

## Module 14. Aseptic Processing and Packaging Systems

Aseptic processing is a continuous operation. The behavior of one part of the system can affect the overall performance of the entire system. In aseptic processing, packages and food product are sterilized in separate systems. The sterile package is then filled with the sterile product, closed, and sealed in the sterile chamber. The processing authority must ensure commercial sterility not only for the product but also the product sterilization system, packaging equipment, and packaging materials. Before processing can begin the processing equipment, packaging equipment, and materials must be pre sterilized. Processing equipment can be pre sterilized using steam or hot water under pressure. Packaging equipment and materials can be pre sterilized utilizing saturated steam, superheated steam, hydrogen peroxide and heat, or other treatments. All processes must be validated. The scheduled process will include the product, product sterile zones, packaging system, and packaging materials. formulation controls such as starches, particle size, and rehydration can change the flow rate of the product through the sterilization tubes. Flow rate must be monitored the flow rate must not be faster than the flow rate in the process schedule. Direct product heating systems include steam injection and steam infusion. Indirect product heating systems include plate heat exchanger, tubular heat exchanger, and scraped surface heat exchanger. Hold tubes must be sloped upward at least .25 inches per foot the diameter length and slope conformed to testing. No portion of the tube is heated but can be insulated. Each fluid food particle may receive a different degree of sterility depending on the length of time the particle spends in the holding tube. Resident time of the fastest moving particle is determined by a processing authority. The holding tube must be designed so that every particle of food remains in the tube for the specified time in the process schedule. Other equipment and controls include temperature indicating devices and recorders. temperature indicating devices must meet requirements must be checked for accuracy, must have calibration records and the bulb in vicinity of recorder. The recorder should be accurate, and the bulb should be located at the exit end of the hold tube. The process may have multiple diversion valve locations in case of a temperature drop or a pressure drop in product to product regenerator. Product to product re generators are used for simultaneously cooling sterilized product and heating unsterilized product. The pressure of the sterilized product is greater than the pressure on the unsterilized product. Back pressure devices, valves, or orifices may be used to maintain pressure to prevent flashing of the product in the whole two. If the pressure in the system drops, water in the product turns to steam.

Manually operated systems rely on review of production logs and recording charts to verify process schedule was delivered. Automated systems prevent packaging non sterile product. Operations should be verified at startup by following the process scheduled, ensuring process monitor temperature at the coldest point downstream of the tube, and determine how the establishment prevents deviations during switchover from water to product. Operational records include temperature indicating device at the end of the hold tube, temperature recording device at the end of whole tube, temperature recorder-controller at the final heater outlet, re-generator differential pressure record, product flow rate, surge tank sterile air over pressure, performance of steaming seals, and pre sterilization records.

Possible process deviations include temperature drop and hold tube, loss of differential pressure in regular generator, loss of sterile air pressure or other protection in the surge tank, loss of sterile air/gas to sterile zones, critical factors in the process schedule outside specification, or speed of variable speed

pump too high. Aseptic processing must have written procedures for cleaning and re sterilizing the system. If re sterilization procedure differs from startup, verification of the procedure is from a process authority. Factors to consider when reprocessing include previously processed product may exhibit different flow characteristics due to starch or binders. Verify whether affected lots are to be reprocessed separately, together, or blended with new product.

Packaging must also be sterilized utilizing the establishment sterilization systems. For example, cans and lids can be sterilized using superheated steam.

Aseptic system targets the same microorganisms as a typical commercial sterile low acid canned product. Aseptic systems consist of a means to heat the food, a timing pump, a hold tube, and a cooling system. Downstream from the hold tube must be brought to commercial sterility before filling. The thermal process of the food is performed in the hold tube by controlling flow rate, residence time, and temperatures. Aseptic zones of machines create and maintain a sterile zone for filling and sealing. Sterilizing agents such as heat, chemicals, irradiation, or a combination of treatments are used to treat packaging materials or machine surfaces.