901:11-3-07 Corrective actions.

- (A) Whenever a deviation from a critical limit occurs, a frozen dessert manufacturer shall take corrective action either by:
 - (1) Following a corrective action plan that is appropriate for the particular deviation, or
 - (2) Following the procedures in paragraph (C) of this rule.
- (B) A frozen dessert manufacturer may develop written corrective action plans, which become part of their HAACP plans in accordance with paragraph (B)(2)(e) of rule 901:11-3-06 of the Administrative Rule, by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:
 - (1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and
 - (2) The cause of the deviation is corrected.
- (C) When a deviation from a critical limit occurs and the frozen dessert manufacturer does not have a corrective action plan that is appropriate for that deviation, the manufacturer shall:
 - (1) Segregate and hold the affected product, at least until the requirements of paragraphs (C)(2) and (C)(3) of this rule are met;
 - (2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual who is qualified in accordance with rule 901:11-3-11 of the Administrative Code;
 - (3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
 - (4) Take corrective action, when necessary, to correct the cause of the deviation;
 - (5) Perform or obtain a timely reassessment to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.
- (D) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with paragraph (A)(3)(b) of rule 901:11-3-08 of the Administrative Code and the recordkeeping requirements of rule 901:11-3-09 of the Administrative Code.

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