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Series

Food Defense (FD) Audit Standard

June 2022

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INTRODUCTION

This document is designed to give guidance to Specialty Crops Inspection Division personnel of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Specialty Crops Programs (SC).

Compliance with the Agricultural Marketing Service guidelines does not excuse failure to comply with the Food, Drug, and Cosmetic Act or any other applicable Federal or State laws or regulations. SCI Division is responsible for grading/inspecting, audits and standardization programs of fresh and/or processed fruits and vegetables and related products. The legal authority for grading, auditing and standardization activities are the Agricultural Marketing Acts of 1936 and 1946, as amended.

Applicants may obtain inspections and audits of any fresh and/or processed fruit and vegetable and related products for which they have a financial interest. The inspection service is voluntary and self-supporting and is offered on a fee-for-service basis.

GUIDE FOR ELECTRONIC USAGE

The AIM system of instructional manuals is available electronically in Adobe Acrobat Portable Document Format (PDF) at the following intranet address:

<https://usdagcc.sharepoint.com/sites/ams/AMS-SCI/SitePages/Home.aspx>.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined [blue text](#)) available to the PDF user. Clicking on a hyperlink takes the reader to a web site with information relating to the subject. Hypertext links the reader to a different page within the current manual, or a different manual, with information relating to the subject. For example, the hypertext in the Table of Contents allows a reader to go directly to the section of interest in the manual by clicking on the section title.

PDF offers a variety of tools depending on the Adobe version the reader has. The newer the version, the more tools available. PDF documents are easily searchable for content within a document or within multiple documents. To learn about the variety of PDF search options:

- Click on the “Help” tab on the top of any page in Adobe Acrobat,
- Then click on the “Adobe Acrobat Help” bar,
- Type the word “Search” in the “Search” box, and click on the “Search” button,
- A series of options will become available,
- Click on the “Access Search Features” link and follow the instructions for the type of search you are interested in.

HOW TO USE THIS STANDARD

The Food Defense Audit Standard is used as a scope as part of a Plant Systems Audit (PSA) Program audit. It may be used in addition to the Good Manufacturing Practices (GMP) Audit Standard or as a standalone scope.

The standard includes the requirements of the [Food Drug Administration Food Safety Modernization Act \(FSMA\) Mitigation Strategies to Protect Food Against Intentional Adulteration, 21 CFR Part 121](#). This rule applies to both domestic and foreign companies that are required to register with the FDA as food facilities under the Federal Food, Drug, and Cosmetic (FD&C) Act.

The standard includes the following components:

- Requirement – a statement of the expectation for compliance to the audit standard.
- Reference – text from the cited source of the requirement.
- Citation – the source of the Reference.
- Auditor Guidance – a brief description of the evidence the auditor must find to verify compliance. Additional auditor guidance is in the PSA Program Auditor Manual.
- Documentation – an indication of the type of required documentation.
 - Policy and Procedures – Documented guidance that describes general goals and acceptable specified way(s) to carry out an activity or process. Documentation also should identify the established forms used to show implementation.
 - Record - A document that states results achieved or provides evidence of activities performed. Examples of records include checklists, bills of lading, process charts, certificates of assurance, and analytical test results.

For instructions on use of this standard, including the associated checklist and the rating system for the audit outcome, please see the PSA Program Auditor Manual (in development). Additional information on the PSA Program can be found on the AMS website at <https://www.ams.usda.gov/services/auditing/plant-audits>.

FOOD DEFENSE AUDIT STANDARD

1.1 Food Defense Plan

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.1.1	<p>The facility must have and implement a written food defense plan.</p> <p>The facility must keep documentation and records of the plan’s implementation.</p>	<p>Requirement for a food defense plan. You must prepare, or have prepared, and implement a written food defense plan.</p> <p>Records. The food defense plan required by this section is a record that is subject to the requirements of subpart D of this part.</p>	<p>Subpart C— Food Defense Measures 21 CFR 121.126 (a) (c)</p>	<p>Verify that a food defense plan has been developed and implemented. As you review implementation, confirm employee understanding via interviews, as appropriate.</p>	<p>Policy, Record</p>
1.1.2	<p>The written food defense plan must include:</p> <ul style="list-style-type: none"> - The written vulnerability assessment; - The written mitigation strategies; - The written procedures for the food defense monitoring of the implementation of the mitigation strategies; - The written procedures for food defense corrective actions; and - The written procedures for food defense verification. 	<p>Contents of a food defense plan.</p> <p>The written food defense plan must include:</p> <ol style="list-style-type: none"> (1) The written vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps as required by § 121.130(c); (2) The written mitigation strategies, including required explanations, as required by § 121.135(b); (3) The written procedures for the food defense monitoring of the implementation of the mitigation strategies as required by § 121.140(a); (4) The written procedures for food defense corrective actions as required by § 121.145(a)(1); and (5) The written procedures for food defense verification as required by § 121.150(b). 	<p>(b)</p>	<p>Verify that the plan includes the required elements. It must include a record of the vulnerability assessment. The assessment will identify ways that they will prevent the identified risks (mitigation steps). The plan must document the mitigation procedures, how they will monitor them, the corrective action procedure, and the verification or review procedures.</p>	<p>Policy, Record</p>

1.2 Personnel Qualifications and Training

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.2.1	<p>All facility personnel must receive training in food defense awareness (as new employee and annually).</p> <p>All personnel who perform activities associated with food defense procedures must:</p> <ul style="list-style-type: none"> - Be, or be under the supervision of, a qualified individual to perform their assigned duties, and - Receive externally provided training on the principles of food defense or have experience that prepares them for the assigned task. 	<p>Qualifications of individuals who perform activities under subpart C of this part.</p> <p>(a) Applicability. You must ensure that each individual who performs activities required under subpart C of this part is a qualified individual as that term is defined in § 121.3.</p> <p>(b) Qualifications of individuals assigned to an actionable process step. Each individual assigned to an actionable process step (including temporary and seasonal personnel) or in the supervision thereof must:</p> <p>(1) Be a qualified individual as that term is defined in § 121.3—i.e., have the appropriate education, training, or experience (or a combination thereof) necessary to properly implement the mitigation strategy or combination of mitigation strategies at the actionable process step; and</p> <p>(2) Receive training in food defense awareness.</p>	<p>Subpart A 21 CFR 121.4 (a) and (b)</p>	<p>Verify that all facility employees have received food defense training. This may be internally delivered training for those employees who do not have direct responsibilities associated with the documented food defense procedures.</p> <p>For those employees who are responsible for implementation of any of the documented food defense procedures, and their supervisors, they must receive externally provided training on the principles of food defense or have experience that prepares them for the assigned tasks.</p> <p>The Food Safety Preventive Controls Alliance course on Food Defense Awareness is an example of an external course for general employees who are responsible for specific tasks.</p> <p>https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration</p>	<p>Record</p>

<p>1.2.2</p>	<p>Individuals assigned the following tasks must be qualified individuals:</p> <ul style="list-style-type: none"> - Preparation of the food defense plan; - Completion of a vulnerability assessment; - Identification and explanation of the mitigation strategies; and - Reanalysis of the food defense plan. <p>These individuals must receive externally provided training, specific to the task that they are assigned.</p> <p>Approved courses for a qualified individual are available on the Food Safety Preventive Controls Alliance website, https://www.ifsh.iit.edu/fspca/courses/intentional-a-dulteration</p> <p>Training records must be maintained for the qualified individuals.</p>	<p>Qualifications of individuals for certain activities described in paragraph (c)(3) of this section. Each individual assigned to certain activities described in paragraph (c)(3) of this section must:</p> <p>(1) Be a qualified individual as that term is defined in § 121.3—i.e., have the appropriate education, training, or experience (or a combination thereof) necessary to properly perform the activities; and</p> <p>(2) Have successfully completed training for the specific function at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities. 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.</p> <p>This individual may be, but is not required to be, an employee of the facility.</p> <p>(3) One or more qualified individuals must do or oversee:</p> <p>(i) The preparation of the food defense plan as required in § 121.126;</p> <p>(ii) The conduct of a vulnerability assessment as required in § 121.130;</p> <p>(iii) The identification and explanation of the mitigation strategies as required in § 121.135; and</p> <p>(iv) Reanalysis as required in § 121.157.</p>	<p>(c)</p>	<p>Verify that the staff who have been assigned the formal tasks of developing and/or reassessing the food defense plan have training specific to the assigned task. The training must be at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities.</p> <p>Approved courses for a qualified individual are available on the Food Safety Preventive Controls Alliance website, https://www.ifsh.iit.edu/fspca/courses/intentional-a-dulteration</p> <p>Verify that records of training are maintained.</p>	<p>Record</p>
<p>1.2.3</p>	<p>Responsibility for ensuring compliance by individuals with the food defense requirements must be</p>	<p>Additional qualifications of supervisory personnel. Responsibility for ensuring compliance by individuals with the</p>	<p>(d)</p>	<p>Verify education, training, or experience of supervisors' specific job duties by reviewing</p>	<p>Record</p>

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	clearly assigned to supervisory personnel with a combination of education, training, and experience necessary to supervise the activities.	requirements of this part must be clearly assigned to supervisory personnel with a combination of education, training, and experience necessary to supervise the activities under this subpart.		training records. Ask to see any certificates from a associated training.	
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1.3 Vulnerability Assessment

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.3.1	<p>The facility must conduct or have conducted a vulnerability assessment for each type of food manufactured, processed, packed, or held at the facility to identify significant vulnerabilities and actionable process steps. Appropriate methods must include, at a minimum, an evaluation of:</p> <ul style="list-style-type: none"> - The potential public health impact (e.g., severity and scale) if a contaminant were added; - The degree of physical access to the product; and - The ability of an attacker to successfully contaminate the product. 	<p>Requirement for a vulnerability assessment. You must conduct or have conducted a vulnerability assessment for each type of food manufactured, processed, packed, or held at your facility using appropriate methods to evaluate each point, step, or procedure in your food operation to identify significant vulnerabilities and actionable process steps. Appropriate methods must include, at a minimum, an evaluation of:</p> <ol style="list-style-type: none"> (1) The potential public health impact (e.g., severity and scale) if a contaminant were added; (2) The degree of physical access to the product; and (3) The ability of an attacker to successfully contaminate the product. 	Subpart C 21 CFR 121.130 (a)	<p>Verify that as part of the development of the food defense plan, the facility has performed a vulnerability assessment for each type of food handled at the location, and all associated points, steps, or procedures. Have significant vulnerabilities been identified?</p> <p>Have steps been identified to reduce or eliminate the risks? These become the mitigation strategies reviewed under 1.4.</p> <p>Did the assessment include consideration of a potential public health impact, the physical access to the product, and the ability of an attacker to contaminate product?</p>	
1.3.2	The vulnerability assessment must consider the possibility of an inside attacker.	Inside attacker. The assessment must consider the possibility of an inside attacker.	(b)	Did the vulnerability assessment include the risk of an employee intentionally contaminating food?	
1.3.3	The vulnerability assessment must be documented.	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.	(c)	Is the assessment documented and available for your review?	Record

1.4 Mitigation Strategies

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.4.1	The facility must identify and implement mitigation strategies at each actionable process step and include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability.	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.	Subpart C 21 CFR 121.135 (a)	Are the mitigation strategies documented in the food defense plan as part of the vulnerability assessment? Make note of the mitigation strategies that have been developed and implemented. Does the food defense plan explain how it minimizes or eliminates the risk?	Record
1.4.2	Mitigation strategies and accompanying explanations must be written.	Mitigation strategies and accompanying explanations must be written.	(b)	Are the mitigation strategies and explanations documented?	Record
1.4.3	Mitigation strategies must be subject to monitoring, corrective actions, and verification activities.	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	21 CFR 121.138	Has the facility identified the ways that management will monitor the mitigation strategies and will perform corrective action if strategies are found not to be working, and how verification of the plan will take place? These procedures will be identified in the food defense plan.	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
		(c) Food defense verification in accordance with § 121.150.			
1.4.3.1	The facility must establish and implement written procedures for the monitoring of mitigation strategies. The monitoring activities must be documented.	<p>Food defense monitoring. As appropriate to the nature of the mitigation strategy and its role in the facility’s food defense system:</p> <p>(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.</p> <p>(b) Food defense monitoring. You must monitor the mitigation strategies with a adequate frequency to provide assurances that they are consistently performed.</p> <p>(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 § 21.150(a)(3)(i).</p> <p>(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.</p>	21 CFR 121.140	<p>Ask to see the documented procedures for the monitoring of the food defense mitigation actions. These may include procedures for inspecting the facility on a regular basis to see such things as:</p> <ul style="list-style-type: none"> - exterior lighting is working. - exterior doors are locked to prevent outside access. - employees are appropriately restricted to work areas. - bulk storage containers are locked. <p>These actions may also include background checks of new employees, the implementation of employee identification cards/fobs, an alarm system that monitors the facility during off hours, etc.</p> <p>Ask to see the associated records that document when and by whom these actions have occurred.</p>	Policy, Record

<p>1.4.3.2</p>	<p>If mitigation strategies are not properly implemented, the facility must establish and implement corrective action procedures. The corrective action must describe the steps to be taken to ensure that appropriate action is taken to correct and prevent identified problems. The corrective and preventive actions must be documented as records.</p>	<p>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).</p>	<p>21 CFR 121.145</p>	<p>Verify that a documented procedure is established for corrective action if the facility determines that a mitigation procedure has not been performed. This could be as a result of their monitoring activities. Do they maintain records of the corrective action?</p>	<p>Policy, Record</p>
<p>1.4.3.3</p>	<p>The facility must establish and implement written procedures to verify that:</p> <ul style="list-style-type: none"> - Food defense monitoring is being conducted; - Appropriate decisions about food defense corrective actions are being made; - Mitigation strategies are properly implemented and 	<p>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: (1) Verification that food defense monitoring is being conducted as required by § 121.138 (and in accordance with § 121.140);</p>	<p>21 CFR 121.150</p>	<p>Identify if the facility has documented procedures to make sure their food defense mitigation and monitoring steps, and the planned reanalysis of the plan are being performed. These should be identified in the food defense plan.</p>	<p>Policy, Record</p>

	<p>are significantly minimizing or preventing the significant vulnerabilities; and</p> <ul style="list-style-type: none"> - Reanalysis of the food defense plan has occurred as required. <p>The verification activities must include:</p> <ul style="list-style-type: none"> - Review of the food defense monitoring and food defense corrective actions records within appropriate timeframes; and - Other activities appropriate for verification of proper implementation of mitigation strategies. <p>The verification activities must be documented as records.</p>	<p>(2) Verification that appropriate decisions about food defense corrective actions are being made as required by § 121.138 (and in accordance with § 121.145);</p> <p>(3) Verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities. To do so, you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the mitigation strategy and its role in the facility's food defense system:</p> <p>(i) Review of the food defense monitoring and food defense corrective actions records within appropriate timeframes to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food defense plan, the mitigation strategies are properly implemented, and appropriate decisions were made about food defense corrective actions; and</p> <p>(ii) Other activities appropriate for verification of proper implementation of mitigation strategies; and</p> <p>(4) Verification of reanalysis in accordance with § 121.157.</p> <p>(b) Written procedures. You must establish and implement written procedures, including the frequency for which they are to be performed, for verification activities conducted according to § 121.150(a)(3)(ii).</p> <p>(c) Documentation. All verification activities conducted in accordance with this section must be documented in records.</p>		<p>Document how often the review occurs and who is responsible for performing the review.</p> <p>Are there records of this review?</p>	
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1.5 Food Defense Plan Reanalysis

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.5.1	The facility must conduct a reanalysis of the food defense plan as a whole at least once every 3 years.	(a) You must conduct a reanalysis of the food defense plan, as a whole at least once every 3 years.	21 CFR 121.157 (a)	Verify that the facility has a plan to reanalyze the food defense plan. How often do they do this? Is it done at least every three years? Who is responsible for performing this?	Policy
1.5.2	<p>The facility must conduct a reanalysis of the food defense plan as a whole, or the applicable portion of the plan, whenever:</p> <ul style="list-style-type: none"> - A significant change made in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability; - New information is available about potential vulnerabilities associated with the food operation or facility; - The facility has found that a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole is 	<p>You must conduct a reanalysis of the food defense plan as a whole, or the applicable portion of the food defense plan:</p> <p>(1) Whenever a significant change made in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability;</p> <p>(2) Whenever you become aware of new information about potential vulnerabilities associated with the food operation or facility;</p> <p>(3) Whenever you find that a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole is not properly implemented; and</p> <p>(4) Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding including, as appropriate, results from the Department of Homeland Security biological, chemical,</p>	(b)	Does the facility’s policy for reanalysis of the plan identify the need to do it when something has changed at the facility, when the facility identifies a need for a change, or if required by FDA?	Policy

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
	not properly implemented; and - FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.	radiological, or other terrorism risk assessment.			
1.5.3	The reanalysis of the food defense plan must be completed prior to any change in activities, within 90 days of the start of a associated production, or later with written justification.	You must complete such reanalysis required by paragraphs (a) and (b) of this section and implement any additional mitigation strategies needed to address the significant vulnerabilities identified, if any: (1) Before any change in activities (including any change in mitigation strategy) at the facility is operative; (2) When necessary within 90-calendar days after production; and (3) Within a reasonable timeframe, providing a written justification is prepared for a timeframe that exceeds 90 days after production of the applicable food first begins.	(c)	Verify that the facility understands the need to reanalyze the plan before they make changes in their facility or procedures. The company may have a change management policy – does it include a step to consider the food defense implications?	Policy
1.5.4	The facility must revise the written food defense plan if a significant change in the activities conducted at the facility creates a reasonable	You must revise the written food defense plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously	(d)	Verify that the facility has made the appropriate changes in their food defense plan if they identified the need as part of a reanalysis or the	Policy

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
	potential for a new vulnerability or a significant increase in a previously identified vulnerability or document the basis for the conclusion that no revisions are needed.	identified vulnerability or document the basis for the conclusion that no revisions are needed.		implementation of a change in a process or the facility.	

1.6 Records

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.6.1	Food defense records must: <ul style="list-style-type: none"> - Be kept as original records, true copies, or electronic records; - Contain the actual values and observations obtained during food defense monitoring; - Be accurate, indelible, and legible; - Be created concurrently with performance of the activity documented; and - Be as detailed as necessary to provide history of work performed. 	Records subject to the requirements of this subpart. (a) Except as provided by paragraph (b) of this section, all records required by subpart C of this part are subject to all requirements of this subpart. (b) The requirements of § 121.310 apply only to the written food defense plan. § 121.305 General requirements applying to records. Records must: (a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, micro film, microfiche, or other accurate reproductions of the original records), or electronic records; (b) Contain the actual values and observations obtained during food defense monitoring; (c) Be accurate, indelible, and legible; (d) Be created concurrently with performance of the activity documented; (e) Be as detailed as necessary to provide history of work performed; and	Subpart D— Requirements Applying to Records That Must Be Established and Maintained 21 CFR 121.301	Ask the facility how they manage their records associated with the food defense plan and procedures. Make sure that the records are available as either a hard copy or electronic record.	Record
1.6.2	Records must include: <ul style="list-style-type: none"> - Information adequate to identify the facility (e.g., the name, and when necessary, the location of the facility); 	(f) Include: (1) Information adequate to identify the facility (e.g., the name, and when necessary, the location of the facility); (2) The date and, when appropriate, the time of the activity documented; (3) The signature or initials of the person performing the activity; and		Review a few of the records to see if they identify the facility, are initialed or signed by the person performing the work, and if they identify when the procedure was done.	Record

	<ul style="list-style-type: none"> - The date and, when appropriate, the time of the activity documented; - The signature or initials of the person performing the activity; and - Where appropriate, the identity of the product and the lot code, if any. 	<p>(4) Where appropriate, the identity of the product and the lot code, if any.</p> <p>(g) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.</p>			
1.6.3	The food defense plan must be signed and dated by the owner, operator, or agent in charge of the facility when it is first completed, and when modified.	<p>Additional requirements applying to the food defense plan.</p> <p>The owner, operator, or agent in charge of the facility must sign and date the food defense plan:</p> <ul style="list-style-type: none"> (a) Upon initial completion; and (b) Upon any modification. 	21 CFR 121.310	Ask to see where the facility owner or manager has signed and dated the food defense plan. Is the date on or after the most recent edition of the plan? The signature can be an actual signature or an electronic signature.	Record
1.6.4	<p>Food defense records:</p> <ul style="list-style-type: none"> - Must be retained at the facility for at least 2 years after the date they were prepared or after their use is discontinued. - Except for the food defense plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request. The food defense plan must remain onsite. 	<p>Requirements for record retention.</p> <ul style="list-style-type: none"> (a)(1) All records required by this part must be retained at the facility for at least 2 years after the date they were prepared. (2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as exempt as a very small business must be retained at the facility as long as necessary to support the status of a facility as a very small business during the applicable calendar year. (b) The food defense plan must be retained for at least 2 years after its use is discontinued. 	21 CFR 121.315	Ask how long the food defense records are maintained and where they are maintained.	Record

	<p>- If the plant or facility is closed for a prolonged period, the food defense plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility upon request.</p>	<p>(c) Except for the food defense plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food defense plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.</p> <p>(d) If the facility is closed for a prolonged period, the food defense plan may be transferred to some other reasonably accessible location but must be returned to the facility within 24 hours for official review upon request.</p>			
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REFERENCE LINKS**Version Date
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|--------------------------|--|--|-------|
| <input type="checkbox"/> | Insert Link Title:
Insert full website address | PSA Auditor Manual (in development) | _____ |
| <input type="checkbox"/> | Insert Link Title:
https://www.ams.usda.gov/sites/default/files/media/GMPAuditStandard.pdf | GMP Audit Standard | _____ |
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