1 hour.				
(2) *Container sterilizing, filling, and closing operation*—(i) *Equipment*—(A) *Recording device.* The container and closure sterilization system and product filling and closing system shall be instrumented to demonstrate that the required sterilization is being accomplished continuously. Recording devices shall be used to record, when applicable, the sterilization media flow rates, temperature, concentration, or other factors. When a batch system is used for container sterilization, the sterilization conditions shall be recorded.				
(B) *Timing method(s).* A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment specified in the scheduled process, or to control the				

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sterilization cycle at the rate specified in the scheduled process. A means of preventing unauthorized speed changes must be provided. A lock or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.				
(ii) *Operation*—(A) *Startup.* Before the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.				
(B) *Loss of sterility.* A system shall be provided to stop packaging operations, or alternatively to ensure segregation of any product packaged when the packaging conditions fall below scheduled processes. Compliance with this requirement may be accomplished by diverting product away from the filler, by preventing containers from entering the filler, or by other suitable means. In the event				

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product is packaged under conditions below those specified in the scheduled process, all such product shall be segregated from product that received the scheduled process. The processing deviation shall be handled in accordance with §113.89. In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.				
(C) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates, temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.				
(3) *Incubation.* Incubation tests should be conducted on a representative sample of containers of product				

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from each code; records of the test results should be maintained.				
(4) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. Such measurements and recordings should be done at intervals not to exceed 15 minutes.				
(h) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing changes in flame intensity and unauthorized speed changes on the conveyor shall be				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
provided. A lock or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the entry and at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained. Such measurements and recordings should be done at intervals not to exceed 15 minutes.				
(1) *Process interruption.* In the event of process interruption wherein the temperature of the product may have dropped, an authorized, scheduled emergency plan approved by a qualified person having expert knowledge of the process requirements may be used.				
(2) *Critical factors.* Critical factors specified in the scheduled process shall be measured and recorded				

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on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.				
(i) *Equipment and procedures for thermal processing of foods wherein critical factors such as water activity are used in conjunction with thermal processing.* The methods and controls used for the manufacture, processing, and packing of such foods shall be as established in the scheduled process and shall be operated or administered in a manner adequate to ensure that the product is safe. The time and temperature of processing and other critical factors specified in the scheduled process shall be measured with instruments having the accuracy and dependability adequate to ensure that the requirements of the scheduled process are met. All measurements shall be made and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process.				

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(j) *Other systems.* All systems, whether or not specifically mentioned in this part, for the thermal processing of low-acid foods in hermetically sealed containers shall conform to the applicable requirements of this part and the methods and controls used for the manufacture, processing, and packing of these foods shall be as established in the scheduled process. These systems shall be operated or administered in a manner adequate to ensure that commercial sterility is achieved. Critical factors specified in the scheduled process shall be measured and recorded at intervals of sufficient frequency to ensure that the critical factors are within the limits specified in the scheduled process. [76 FR 11906, Mar. 3, 2011; 76 FR 81363, Dec. 28, 2011]				
Subpart D—Control of Components, Food Product Containers, Closures, and In-Process Materials				
§113.60 Containers.				
(a) *Closures.* Regular observations shall be maintained during production runs for gross closure defects. Any such defects shall be recorded and corrective action				

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taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used and shall record the observations made. For double-seam cans, each can should be examined for cutover or sharpness, skidding or deadheading, false seam, droop at the crossover or lap, and condition of inside of countersink wall for evidence of broken chuck. Such measurements and recordings should be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closing machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. When irregularities are found, the corrective action shall be recorded.				

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<table>
<tr><th>TITLE 21—FOOD AND DRUGS, CHAPTER 1
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<tr><td>(1) Teardown examinations for double-seam cans shall be performed by a qualified individual and the results therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seaming station to ensure maintenance of seam integrity. Such examinations and recordings should be made at intervals not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective action taken, if any, shall be noted.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>(i) Required and optional can seam measurements:

(a) Micrometer measurement system:

<table><tr><th>Required</th><th>Optional</th></tr><tr><td>Cover hook</td><td>Overlap (by calculation).</td></tr><tr><td>Body hook</td><td>Countersink.</td></tr></table></td><td></td><td></td><td></td><td>For a Diagram see 21 CFR 113.60(a)(1)(i)(c)</td></tr>
</table>

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Width (length, height)	
Tightness (observation for wrinkle)	
Thickness	

(*b*) Seam scope or projector:

Required	Optional
Body hook	Width (length, height).
Overlap	Cover hook.
Tightness (observation for wrinkle)	Countersink.
Thickness by micrometer	

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(*c*) Can double seam terminology: [Diagram: View or download PDF] [Legend:] (*1*) "Crossover": The portion of a double seam at the lap. (*2*) "Cutover": A fracture, sharp bend, or break in the metal at the top of the inside portion of the double seam. (*3*) "Deadhead": A seam which is incomplete due to chuck spinning in the countersink. (*4*) "Droop": Smooth projection of double seam below bottom of normal seam. (*5*) "False seam": A small seam breakdown where the cover hook and the body hook are not overlapped. (*6*) "Lap": Two thicknesses of material bonded together.				
(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three				

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measurements shall be made at points approximately 120° apart, excluding the side seam.				
(iii) Overlap length can be calculated by the following formula: The theoretical overlap length = CH + BH + T − W, where CH = cover hook BH = body hook T = cover thickness, and W = seam width (height, length)				
(2) For glass containers with vacuum closures, capper efficiency must be checked by a measurement of the cold water vacuum. This shall be done before actual filling operations, and the results shall be recorded.				
(3) For closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals				

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of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.				
(b) *Cooling water.* Container cooling water shall be chlorinated or otherwise sanitized as necessary for cooling canals and for recirculated water supplies. There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler.				
(c) *Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code that shall be permanently visible to the naked eye. When the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, if the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code				

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shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers that constitute the batch do not extend over a period of more than one personnel shift.				
(d) *Postprocess handling.* Container handling equipment used in handling filled containers shall be designed, constructed, and operated to preserve the can seam or other container closure integrity. Container handling equipment, including automated and non-automated equipment, shall be checked with sufficient frequency and repaired or replaced as necessary to prevent damage to containers and container closures. When cans are handled on belt conveyors, the conveyors should be constructed to minimize contact by the belt with the double seam, *i.e.,* cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, *etc.* should be replaced with new nonporous material. All				

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tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. [44 FR 16215, Mar. 16, 1979, as amended at 76 FR 11922, Mar. 3, 2011]				
Subpart E—Production and Process Controls				
§113.81 Product preparation.				
(a) Before using raw materials and ingredients susceptible to microbiological contamination, the processor shall ensure that those materials and ingredients are suitable for use in processing low-acid food. Compliance with this requirement may be accomplished by receiving the raw materials and ingredients under a supplier's guarantee that they are suitable for use, by examining them for their microbiological condition, or by other acceptable means.				
(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time,				

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and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. If the blanched food product is washed before filling, potable water should be used.				
(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.				
(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. Compliance with the requirement may be accomplished by heat exhausting, mechanical exhausting, hot brining, or steam injection.				
(e) When the maintenance of pH (above 4.6) of a normally low-acid food is a basis for a scheduled process, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets				

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that of the scheduled process. The methodology described in §114.90 of 21 CFR 114 should be used.				
(f) When the scheduled process sets forth critical factors to prevent the growth of microorganisms not destroyed by the thermal process, the factors shall be carefully controlled to ensure that the limits established in the scheduled process are not exceeded. When normally low-acid foods require sufficient solute to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium water activity (a_w) of the finished product meets that of the scheduled process. The scheduled thermal processes for foods having an a_w greater than 0.85 and less than the a_w that would allow the growth of spores of microorganisms of public health significance shall be sufficient to render the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.				
§113.83 Establishing scheduled processes.				

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Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Variations include those that occur due to seasonal or growing fluctuations, variety differences, supplier processes, reprocessing, and mixing a batch of processed product with the same unprocessed product before it is processed. Critical factors, e.g., minimum headspace, consistency, maximum fill-in or drained weight, a_w, *etc.,* that may affect the scheduled process, shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, the use of microbial thermal death time data, process calculations based on product heat penetration data,				

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and inoculated packs. Calculation shall be performed according to procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for confirmation of the scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial production runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination. [76 FR 11922, Mar. 3, 2011]				

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§113.87 Operations in the thermal processing room.				
(a) Operating processes and retort venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or be made readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration. Scheduled processes must be made readily available to the supervisor and any duly authorized employee of the Food and Drug Administration.				
(b) A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process. Each retort basket, truck, car, or crate used to hold containers in a retort, or one or more containers therein, shall, if it contains any retorted food product, be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means that will indicate visually, to thermal processing				

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personnel, those units that have been retorted. A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting for all retort baskets, trucks, cars, or crates, to ensure that each unit of product has been retorted. A record of these checks should be made.				
(c) The initial temperature of the contents of the containers to be processed shall be accurately determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process. For those operations that use water during the filling of the retort or during processing, provision shall be made to ensure that the water will not, before the start of each thermal process, lower the initial temperature of the product below that specified in the scheduled process. The temperature-indicating device used to determine the initial temperature shall be tested for accuracy against a reference device for which the accuracy is				

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traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device, by appropriate standard procedures, with sufficient frequency to ensure that initial temperature measurements are accurate. Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with §113.100(c) and (d).				
(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time and venting time specified in the scheduled process are achieved. Pocket or wrist watches are not considered satisfactory for timing purposes. Digital clocks may be used if the operating process and the venting schedule have a 1-minute or greater safety factor over the scheduled process.				
(e) Clock times on temperature-recording device records shall reasonably correspond to the time of				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
day on the processing records to provide correlation of these records.				
(f) The steam supply to the thermal processing system shall be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands of steam by the plant.				
(g) If mufflers are used on bleeders or vent systems, evidence that the bleeders or vents are operated in a manner that does not significantly impede the removal of air shall be kept on file. This evidence may be in the form of heat distribution data or other satisfactory evidence such as a letter from the manufacturer, the designer, or a competent processing authority. [44 FR 16215, Mar. 16, 1979, as amended at 76 FR 11923, Mar. 3, 2011]				
§113.89 Deviations in processing, venting, or control of critical factors.				
Whenever any process is less than the scheduled process or when critical factors are out of control for any low-acid food or container system as disclosed				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
from records by processor check or otherwise, the commerical processor of that low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, must set aside that portion of the product involved for further evaluation as to any potential public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless this evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside shall be either fully reprocessed to render it commercially sterile or destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commerical sterility or after the determination that no significant potential for public				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed. All process deviations involving a failure to satisfy the minimum requirements of the scheduled process, including emergencies arising from a jam or breakdown of a continuous agitating retort necessitating cooling the retort for repairs, shall be recorded and made the subject of a separate file (or a log identifying the appropriate data) detailing those deviations and the actions taken.				
Subpart F—Records and Reports				
§113.100 Processing and production records.				
(a) Processing and production information shall be entered at the time it is observed by the retort or processing system operator, or other designated person, on forms that include the product, the code number, the date, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the initial temperature, the actual processing time, the				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
temperature-indicating device and temperature-recording device readings, and other appropriate processing data. Closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:				
(1) *Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and temperature to which vented.				
(2) *Agitating retorts.* Functioning of condensate bleeder; retort speed; and, when specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.				
(3) *Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, when the scheduled process specifies maintenance of particular temperatures in				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.				
(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature-indicating device and the temperature-recording device; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate, as determined by the flow controlling device or by filling and closing rates; sterilization media flow rate or temperature or both; retention time of containers, and closures when applicable, in the sterilizing environment; and, when a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.				
(5) *Flame sterilizers.* Container conveyor speed; surface temperature at the beginning and at the end of the holding period; nature of container.				
(6) *Food preservation methods wherein critical factors such as water activity are used in conjunction with*				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
thermal processing. Product formulation and scheduled processes used, including the thermal process, its associated critical factors, as well as other critical factors, and results of a_w determinations.				
(7) *Other systems.* Critical factors specified in the formulation of the product or in the scheduled process.				
(b) Temperature-recording device records shall be identified by date, retort number, and other data as necessary, so they can be correlated with the record of lots processed. Each entry on the processing and production records shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and this retort or processing system operator or other designated person shall sign or initial each record form. Not later than 1 working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
processing and production records for completeness and to ensure that the product received the scheduled process. The records, including temperature-recording device records, shall be signed or initialed and dated by the reviewer.				
(c) Records of the accuracy of a temperature-indicating device shall include: (1) A reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device; (2) The name of the manufacturer of the temperature-indicating device; (3) The identity of the reference device, equipment, and procedures used for the accuracy test and to adjust the temperature-indicating device or, if an outside facility is used to conduct the accuracy test for the temperature-indicating device, a guarantee, certificate of accuracy, certificate of calibration, or				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a National Institute of Standards and Technology (NIST) or other national metrology institute standard; (4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device; (5) The date and results of each accuracy test, including the amount of calibration adjustment; and (6) The date on or before which the next accuracy test must be performed.				
(d) Records of the accuracy of a reference device maintained by the processor shall include:				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(1) A reference to the tag, seal, or other means of identity used by the processor to identify the reference device; (2) The name of the manufacturer of the reference device; (3) The identity of the equipment and reference to procedures used for the accuracy test and to adjust or calibrate the reference device or, if an outside facility is used to conduct the accuracy test for the reference device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a NIST or other national metrology institute standard;				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 **SUBCHAPTER B** **PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)**	**Audit Standard Language**	**Analysis of Alignment of Audit Standard**	**Description of Gaps and Actions to Align**	**Additional Comments**
(4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device; (5) The date and results of each accuracy test, including the amount of calibration adjustment; and (6) The date on or before which the next accuracy test must be performed.				
(e) Records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed. The records shall be signed or initialed and dated by the reviewer.				
(f) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS (LACF)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
may have become contaminated or otherwise rendered unfit for their intended use.				
(g) Copies of all records provided for in this part, except those required under §113.83 establishing scheduled processes, shall be retained at the processing plant for a period of not less than 1 year from the date of manufacture, and at the processing plant or other reasonably accessible location for an additional 2 years. If, during the first year of the 3-year record-retention period, the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.				
(h) Records of this part may be maintained electronically, provided they are in compliance with 21 CFR part 11 of . [44 FR 16215, Mar. 16, 1979, as amended at 76 FR 11923, Mar. 3, 2011]				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 108—EMERGENCY PERMIT CONTROL	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Subpart B—Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit				
§108.35 Thermal processing of low-acid foods packaged in hermetically sealed containers.				
(a) Inadequate or improper manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers may result in the distribution in interstate commerce of processed foods that may be injurious to health. The harmful nature of such foods cannot be adequately determined after these foods have entered into interstate commerce. The Commissioner of Food and Drugs therefore finds that, in order to protect the public health, it may be necessary to require any commercial processor, in any establishment engaged in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers, to obtain and hold a temporary emergency permit provided for under section 404 of the Federal Food, Drug,				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 108—EMERGENCY PERMIT CONTROL	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
and Cosmetic Act. Such a permit may be required whenever the Commissioner finds, after investigation, that the commercial processor has failed to fulfill all the requirements of 21 CFR 108.35, including registration and the filing of process information, and the mandatory portions of part 21 CFR 113 of . These requirements are intended to ensure safe manufacture, processing, and packing procedures and to permit the Food and Drug Administration to verify that these procedures are being followed. Such failure shall constitute a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the act to that establishment, pursuant to the procedures established in subpart A of this part.				
(c) *Registration and process filing*—(1) *Registration.* A commercial processor when first engaging in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers in any State, as				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 108—EMERGENCY PERMIT CONTROL	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register with the Food and Drug Administration on Form FDA 2541 (food canning establishment registration) information including (but not limited to) his name, principal place of business, the location of each establishment in which such processing is carried on, the processing method in terms of the type of processing equipment employed, and a list of the low-acid foods so processed in each such establishment. These forms are available from the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form shall be submitted to the LACF Registration Coordinator (HFS-618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. These forms also are available on the				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 108—EMERGENCY PERMIT CONTROL	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Food and Drug Administration's Web site at http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm . For electronic submission go to FDA's Industry Systems Web site at www.access.fda.gov. Commercial processors duly registered in accordance with 21 CFR 108.35 shall notify the Food and Drug Administration not later than 90 days after such commercial processor ceases or discontinues the manufacture, processing, or packing of thermally processed foods in any establishment: *Provided,* that such notification shall not be required as to the temporary cessation necessitated by the seasonal character of the particular establishment's production or caused by temporary conditions including but not limited to strikes, lockouts, fire, or acts of God.				
(2) *Process filing.* A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall, not later than 60 days after				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 108—EMERGENCY PERMIT CONTROL	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
registration and prior to the packing of a new product, provide the Food and Drug Administration information as to the scheduled processes including but not limited to the processing method, type of retort or other thermal processing equipment employed, minimum initial temperatures, times and temperatures of processing, sterilizing value (Fo), or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process, for each such low-acid food in each container size: *Provided,* that the filing of such information does not constitute approval of the information by the Food and Drug Administration, and that information concerning processes and other data so filed shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905. This information shall be submitted on the following forms as appropriate: Form FDA 2541d (Food Process Filing for Low-Acid				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 108—EMERGENCY PERMIT CONTROL	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Retorted Method), Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method), or Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems). These forms are available from the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form(s) shall be submitted to the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. These forms also are available on the Food and Drug Administration's Web site at http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm. For electronic submission, go to FDA's Industry Systems Web site at www.access.fda.gov.				

NOTE: This template does not include certain requirements that may be pertinent to determining compliance with 21 CFR Part 113 and Part 108 (e.g., definitions and certain emergency permit procedures in 21 CFR part 108). "Shall" is used to state mandatory requirements. "Should" is used to state recommended or advisory procedures or to identify recommended equipment. . In addition to meeting the applicable requirements of 21 CFR Parts 108 and 113, LACF processors of foods intended for consumption in the U.S. are also required to comply with any other pertinent FDA regulatory requirements outside the elements included in the template (e.g., applicable requirements in 21 CFR part 117 related to current good manufacturing practices and emergency permit procedures in 21 CFR part 108 subpart A, as applicable).

TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 108—EMERGENCY PERMIT CONTROL	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(i) If all the necessary information is not available for existing products, the processor shall, at the time the existing information is provided to the Food and Drug Administration request in writing an extension of time for submission of such information, specifying what additional information is to be supplied and the date by which it is to be submitted. Within 30 working days after receipt of such request the Food and Drug Administration shall either grant or deny such request in writing.				
(ii) If a packer intentionally makes a change in a previously filed scheduled process by reducing the initial temperature or retort temperature, reducing the time of processing, or changing the product formulation, the container, or any other condition basic to the adequacy of scheduled process, he shall prior to using such changed process obtain substantiation by qualified scientific authority as to its adequacy. Such substantiation may be obtained by telephone, telegram, or other media, but must be promptly				

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TITLE 21—FOOD AND DRUGS, CHAPTER 1 SUBCHAPTER B PART 108—EMERGENCY PERMIT CONTROL	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
recorded, verified in writing by the authority, and contained in the packer's files for review by the Food and Drug Administration. Within 30 days after first use, the packer shall submit to the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740 a complete description of the modifications made and utilized, together with a copy of his file record showing prior substantiation by a qualified scientific authority as to the safety of the changed process. Any intentional change of a previously filed scheduled process or modification thereof in which the change consists solely of a higher initial temperature, a higher retort temperature, or a longer processing time, shall not be considered a change subject to this paragraph, but if that modification is thereafter to be regularly scheduled, the modified process shall be promptly filed as a scheduled process,				

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accompanied by full information on the specified forms as provided in this paragraph.				
(iii) Many packers employ an "operating" process in which retort operators are instructed to use retort temperatures and/or processing times slightly in excess of those specified in the scheduled process as a safety factor to compensate for minor fluctuations in temperature or time to assure that the minimum times and temperatures in the scheduled process are always met. This would not constitute a modification of the scheduled process.				
(3) *Process adherence and information.* (i) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers in any registered establishment shall process each low-acid food in each container size in conformity with at least the scheduled processes and modifications filed pursuant to paragraph (c)(2) of 21 CFR 108.35.				

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(ii) Process information availability: When requested by the Food and Drug Administration in writing, a commercial processor engaged in thermal processing of low-acid foods packaged in hermetically sealed containers shall provide the Food and Drug Administration with any information concerning processes and procedures which is deemed necessary by the Food and Drug Administration to determine the adequacy of the process: *Provided,* That the furnishing of such information does not constitute approval of the information by the Food and Drug Administration, and that the information concerning processes and other data so furnished shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905.				
(d) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall promptly report to the Food and Drug Administration any instance of spoilage or process deviation the				

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nature of which indicates potential health significance where any lot of such food has in whole or in part entered distribution.				
(e) A commercial processor engaged in thermal processing of low-acid foods packaged in hermetically sealed containers shall promptly report to the Food and Drug Administration any instance wherein any lot of such food, which may be injurious to health by reason of contamination with microorganisms, has in whole or in part entered distribution.				
(f) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall have prepared and in his files a current procedure which he will use for products under his control and which he will ask his distributor to follow, including plans for effecting recalls of any product that may be injurious to health; for identifying, collecting, warehousing, and controlling the product; for determining the effectiveness of such recall; for notifying the				

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Food and Drug Administration of any such recall; and for implementing such recall program.				
(g) All operators of retorts, thermal processing systems, aseptic processing and packaging systems, or other thermal processing systems, and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, aseptic processing and packaging systems operations or other thermal processing systems operations, and container closure inspections, and has satisfactorily completed the prescribed course of instruction: *Provided,* That this requirement shall not apply in the State of California as listed in paragraph (j) of 21 CFR 108.35. The Commissioner will not withhold approval of any school qualified to give such instruction.				
(h) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall prepare,				

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review, and retain at the processing plant for a period of not less than one year, and at the processing plant or other reasonably accessible location for an additional two years, all records of processing, deviations in processing, container closure inspections, and other records specified in 21 CFR part 113 of. If during the first year of the three-year record retention period the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack. Upon written demand during the course of a factory inspection pursuant to section 704 of the act by a duly authorized employee of the Food and Drug Administration, a commercial processor shall permit the inspection and copying by such employee of these records to verify the adequacy of processing, the integrity of container closures, and the coding of the products.				

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(i) This section shall not apply to the commercial processing of any food processed under the continuous inspection of the meat and poultry inspection program of the Food Safety and Inspection Service of the Department of Agriculture under the Federal Meat Inspection Act (34 Stat. 1256, as amended by 81 Stat. 584 (21 U.S.C. 601 *et seq.*)) and the Poultry Products Inspection Act (71 Stat. 441, as amended by 82 Stat. 791 (21 U.S.C. 451 *et seq.*)).				
(j) *Compliance with State regulations.* (1) Wherever the Commissioner finds that any State regulates the commercial thermal processing of low-acid foods in accordance with effective regulations specifying at least the requirements of part 113 of this chapter, he shall issue a notice stating that compliance with such State regulations shall constitute compliance with part 113 of this chapter. However, the provisions of this section shall remain applicable to the commercial processing of low-acid foods in any such State, except that, either the State through				

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its regulatory agency or each processor of low-acid foods in such State shall file with the Center for Food Safety and Applied Nutrition the registration information and the processing information prescribed in paragraph (c) of this section. (2) The Commissioner finds that the regulations adopted by the State of California under the laws relating to cannery inspections governing thermal processing of low-acid foods packaged in hermetically sealed containers satisfy the requirements of part 113 of this chapter. Accordingly, processors, who under the laws relating to cannery inspections are licensed by the State of California and who comply with such state regulations, shall be deemed to comply with the requirements of part 113 of this chapter.				
(k) *Imports.* (1) This section shall apply to any foreign commercial processor engaged in the				

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thermal processing of low-acid foods packaged in hermetically sealed containers and offering such foods for import into the United States except that, in lieu of providing for the issuance of an emergency permit under paragraph (a) of this section, the Commissioner will request the Secretary of the Treasury to refuse admission into the United States, pursuant to section 801 of the act, of any such low-acid foods which the Commissioner determines, after investigation, may result in the distribution in interstate commerce of processed foods that may be injurious to health as set forth in paragraph (a) of this section. (2) Any such food refused admission shall not be admitted until such time as the Commissioner may determine that the commercial processor offering the food for import is in compliance with the requirements and conditions of this section and that such food is not injurious to health. For the purpose of making such determination, the Commissioner reserves the right for a duly authorized				

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employee of the Food and Drug Administration to inspect the commercial processor's manufacturing, processing, and packing facilities.				
(l) The following data and information submitted to the Food and Drug Administration pursuant to this section are not available for public disclosure unless they have been previously disclosed to the public as defined in 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in 20.81 of this chapter: (1) Manufacturing methods or processes, including quality control information. (2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not				

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reveal data or information which is not available for public disclosure under this provision is available for public disclosure. (3) Quantitative or semiquantitative formulas.				