the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules shall be maintained on file by the establishment. Upon request by Program employees, the establishment shall make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment shall provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors shall not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

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§ 381.303 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule shall be measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

(a) *General.* (1) Maximum fill-in weight or drained weight;

(2) Arrangement of pieces in the container;

(3) Container orientation during thermal processing;

(4) Product formulation;

(5) Particle size;

(6) Maximum thickness for flexible, and to some extent semirigid containers during thermal processing;

(7) Maximum pH;

(8) Percent salt;

(9) Ingoing (or formulated) nitrite level (ppm);

(10) Maximum water activity; and

(11) Product consistency or viscosity.

(b) *Continuous rotary and batch agitating retorts.* (1) Minimum headspace; and

(2) Retort reel speed.

(c) *Hydrostatic retorts.* (1) Chain or conveyor speed.

(d) *Steam/air retorts.* (1) Steam/air ratio; and

(2) Heating medium flow rate.

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§ 381.304 Operations in the thermal processing area.

(a) *Posting of processes.* Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, shall be posted in a conspicuous place near the thermal processing equipment. Alternatively, such information shall be available to the thermal processing system operator and the inspector.

(b) *Process indicators and retort traffic control.* A system for product traffic control shall be established to prevent product from bypassing the thermal processing operation. Each basket, crate or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, shall be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed. Exposed heat sensitive indicators attached to container vehicles shall be removed before such vehicles are refilled with unprocessed product. Container loading systems for crateless retorts shall be designed to prevent unprocessed product from bypassing the thermal processing operation.

(c) *Initial temperature.* The initial temperature of the contents of the coldest container to be processed shall be determined and recorded by the establishment at the time the processing cycle begins to assure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule. Thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins shall be operated to assure that such

water will not lower the temperature of the product below the minimum initial temperature specified in the process schedule.

(d) *Timing devices.* Devices used to time applicable thermal processing operation functions or events, such as process schedule time, come-up time and retort venting, shall be accurate to assure that all such functions or events are achieved. Pocket watches and wrist watches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If such clocks do not display seconds, all required timed functions or events shall have at least a 1-minute safety factor over the specified thermal processing operation times. Temperature/time recording devices shall correspond within 15 minutes to the time of the day recorded on written records required by § 381.306.

(e) *Measurement of pH.* Unless other methods are approved by the Administrator, potentiometric methods using electronic instruments (pH meters) shall be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

§ 381.305 Equipment and procedures for heat processing systems.

(a) *Instruments and controls common to different thermal processing systems*—(1) *Indicating temperature devices.* Each retort shall be equipped with at least one indicating temperature device that measures the actual temperature within the retort. The indicating temperature device, not the temperature/time recording device, shall be used as the reference instrument for indicating the process temperature.

(i) *Mercury-in-glass thermometers.* A mercury-in-glass thermometer shall have divisions that are readable to 1 °F (or 0.5 °C) and whose scale contains not more than 17 °F/inch (or 4.0 °C/cm) of graduated scale. Each mercury-in-glass thermometer shall be tested for accuracy against a known accurate standard upon installation and at least once a year to ensure its accuracy. Records that specify the date, standard used, test method, and the person or testing authority performing the test shall be maintained on file by the establishment and made available to Program employees. A mercury-in-glass thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired and tested for accuracy before further use, or replaced.

(ii) *Other devices.* Temperature-indicating devices used in lieu of mercury-in-glass thermometers, such as resistance temperature detectors, shall meet known, accurate standards for such devices when tested for accuracy. The records of such testing shall be available to FSIS program employees.

(2) *Temperature/time recording devices.* Each thermal processing system shall be equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy shall be equal to or better than 1 °F (or 0.5 °C) at the process temperature. The temperature recording chart should be adjusted to agree with, but shall never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment shall be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism shall be accurate.

(i) *Chart-type devices.* Devices using charts shall be used only with the correct chart. Each chart shall have a working scale of not more than 55 °F/inch (or 12 °C/cm) within a range of 20 °F (or 11 °C) of the process temperature. Chart graduations shall not exceed 2 °F (or 1 °C) within a range of 10 °F (or 5 °C) of the process temperature. Multipoint plotting chart-type devices shall print temperature readings at intervals that will assure that the parameters of the process time and process temperature have been met. The