Ohio Administrative Code

Rule 901:3-3-10 Aseptic processing and packaging systems-product sterilizer operation.

Effective: August 22, 2013

(A) Start up.

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.

If product is 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 deviation shall be handled in accordance with paragraph (D) of rule 901:3-3-17 of the Administrative Code. 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) Regenerator

If product is subjected to loss of proper pressure in the regenerator and the product is filled into containers, the product shall be segregated from product that received the scheduled process and shall be reprocessed or destroyed. 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 has been corrected and the affected system has been returned to a condition of commercial sterility.

(D) Aseptic surge tank.

When an aseptic surge tank is used, conditions of commercial sterility may be lost when the sterile air over pressure 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) Observations and recordings.

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:

(1) Temperature-indicating device in holding tube outlet.

(2) Temperature recorder in holding tube outlet.

(3) Temperature recorder-controller at final heater outlet.

(4) Differential pressure recorder-controller, if a product-to-product regenerator is used.

(5) Product flow rate as established by the metering pump or as determined by filling and closing rates and, if an aseptic surge tank is used, sterile air pressure or other protection means; and

(6) Proper performance of seam seals or other similar devices.