

(c) *Written vulnerability assessment.* Regardless of the outcome, the vulnerability assessment must be written and must include an explanation as to why each point, step, or procedure either was or was not identified as an actionable process step.

§ 121.135 Mitigation strategies for actionable process steps.

(a) You must identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act. For each mitigation strategy implemented at each actionable process step, you must include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step.

(b) Mitigation strategies and accompanying explanations must be written.

§ 121.138 Mitigation strategies management components.

Mitigation strategies required under § 121.135 are subject to the following mitigation strategies management components as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of each such mitigation strategy and its role in the facility's food defense system:

(a) Food defense monitoring in accordance with § 121.140;

(b) Food defense corrective actions in accordance with § 121.145; and

(c) Food defense verification in accordance with § 121.150.

§ 121.140 Food defense monitoring.

As appropriate to the nature of the mitigation strategy and its role in the facility's food defense system:

(a) *Written procedures.* You must establish and implement written procedures, including the frequency with which they are to be performed, for food defense monitoring of the mitigation strategies.

(b) *Food defense monitoring.* You must monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed.

(c) *Records*—(1) *Requirement to document food defense monitoring.* You must document the monitoring of mitigation strategies in accordance with this section in records that are subject to verification in accordance with § 121.150(a)(1) and records review in accordance with § 121.150(a)(3)(i).

(2) *Exception records.* Records may be affirmative records demonstrating the mitigation strategy is functioning as intended. Exception records demonstrating the mitigation strategy is not functioning as intended may be adequate in some circumstances.

§ 121.145 Food defense corrective actions.

(a) *Food defense corrective action procedures.* As appropriate to the nature of the actionable process step and the nature of the mitigation strategy:

(1) You must establish and implement written food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented.

(2) The food defense corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy; and

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur.

(b) *Records.* All food defense corrective actions taken in accordance with this section must be documented in records that are subject to food defense verification in accordance with § 121.150(a)(2) and records review in accordance with § 121.150(a)(3)(i).

§ 121.150 Food defense verification.

(a) *Food defense verification activities.* Food defense verification activities must include, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system: