

§ 117.180

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food safety system, any additional preventive controls needed to address the hazard identified:

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or

(2) When necessary to demonstrate the control measures can be implemented as designed:

(i) Within 90 calendar days after production of the applicable food first begins; or

(ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90-calendar days after production of the applicable food first begins.

(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or document the basis for the conclusion that no revisions are needed.

(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.

(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

§ 117.180 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 117.126(a)(2));

(2) Validation of the preventive controls (§ 117.160(b)(1));

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food;

(4) Determination that validation is not required (§ 117.160(c)(5));

(5) Review of records (§ 117.165(a)(4));

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;

(7) Reanalysis of the food safety plan (§ 117.170(d)); and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.

(b) A qualified auditor must conduct an onsite audit (§ 117.435(a)).

(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 117.190 Implementation records required for this subpart.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation, as required by § 117.136(b), of the basis for not establishing a preventive control in accordance with § 117.136(a);

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

- (iii) Verification of corrective actions;
 - (iv) Calibration of process monitoring and verification instruments;
 - (v) Product testing;
 - (vi) Environmental monitoring;
 - (vii) Records review; and
 - (viii) Reanalysis;
- (5) Records that document the supply-chain program; and
- (6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.
- (b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Modified Requirements

§ 117.201 Modified requirements that apply to a qualified facility.

(a) *Attestations to be submitted.* A qualified facility must submit the following attestations to FDA:

(1) An attestation that the facility is a qualified facility as defined in § 117.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) An attestation that you have identified the potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

(b) *Procedure for submission.* The attestations required by paragraph (a) of this section must be submitted to FDA by one of the following means:

(1) *Electronic submission.* To submit electronically, go to <http://www.fda.gov/furls> and follow the instructions. This

Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) *Submission by mail.* (i) You must use Form FDA 3942a. You may obtain a copy of this form by any of the following mechanisms:

(A) Download it from <http://www.fda.gov/pchfrule>;

(B) Write to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Dr., College Park, MD 20740; or

(C) Request a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

(ii) Send a paper Form FDA 3942a to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Dr., College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

(c) *Frequency of determination of status and submission.* (1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By December 17, 2018, for a facility that begins manufacturing, processing, packing, or holding food before September 17, 2018;

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding food after September 17, 2018; or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified facility” to “qualified facility” based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form 3942a by July 31 of the applicable calendar year.