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