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Course Description

This training course is targeted towards food professionals tasked with identifying and explaining mitigation strategies as mandated under FDA’s "Mitigation Strategies to Protect Food Against Intentional Adulteration" (IA) rule. By successfully completing this course, the learner will have satisfied the training requirement within the rule to perform this specific activity.
Disclaimer

Please note that this course qualifies an individual to identify and explain mitigation strategies ONLY. To perform other activities as required by the IA rule, such as developing the food defense plan, conducting a vulnerability assessment (VA), or performing a reanalysis, you must take the specific training developed for that activity or be otherwise qualified through job experience. See the Resources tab for information about other available trainings.

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Course Modules

This course is divided into seven modules:

- Module 1: Food Defense Measures Overview
- Module 2: Vulnerability Assessments Overview
- Module 3: Mitigation Strategies Overview
- Module 4: Mitigation Strategy Approaches
- Module 5: Limiting the Degree of Access
- Module 6: Reducing the Likelihood of a Successful Contamination
- Module 7: Considering Existing Facility Practices

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Course Objectives

After completing this course, you will be able to:

1. Explain food defense measures.
2. Describe a vulnerability assessment.
3. Describe mitigation strategy principles.
4. Consider mitigation strategy approaches.
5. Explain mitigation strategies that restrict access.
6. Explain mitigation strategies that reduce the likelihood of a successful contamination.
7. Evaluate existing facility practices.

Module 1: Food Defense Measures Overview
Welcome and Introduction

Welcome to Module 1: "Food Defense Measures Overview"

After completing this module, you will be able to:
1. Explain intentional adulteration.
2. Explain food defense.
3. Explain the general requirements of the Intentional Adulteration rule.
4. Describe the contents of a food defense plan.
5. Explain the training and qualifications required for identification and explanation of mitigation strategies.

What Is Intentional Adulteration?

- Intentional Adulteration: The deliberate contamination of food with a biological, chemical, radiological, or physical agent by an individual or group of individuals with the intent to cause wide scale public health harm.
- Congress mandated FDA to issue regulations that protect the public from intentional adulteration.
- FDA issued a final regulation, Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR Part 121), which requires covered facilities to identify and protect their most vulnerable points against intentional adulteration. As mentioned earlier, we call this the IA rule for short.
What Is Food Defense?

**Food Defense:**
The effort to protect food from intentional acts of adulteration intended to cause widespread public health harm (21 CFR Part 121.3)

- Efforts include measures taken to reduce or eliminate the possibility that an intentional adulteration event would occur.
- The IA rule requires the development and implementation of a food defense plan.

Why Is Food Defense Important?

- Intentional adulteration of the food supply can result in catastrophic public health consequences including severe illness and death.
- In addition to illnesses and deaths, potential impacts include public loss of confidence in the food supply, harmed company reputations, and job losses.
- Malicious individuals, including terrorists, may see this as an opportunity to harm the public.
Intentional Adulteration Rule Requirements

- The Food Defense Plan must contain the following items:
  - Vulnerability assessment
  - Identification and implementation of mitigation strategies
  - Food defense monitoring
  - Food defense corrective actions
  - Food defense verification
- Additional requirements include:
  - Training
  - Record keeping
  - Reanalysis

For More Information on the IA Rule

- **IA Rule**
- **FDA Fact Sheet for the IA Rule**

For more information on the IA Rule Overview course, click "Resources" above.
You have now completed Module 1.

Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:

1. Explain intentional adulteration.
2. Explain food defense.
3. Explain the general requirements of the Intentional Adulteration rule.
4. Describe the contents of a food defense plan.
5. Explain the training and qualifications required for identification and explanation of mitigation strategies.
Welcome to "Identification and Explanation of Mitigation Strategies" training. This training course is targeted towards food professionals responsible for identifying and explaining mitigation strategies as mandated under FDA's "Mitigation Strategies to Protect Food Against Intentional Adulteration," also called the IA rule for short. After successfully completing this course, the learner will have satisfied the training requirement within the rule to perform this specific activity.

Please note that this course trains an individual to identify and explain mitigation strategies ONLY. To perform other activities as required by the IA rule, such as developing the food defense plan, conducting a vulnerability assessment (sometimes called VA for short) or performing a reanalysis, you must take the specific training developed for that activity or be otherwise qualified through job experience. Please click on the resources tab for information about other available trainings.
Course Modules Transcript

This course is divided into seven modules:
Module 1 is Food Defense Measures Overview;
Module 2 is Vulnerability Assessments Overview;
Module 3 is Mitigation Strategies Overview;
Module 4 is Mitigation Strategy Approaches;
Module 5 is Limiting the Degree of Access;
Module 6 is Reducing the Likelihood of a Successful Contamination; and
Module 7 is Considering Existing Facility Practices.

Course Objectives Transcript

After completing this course, you will be able to:
1. Explain food defense measures;
2. Describe a vulnerability assessment;
3. Describe mitigation strategy principles;
4. Consider mitigation strategy approaches;
5. Explain mitigation strategies that restrict access;
6. Explain mitigation strategies that reduce the likelihood of a successful contamination; and
7. Evaluate existing facility practices.
Welcome to Module 1, Food Defense Measures Overview. This module will explain food defense measures.

After completing this module, you will be able to:
1. Explain intentional adulteration;
2. Explain food defense;
3. Explain the general requirements of the Intentional Adulteration rule;
4. Describe the contents of a food defense plan; and
5. Explain the training and qualifications required for identification and explanation of mitigation strategies.

Intentional adulteration is the deliberate contamination of food with a biological, chemical, radiological, or physical agent by an individual or group of individuals with the intent to cause wide scale public health harm.

Congress mandated FDA to publish regulations that protect the public from intentional adulteration.

FDA issued their final regulation, "Mitigation Strategies to Protect Food Against Intentional Adulteration" (21 CFR Part 121), which requires covered facilities to identify and protect their most vulnerable points against intentional adulteration. As mentioned earlier, we call this the IA rule for short.
Food defense is defined by the IA rule as the effort to protect food from intentional acts of adulteration intended to cause wide scale public health harm. These efforts include measures taken to reduce or eliminate the possibility that an intentional adulteration event would occur. There are many measures that can be implemented for food defense purposes but the most important is a food defense plan.

Intentional adulteration of the food supply can result in catastrophic public health consequences including severe illness and death. In addition to illnesses and deaths, potential impacts include public loss of confidence in the food supply, harmed company reputations, and job losses.

Malicious individuals, including terrorists, may adulterate the food supply as an opportunity to harm the public and gain notoriety to further their cause. Unfortunately, intentional adulteration has already occurred. In December 2013, there were at least 2,843 mild foodborne illnesses reported and 6.4 million packages of various frozen foods recalled because a disgruntled contract employee at a food facility in Japan intentionally adulterated several frozen foods with a pesticide. This is an example of why food defense plans and other food defense measures are so important—they aim to prevent these potentially devastating events.
Module 1: Food Defense Measures Overview

Intentional Adulteration Rule Requirements Transcript

The IA rule aims to prevent or significantly minimize intentional acts of food adulteration, including acts of terrorism, intended to cause wide scale public health harm. This is accomplished by requiring that covered facilities develop and implement a food defense plan that includes a vulnerability assessment that identifies actionable process steps, identification and implementation of mitigation strategies at those actionable process steps to significantly minimize or prevent the significant vulnerabilities, and mitigation strategy management components including food defense monitoring, food defense corrective actions, and food defense verification. Reanalysis of the food defense plan is also required under certain conditions. The IA rule also has records and training requirements. The IA rule has detailed information on who is covered by this rule and what activities are exempted.

For More Information on the IA Rule Transcript

On the screen you will see links to the IA rule and the FDA IA Rule Fact Sheet. The link to the IA Rule will take you to the full text of the regulation and the FDA IA Rule Fact Sheet provides a brief summary of the rule’s provisions, coverage, and exemptions respectively. These are also available through the Resources tab above.

Additionally, the Food Safety Preventive Controls Alliance has developed an online course that provides an overview of the IA rule requirements. To access this course visit the Resources tab above.
The IA rule details specific training and qualifications required for various activities. In order to be qualified to identify and explain mitigation strategies, you must be a qualified individual and successfully complete training for this activity at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience. According to the IA rule, a qualified individual is defined as a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under subpart C of the rule, as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment. Successful completion of this training course satisfies the training requirement for this activity.

You have now completed Module 1. Let’s review what you have learned before you move on to the knowledge checks.

In this module, you learned to:
1. Explain intentional adulteration;
2. Explain food defense;
3. Explain the general requirements of the Intentional Adulteration rule;
4. Describe the contents of a food defense plan; and
5. Explain the training and qualifications required for identification and explanation of mitigation strategies.

Let’s see what you remember about what you just learned.
Resources

- Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types
- FDA Fact Sheet for the IA Rule
- FDA Technical Assistance Network (TAN)
- Food Defense Mitigation Strategies Database (FDMSD)
- FSPCA Intentional Adulteration Training and Materials
- IA Rule
- IA Rule Overview Course

Help

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*Holidays may affect these hours
Welcome and Introduction

Welcome to Module 2: "Vulnerability Assessments Overview"

After completing this module, you will be able to:

1. Define significant vulnerabilities.
2. Define actionable process steps.
3. Explain the vulnerability assessment requirements.
Requirements of a Vulnerability Assessment

**Definitions:**
- **Significant Vulnerability:** A vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm (21 CFR Part 121.3)
- **Actionable Process Steps:** A point, step, or procedure in a food process where a significant vulnerability exists and at which mitigation strategies can be applied and are essential to significantly minimize or prevent the significant vulnerability (21 CFR Part 121.3)

- A VA is a systematic assessment of points, steps or procedures to identify and rank vulnerabilities to intentional adulteration.
- The goal of a VA is to distinguish vulnerabilities from significant vulnerabilities, and identify actionable process steps (APSs).
- APSs are where mitigation strategies must be applied to significantly minimize or prevent the significant vulnerability at that step.

Requirements of the Vulnerability Assessment (continued)

- VAs, at a minimum, must consider for each point, step, or procedure the following:
  - Element 1: Potential public health impact if a contaminant were successfully added to the product at that step;
  - Element 2: Degree of physical access to the product; and
  - Element 3: Ability of an attacker to successfully contaminate the product.
  - We will refer to these as the "three fundamental elements" or the "three elements."
Requirements of the Vulnerability Assessment (continued)

- The possibility of an inside attacker must also be considered during the VA. An inside attacker should be assumed to have:
  - Legitimate access to the facility (e.g., be an employee, contractor, driver, authorized visitor, etc.);
  - A basic understanding of facility operations and the food product(s) under production;
  - The ability to acquire and deploy a contaminant that is highly lethal, capable of withstanding the food production process, and undetectable via simple observation if added to food; and
  - The intent to cause wide scale public health harm.

- A VA must be conducted on each type of food produced.
  - Products and processes that are similar can be grouped together and assessed as a single group.
  - The VA considers inherent characteristics at each process step when evaluating the vulnerability at that step.
  - The result of the VA is a list of actionable process steps and why they were considered significantly vulnerable.
    - The significant vulnerabilities are what mitigation strategies seek to significantly minimize or prevent.
Mitigation Strategies

Requirements of the Vulnerability Assessment (continued)

- Facilities have the flexibility to choose a method for the VA so long as, at each point or step in the process, the three fundamental elements have been considered (public health impact, accessibility, and ability of an attacker to successfully contaminate the product), as well as the inside attacker.

- The Key Activity Type (KAT) method is considered an appropriate method to conduct a VA.

For more information on the Key Activity Types course, please click "Resources" above

External Link:
- Click here to view FDA's draft guidance on the IA rule

Requirements of the Vulnerability Assessment (continued)

- Regardless of the outcome or the methodology used, the VA must be written and must include an explanation as to why each point, step, or procedure either was or was not identified as an APS.

Worksheet 1-C: Vulnerability Assessment Analysis Summary

<table>
<thead>
<tr>
<th></th>
<th>Process Step</th>
<th>Process Description</th>
<th>Vulnerability Assessment Method</th>
<th>Explanation</th>
<th>Actionable Process Step</th>
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<td>1</td>
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Applying the Vulnerability Assessment Results

- The written VA and explanation as to why a process step was or was not identified as an actionable process step will assist you in identifying appropriate mitigation strategies.

For information on available vulnerability assessment courses, click "Resources" above

Summary

You have now completed Module 2.
Let’s review what you have learned before you move on to the knowledge checks.
In this module, you learned to:

1. Define significant vulnerabilities.
2. Define actionable process steps.
3. Explain the vulnerability assessment requirements.
Module 2: Vulnerability Assessments Overview

Welcome and Introduction Transcript

Welcome to Module 2, Vulnerability Assessments Overview. This module will provide an overview of vulnerability assessments.

After completing this module, you will be able to:
1. Define significant vulnerabilities;
2. Define actionable process steps; and
3. Explain the vulnerability assessment requirements.

Requirements of a Vulnerability Assessment Transcript

Recognizing that all points, steps, or procedures have some level of vulnerability, the goal of a vulnerability assessment, otherwise known as a "VA," is to identify which of these points have what the IA rule terms "significant vulnerabilities."

A significant vulnerability is defined as a vulnerability in a food process that, if exploited, could be expected to cause wide scale public health harm. Points that have these are called actionable process steps.

An actionable process step is a point, step, or procedure in a food process where a significant vulnerability exists and at which mitigation strategies can be applied and are essential to significantly minimize or prevent the significant vulnerability. In other words, an actionable process step is where the food is highly vulnerable to an intentional adulteration attack. To further clarify what we mean by a point, step or procedure, these refer to activities related to manufacturing, processing, packing, or holding of a food product.
The vulnerability assessment, at a minimum, must consider for each point, step, or procedure: Element 1, the potential public health impact if a contaminant were added to the product at that step, Element 2, the degree of physical access to the product, and Element 3, the ability of an attacker to successfully contaminate the product. We refer to these as the three fundamental elements or the three elements.

The VA must also consider the possibility of an inside attacker. When we say "Inside Attacker," we mean an attacker who has legitimate access to the facility, like an employee, contractor, authorized visitor, etc., and who has a basic understanding of facility operations, the ability to acquire and deploy a contaminant that is highly lethal, capable of withstanding the food production process, and undetectable via simple observation if added to food, and the intent to cause wide scale public health harm.
A vulnerability assessment must be conducted for each type of food produced by the facility. However, products and processes that are similar may be grouped together and assessed as a single group. For example, if a facility manufactures yogurt with different fruit flavor add-ins and the processing steps for these lines are the same, the facility may group these food products into one food type (e.g., "yogurt with fruit add-ins") and consider them together for the VA. Actionable process steps can then be identified for all the products in this group. The result of the VA includes a list of actionable process steps and explanations of why they were considered significantly vulnerable. Mitigation strategies are then developed and implemented in order to significantly minimize or prevent these significant vulnerabilities. It is important to mention here that the VA should consider any inherent characteristics at the actionable process steps when determining the existence of significant vulnerabilities. Inherent characteristics are conditions, activities, practices, or characteristics that are integral to the operation of a process step, point, or procedure, such as integrated equipment safety features that stop operation of the processing line to prevent bodily harm when equipment is accessed. These characteristics may have an effect on the vulnerability at an actionable process step which is why they are considered when conducting the vulnerability assessment.

The IA rule VA requirement provides significant flexibility for facilities. FDA is not specifying a particular methodology for vulnerability assessments, so facilities may choose the vulnerability assessment method of their liking as long as it considers, for each point, step, or procedure, the three fundamental elements described earlier. One appropriate method of conducting a vulnerability assessment is using the FDA-identified Key Activity Types.

Over the past 10 to 15 years, FDA has been conducting food defense vulnerability assessments in collaboration with the food industry, academia, and other government partners. FDA combined all of that data together, analyzed it, and found that certain general categories of food processing steps or procedures consistently ranked highly in terms of vulnerability, regardless of the commodity in question. FDA grouped these activities into four general categories of food processing steps or procedures and identified them as key activity types. They are: Bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling and mixing and similar activities.

Please note that in order to use key activities types as a VA method, you must take the appropriate training, or be otherwise qualified through job experience.
Module 2: Vulnerability Assessments Overview

Requirements of the Vulnerability Assessment (continued) Transcript

The outcome of the vulnerability assessment must be written and include an explanation as to why each point, step, or procedure either was or was not identified as an actionable process step. These written documents must be part of the food defense plan. The template shown is one option for documenting a VA and is from FDA’s draft guidance on the IA rule. The FDA does not require a particular format for documenting the VA and facilities have the flexibility to use the template shown or develop their own way to document the VA.

Module 2: Vulnerability Assessments Overview

Applying the Vulnerability Assessment Results Transcript

The written vulnerability assessment and explanations as to why each process step was or was not identified as actionable process steps will assist you in identifying appropriate mitigation strategies. You will hear more about this in later modules. It is important to note that this training does not qualify you to perform a vulnerability assessment. Additional training is needed to be qualified to perform that activity and can be found by clicking "Resources" above.
Summary Transcript

You have now completed Module 2.
Let’s review what you have learned before you move on to the knowledge checks.

In this module, you learned to:
1. Define significant vulnerabilities;
2. Define actionable process steps; and
3. Explain the vulnerability assessment requirements.

Let’s see what you remember about what you just learned.

Resources

- Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types
- FDA Fact Sheet for the IA Rule
- FDA IA Rule
- FDA Technical Assistance Network (TAN)
- Food Defense Mitigation Strategies Database (FDMDSD)
- Additional FSPCA Intentional Adulteration Training and Materials
- IA Rule Overview Course
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*Holidays may affect these hours
Welcome to Module 3: "Mitigation Strategies Overview"

After completing this module, you will be able to:
1. Explain mitigation strategy requirements.
2. Define "significantly minimize."
3. Recognize that mitigation strategies are tailored to facility procedures.
4. Recognize the importance of explanations.
5. Recognize mitigation strategy implementation training needs.
Module 3: Mitigation Strategies Overview

Welcome and Introduction

Welcome to Module 3: "Mitigation Strategies Overview"

After completing this module, you will be able to:

1. Explain mitigation strategy requirements.
2. Define "significantly minimize."
3. Recognize that mitigation strategies are tailored to facility procedures.
4. Recognize the importance of explanations.
5. Recognize mitigation strategy implementation training needs.
Mitigation Strategy Concepts

• You are in the best position to know and you have the flexibility to choose which mitigation strategy(ies) are appropriate for your facility's particular vulnerabilities.

• Mitigation strategies are:
  • Customized to the process step at which they are applied,
  • Tailored to existing facility practices and procedures, and
  • Directed toward the actionable process step's vulnerability, including vulnerability to an insider attack.

• Choose the strategy or combination of strategies that are the most practical.

• What works for your facility may not work for all facilities.

Mitigation Strategy Requirements

Definition:
Mitigation Strategies:
Risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis (21 CFR 121.3)

Significantly Minimize:
To reduce to an acceptable level, including to eliminate (21 CFR 121.3)

• Mitigation strategies must be identified and implemented for each actionable process step.

• Mitigation strategies must be written in the food defense plan:
  • Must include explanation of how the mitigation strategy(ies) significantly minimizes or prevents the significant vulnerability associated with the actionable process step.
Mitigation Strategy Concepts

- You are in the best position to know and you have the flexibility to choose which mitigation strategy(ies) are appropriate for your facility’s particular vulnerabilities.
- Mitigation strategies are:
  - Customized to the process step at which they are applied,
  - Tailored to existing facility practices and procedures, and
  - Directed toward the actionable process step’s vulnerability, including vulnerability to an insider attack.
- Choose the strategy or combination of strategies that are the most practical.
- What works for your facility may not work for all facilities.

Mitigation Strategy Concepts (continued)

- You should design your mitigation strategy(ies) to minimize or prevent the chances an attacker would be successful if they attempted an act of intentional adulteration at an actionable process step by:
  - Minimizing accessibility of the product to an attacker
  - Reducing the opportunity for an attacker to successfully contaminate the product, or
  - A combination of both
- The results of your VA will provide you with the reasons that the actionable process step was significantly vulnerable.
- Mitigation strategies should be cost effective and should not negatively impact food safety or worker safety.
Using Multiple Mitigation Strategies to Achieve Protection

- Sometimes a facility may need to employ multiple mitigation strategies together to achieve sufficient protection of an actionable process step.
- For example:
  - Secondary ingredient handling must take place behind a locked gate. However, many people need access to the area and have keys. So they also increased observation of handling using a security camera with a feed that is observed with reasonable frequency.
- Using multiple mitigation strategies is not required, but facilities may want to consider layering mitigation strategies together to achieve protection.

Mitigation Strategies Explanations

Written explanations are important because they:
- Explain how mitigation strategies significantly minimize or prevent the significant vulnerability.
- Clarify facility's thinking or rationale for how the mitigation strategy protects the APS.
- Specify proper implementation.
- Inform appropriate food defense monitoring, correction actions, and verification procedures.
- Provide critical verification of proper implementation.
Module 3: Summary

You have now completed Module 3.
Let's review what you have learned before you move on to the knowledge checks.
In this module, you learned to:
1. Explain mitigation strategy requirements.
2. Define "significantly minimize."
3. Recognize that mitigation strategies are tailored to facility procedures.
4. Recognize the importance of explanations.
5. Recognize mitigation strategy implementation training needs.

Module 3: Welcome and Introduction Transcript

Welcome to Module 3, Mitigation Strategies Overview. This module will provide an overview of mitigation strategies.

After completing this module, you will be able to:
1. Explain mitigation strategy requirements;
2. Define "significantly minimize."
3. Recognize that mitigation strategies are tailored to facility procedures;
4. Recognize the importance of explanations; and
5. Recognize mitigation strategy implementation training needs.
Mitigation Strategy Management Components

Management components are required for each mitigation strategy:

- Food defense monitoring
- Food defense corrective action
- Food defense verification

Required Training/Qualifications

- As mentioned in Module 1, "Food Defense Measures Overview," individuals identifying and explaining mitigation strategies must:
  - Be a "qualified individual," and
  - Complete training equivalent to standardized curriculum recognized as adequate by the FDA, or be otherwise qualified through job experience
    - This course satisfies the training requirement.
- Front-line employees are responsible for proper implementation of mitigation strategies and must:
  - Complete food defense awareness training, and
  - Complete proper mitigation strategy implementation training
Summary

You have now completed Module 3.

Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:

1. Explain mitigation strategy requirements.
2. Define "significantly minimize."
3. Recognize that mitigation strategies are tailored to facility procedures.
4. Recognize the importance of explanations.
5. Recognize mitigation strategy implementation training needs.

Why Mitigation Strategies Are Needed Transcript

Looking at an intentional adulteration event from the perspective of an attacker, the event would be considered 'successful,' if the attacker were able to introduce a contaminant into a product without detection and the product was consumed causing wide-scale public health harm. Some of the factors that contribute to the likelihood of a successful contamination include: the degree of physical access of the product to an attacker, the ease with which an attacker could introduce an agent into a product, and the ability of an attacker to work unobserved for enough time to introduce an agent to the product. Mitigation strategies, applied at actionable process steps, are designed to address these factors and thereby significantly minimize or prevent the possibility of a successful intentional contamination.
Module 3: Mitigation Strategies Overview

Mitigation Strategy Requirements Transcript

Mitigation strategies are defined as risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis. Significantly minimize means to reduce to an acceptable level, including to eliminate.

Mitigation strategies are required for each actionable process step and they must be written in the food defense plan. The food defense plan must also include written explanations for how the mitigation strategy or strategies significantly minimizes or prevents the significant vulnerability associated with the actionable process step.

Mitigation Strategy Concepts Transcript

Mitigation strategies are facility-specific. You are in the best position to know which mitigation strategy or combination of strategies are appropriate for your facility's particular vulnerabilities and you have the flexibility to make these decisions. What works for your facility may not work for others. Mitigation strategies should be customized to the actionable process step at which they are applied, tailored to existing facility practices and procedures and chosen to significantly reduce or eliminate the actionable process step's vulnerability, including its vulnerability to an inside attacker.
Most appropriate mitigation strategies are designed to minimize the accessibility of the product to an attacker, reduce the opportunity for an attacker to successfully contaminate the product, or a combination of both of these items. These two concepts tie back to Element 2 and Element 3 of a vulnerability assessment dealing with access to the product and the ability to successfully contaminate the product. Because it is efficient and cheaper to process large batches of products in a single step, we generally expect that you would not implement mitigation strategies to reduce the volume of food being processed and thus would not identify strategies designed to address Element 1 of the VA, public health impact. The results of your vulnerability assessment will provide you with the reasons that the actionable process step was significantly vulnerable, which helps to determine which type of mitigation strategy or strategies are most suitable for that actionable process step. Again, you have the flexibility to choose mitigation strategies or combinations of strategies that make the most sense for your facility and these mitigation strategies should be cost effective and should not negatively impact food safety or worker safety.

In some cases, a facility will use multiple mitigation strategies together to achieve sufficient protection of an actionable process step. For example, a facility identifies its secondary ingredient preparation area as an actionable process step. They choose to protect this step by requiring the premixing and measuring of secondary ingredients to take place behind a locked gate. The facility determines that this mitigation strategy contributes to reducing the significant vulnerability at this process step, but does not, by itself, significantly minimize the significant vulnerability here. The facility determines an additional strategy is necessary at this step because of the number of people who require access to the area and have keys to the gate. The facility determines that it is important to be able to observe who is accessing the secondary ingredient preparation area. Therefore, the facility redirects an existing security camera to observe the area when the gate is opened, with the camera feeding to a manned control room where personnel can observe whoever enters the secondary ingredient prep area. It must be noted that constant observation is not required, just observation at intervals that make sense based on the operation. In this case, the facility employs an access restriction mitigation strategy (the locking gate) and an additional mitigation strategy (supported by the camera) to increase observation of the actionable process step. These two strategies work together to significantly minimize the significant vulnerability at the secondary ingredient preparation area. It is not required that you use multiple mitigation strategies to significantly reduce vulnerabilities in all instances, but in some circumstances layering mitigation strategies together is the most practical way to protect the actionable process step. This will depend on the circumstances surrounding your actionable process step including your facility layout, your operation and your significant vulnerabilities. These differences show the importance of choosing mitigation strategies that are tailored to your facility and the reason that the IA rule requirement provides flexibility.
Module 3: Mitigation Strategies Overview

Mitigation Strategies Explanations Transcript

After identifying the most appropriate mitigation strategies for an actionable process step, you must be able to explain your choices. Written explanations of mitigation strategies are important because they detail how mitigation strategies significantly minimize or prevent the significant vulnerability and they will clarify your thinking and rationale for how the mitigation strategy will protect the actionable process step. Mitigation strategy explanations can be relatively brief and straightforward. For example, for a mitigation strategy that consists of a lock to protect access to a storage tank, your explanation may be simply that the lock prevents unauthorized access to the food in the tank, thereby minimizing the significant vulnerability of the storage tank. An actionable process step where several mitigation strategies have been identified may require a slightly lengthier explanation. For example, if your facility restricts access around a mixing tank only to those employees required by job function to be in the area and implements an alarm tone on the mixing tank hatch to notify personnel that someone has accessed the tank, that combination of mitigation strategies would require more explanation than the lock on the storage tank, but still may not be lengthy. You could explain that restricting the area only to those workers required to be there reduces the number of potential individuals who could reasonably intentionally adulterate the food at this step. You could further explain that the alarm tone on the mixing tank lid provides additional protection to the actionable process step by alerting other personnel that someone is accessing the mixing tank, thereby elevating awareness and observation of the mixing tank. Together, both mitigation strategies minimize the significant vulnerability associated with the mixing tank. Mitigation strategy explanations have the benefit of supporting the consistent implementation of the mitigation strategies as well. The written explanations help ensure that the rationale for the identification and implementation of each mitigation strategy is clear to persons responsible for its implementation as well as the monitoring of the mitigation strategy, correcting any deviations of its intended operation, and verifying its proper implementation.

Mitigation Strategy Management Components Transcript

Management components are required for each mitigation strategy to ensure that they are being properly and consistently implemented. These include food defense monitoring, food defense corrective actions, and food defense verification.
Module 3: Mitigation Strategies Overview

Training/Qualifications Required for Identification and Explanation of Mitigation Strategies Transcript

As previously mentioned in module 1, "Food Defense Measures Overview," the IA rule has specific training and qualification requirements for various activities. Successful completion of this training course satisfies the training requirement for identification and explanation of mitigation strategies. But there are other people in your facility that are also important for mitigating significant vulnerabilities. Individuals working at actionable process steps are the ones that will be putting the mitigation strategies into action and therefore they are responsible for proper implementation of the mitigation strategies you have chosen. These individuals, and their supervisors, must complete food defense awareness training and must also receive on the job training to properly implement the mitigation strategies at the actionable process steps where they work.

Module 3: Summary Transcript

You have now completed Module 3.

Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:
1. Explain mitigation strategy requirements;
2. Define "significantly minimize";
3. Recognize that mitigation strategies are tailored to facility procedures;
4. Recognize the importance of explanations; and
5. Recognize mitigation strategy implementation training needs.

Let's see what you remember about what you just learned.
You have now completed Module 3. Let’s review what you have learned before you move on to the knowledge checks.

In this module, you learned to:
1. Explain mitigation strategy requirements;
2. Define “significantly minimize”;
3. Recognize that mitigation strategies are tailored to facility procedures;
4. Recognize the importance of explanations; and
5. Recognize mitigation strategy implementation training needs.

Let’s see what you remember about what you just learned.

Resources

- Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types
- FDA Fact Sheet for the IA Rule
- FDA Technical Assistance Network (TAN)
- Food Defense Mitigation Strategies Database (FDMSD)
- FSPCA Intentional Adulteration Training and Materials
- IA Rule
- IA Rule Overview Course

Help

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*Holidays may affect these hours
Welcome to Module 4: "Mitigation Strategy Approaches"

After completing this module, you will be able to:

1. Explain the importance of considering an inside attacker in mitigation strategy identification.
2. Differentiate between degree of physical access and likelihood of successful contamination.
3. Describe and access FDA's Food Defense Mitigation Strategies Database.
Using Information from Vulnerability Assessments

- The VA that identified your actionable process steps evaluated the following three fundamental elements:
  - Potential public health impact if a contaminant were added at that step,
  - Degree of physical access to product, and
  - Ability of an attacker to successfully contaminate the product.
- The possibility of an inside attacker was an underlying consideration of the evaluation of all three elements.
- Mitigation strategies should be customized to the nature of the significant vulnerability identified in the VA.

Inside Attackers

- Why should you consider inside attackers when identifying mitigation strategies?
  - Based on years of collaboration with law enforcement and intelligence communities, it is widely recognized that the inside attacker poses the highest risk for intentional adulteration of food.
  - There are instances of intentional adulteration in the past that were carried out by an inside attacker.
Module 4: Mitigation Strategy Approaches

Addressing Elements of Vulnerability

- Mitigation strategies usually address either the degree of physical access and/or the likelihood of a successful attack.
  - Minimizing the accessibility of the food or equipment to an inside attacker is usually accomplished through physical barriers or restricted personnel access.
  - Reducing the likelihood of a successful attack is usually accomplished by increasing observation of an area to reduce the opportunity for an inside attacker to successfully contaminate the product without detection.
- In many cases, the appropriate mitigation strategy or combination of strategies will address a combination of both of these elements.
- And again, it is assumed that the person who would attempt to intentionally adulterate the food could be an inside attacker.

Types of Mitigation Strategies

- Mitigation strategies can take many forms, including but not limited to:
  - Technology-assisted mitigation strategies
  - Personnel-based mitigation strategies
  - Operations-based mitigation strategies
The FDMSD is a tool designed by FDA to assist companies with identifying mitigation strategies. The FDMSD provides a range of general mitigation strategies for individuals to consider implementing at points, steps, or procedures to minimize the vulnerability to an intentional attack.

For more information on the Food Defense Mitigation Strategies Database (FDMSD), click "Resources" above or click on the link below:
https://www.cfsanappseexternal.fda.gov/scripts/fooddefense/mitigationstrategies/index.cfm

Mitigation strategies found within the FDMSD are generally designed to address the degree of physical access or the ability of an attacker to successfully contaminate the food. The list of mitigation strategies within the database are written in general terms for wide applicability, but can be tailored. Mitigation strategies must be customized to the facility and actionable process step. Use of the FDMSD is not required.
You have now completed Module 4.
Let's review what you have learned before you move on to the knowledge checks.
In this module, you learned to:

1. Explain the importance of considering an inside attacker in mitigation strategy identification.
2. Differentiate between degree of physical access and likelihood of successful contamination.
3. Describe and access FDA's Food Defense Mitigation Strategies Database.
Using Information from Vulnerability Assessments Transcript

As mentioned in Module 2, “Vulnerability Assessments Overview,” there are three fundamental elements of a VA: (1) public health impact; (2) physical access; and (3) likelihood of successful attack. During a VA, each of these elements is considered to understand how each contributes to the overall vulnerability of each process step while keeping in mind the possibility of an inside attacker. When identifying and implementing mitigation strategies, the consideration of these elements will help to identify the appropriate mitigation strategies and inform the written explanations for your mitigation strategies. Remember that the VA considered the possibility of an inside attacker when evaluating significant vulnerabilities. When considering mitigation strategies you should refer back to the VA conclusions and identify mitigation strategies that adequately address the significant vulnerabilities, including those actions of an inside attacker.

Inside Attackers Transcript

Based on years of collaboration with law enforcement and intelligence communities, it is widely recognized that inside attackers pose the highest risk for intentional adulteration of food. There are instances of intentional adulteration in the past that were carried out by an inside attacker.
Module 4: Mitigation Strategy Approaches

**Addressing Elements of Vulnerability Transcript**

As mentioned in Module 3, “Mitigation Strategies Overview,” it is likely that you will design your mitigation strategies to address either the degree of physical access and/or the likelihood of a successful attack. Element 1, public health impact, usually involves volume of product being processed at a certain point, and it is not expected that facilities would choose to reduce the volume of product produced to mitigate significant vulnerabilities. Minimizing the accessibility of the food or equipment to an inside attacker is usually accomplished through physical barriers or restricted personnel access. Reducing the likelihood of a successful attack is usually accomplished by increasing observation of an area to reduce the opportunity for an inside attacker to successfully contaminate the product without detection. In many cases the appropriate mitigation strategy or combination of strategies will address a combination of both of these elements. And again, it is assumed that the person who would attempt to intentionally adulterate the food could be an inside attacker.

**Types of Mitigation Strategies Transcript**

Mitigation strategies can take many forms. Some strategies may require the implementation of a technology to protect food and others may require specific actions by personnel or changes to facility operations. These are referred to as either technology-assisted, personnel-based, or operations-based mitigation strategies. Regardless of their nature, all of these mitigation strategies are designed to either minimize the accessibility of the product to an inside attacker or reduce the ability of an inside attacker to successfully contaminate the product therefore significantly minimizing or eliminating the significant vulnerability. There may be instances where mitigation strategies may contribute to limiting access to an actionable process step as well as reduce the likelihood of a successful contamination.
Module 4: Mitigation Strategy Approaches

FDA's Food Defense Mitigation Strategies Database (FDMSD) Transcript

The Food Defense Mitigation Strategies Database is a tool designed by FDA to assist you with identifying mitigation strategies. The database provides a range of mitigation strategies for you to consider implementing at your actionable process steps. To access it, click on the link in the textbox at the bottom of the screen.

Module 4: Mitigation Strategy Approaches

Using FDA's FDMSD Transcript

Mitigation strategies found within the database are generally designed to address the degree of physical access, an attacker's ability to successfully contaminate the food or both of these elements. The content of the database was derived from experience conducting VAs with industry, and it can serve as a resource for you to identify mitigation strategies. The strategies found in the database serve as a conceptual starting point to help you identify mitigation strategies, which would then need to be customized to your facility and actionable process steps. The strategies in the database will provide general ideas of mitigation strategies that facilities can then tailor to the specific characteristics of their actionable process steps and their existing policies and procedures. For example, one mitigation strategy in the database reads, "Restrict access to authorized personnel." While this mitigation strategy provides you with a general idea of what to implement at your facility, you must tailor it to your specific actionable process step such as, "Restrict access to the mixer to authorized personnel. These employees wear special red caps and their job function is identified on their employee identification badges. Employees working at the mixer will immediately escort out of the area anyone not authorized to be in the area surrounding the mixer." By tailoring the strategy found in the database to your actionable process step it has now become facility-specific. The FDA provides the database as a free resource for industry. Using the database is not required by the IA rule and can be used at the discretion of the facility.
Module 4: Mitigation Strategy Approaches

Module 4: Summary Transcript

You have now completed Module 4.

Let’s review what you have learned before you move on to the knowledge checks.

In this module, you learned to:

1. Explain the importance of considering an inside attacker in mitigation strategy identification;
2. Differentiate between the degree of physical access and likelihood of a successful contamination; and
3. Describe and access FDA’s Food Defense Mitigation Strategies Database.

Let’s see what you remember about what you just learned.

Resources

- Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types
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Welcome and Introduction

Welcome to Module 5: "Limiting the Degree of Access"

After completing this module, you will be able to:

1. Explain personnel- and operations-based mitigation strategies that reduce access to food.
2. Explain how the use of authorized personnel will reduce access to food.
3. Explain technology-assisted mitigation strategies that reduce access to food.
4. Deduce which strategy best protects actionable process steps.
Minimizing the Accessibility of the Product to an Attacker

- Mitigation strategies designed to reduce the accessibility of the product to an attacker can take many forms, but all such strategies significantly reduce or prevent physical access to the product at the actionable process step.
- These types of mitigation strategies can rely on:
  - Specific actions by personnel that limit access (e.g., the buddy system)
  - Specific actions that take place during operations (e.g., limiting the staging time of ingredients)
  - The implementation of physical measures that physically reduce access (e.g., locks, seals, shields, etc.)

Personnel-Based Mitigation Strategies That Reduce Access

- Personnel-based mitigation strategies are specific actions conducted by personnel to restrict access, rather than using technology.
- The most common way to use personnel-based mitigation strategies is to designate authorized personnel and restrict access to specific actionable process steps to only those people.
  - Authorized personnel are individuals who have been granted permission to be in a specific area and have a need to be present, based on job function.
Module 5: Limiting the Degree of Access

Process of Designating or Establishing Authorized Personnel

- You should establish who should be authorized to be in a particular area based on a deliberative evaluation of the actionable process step, the specific job function requiring human presence, and the quantity and skill level of workers needed to perform the function.

- You should also evaluate the workers in the area for:
  - skill set
  - seniority
  - level of responsibility
  - other factors that may contribute to their trustworthiness for working in a sensitive area of the facility, such as background checks and other vetting processes.

Examples of Personnel-Based Mitigation Strategies

- Limiting access to an actionable process step only to authorized personnel is a mitigation strategy that can reduce the number of people in a sensitive area and significantly minimize accessibility to the product.

- Mitigation strategies that restrict access to and prohibit unauthorized individuals from entering an area may rely on mechanisms to easily identify authorized and unauthorized individuals. (e.g., color coded hard hat, color coded uniforms, clearly visible authorization badges, etc.).

- Typically, personnel-based mitigation strategies that restrict access to an area would be designed around an existing, facility-wide security measure of positively identifying people in the facility and employing some practice to easily identify workers who are authorized to work in the area in question.

- Authorized individuals would be responsible for excluding unauthorized persons from the area.
Examples of Operations-Based Mitigation Strategies

- Changes in normal operational activities can also serve as mitigation strategies to reduce the ability of an attacker to access the food and introduce a contaminant to the product.
- For example:
  - Reduce staging time which limits access to staged ingredients and decreases the attacker's ability to introduce a contaminant.
  - Relocate the staging or short-term storage of partially-used, open ingredient containers to a secure, limited-access part of the facility.

Technology-Assisted Mitigation Strategies That Reduce Access

- Technology-assisted mitigation strategies rely on the implementation of technology to provide a physical barrier that reduces or eliminates access to food or equipment.
- Technology-assisted mitigation strategies are not limited to electronic systems; they could be simple mechanisms preventing access.
Technology-Assisted Mitigation Strategies That Reduce Access

- Some examples of technology-assisted mitigation strategies include:
  - Locks (lock and key, coded key pad)
  - Tamper-evident seals
  - Access cards
  - Doors, gates, lids, shields
  - Automated equipment

Selecting Mitigation Strategies That Reduce Access

- Taking APSs into consideration, in conjunction with what you learned about personnel-based, operations-based and technology-assisted mitigation strategies, you now have sufficient knowledge to identify the most appropriate mitigation strategies to reduce accessibility.

- Mitigation strategies can be:
  - personnel-based
  - operations-based
  - technology-assisted
  - a combination of these

- The facility has the flexibility to decide which mitigation strategy or combination strategies are appropriate based on the facility-specific environment and the significant vulnerability at the actionable process step.
Scenarios in this exercise are examples of potential situations that may be encountered in some facilities but are not based on any specific facility or product. They are intended to assist you in your decision-making with respect to identification and explanation of appropriate mitigation strategies and have been simplified for training purposes. Scenarios are designed to prompt thoughtful consideration for identifying and explaining mitigation strategies, though they may not have all the information you would need in a real-world environment. Additionally, explanations for the mitigation strategies in this exercise provide you with examples of thought processes and justifications for the selection of specific mitigation strategies in these fictitious scenarios only. When developing mitigation strategies for your own facility, you must choose and explain mitigation strategies that are appropriate for your facility.

A facility's VA identifies the primary ingredient storage tank as an APS due to:
- Potential public health impact,
- Unrestricted physical access via unsecured access hatch, and
- Likelihood that an inside attacker could successfully contaminate the food.

Facility concludes that:
- There is no legitimate need to open the hatch when food is in the tank, and
- Locking the hatch would be a simple, cost effective way of significantly reducing accessibility to the ingredient in the tank.
Limiting the Degree of Access Example Scenario

- Facility specifies that the security office will hold the lock's keys and will allow access to them based on approval from the facility security manager or food defense coordinator.
- Facility's food defense plan:
  - Identifies the hatch lock as the mitigation strategy,
  - Explains that the lock on the hatch renders the food in the tank inaccessible, including to an inside attacker, thereby significantly reducing the vulnerability present at this actionable process step.

Limiting the Degree of Access Exercise

Scenario
Mitigation Strategy
Selection Exercise
Limiting the Degree of Access Exercise

In this exercise, you were given information about an actionable process step and asked to consider five different mitigation strategies and whether or not they would be appropriate for this scenario. As stated in the discussions, some of the strategies may be practical and others may not. This example shows you that there are various ways of reducing the significant vulnerability. In your facility, you must take many factors into consideration to choose the best mitigation strategy or combination of strategies that work for your unique situation, and you must be able to explain how the chosen strategy(ies) are reducing the significant vulnerability at each actionable process step.

Summary

You have now completed Module 5.

In this module, you learned to:

1. Explain personnel and operations-based mitigation strategies that reduce access to food.
2. Explain how the use of authorized personnel will reduce access to food.
3. Explain technology-assisted mitigation strategies that reduce access to food.
4. Deduce which strategies best protect the actionable process steps.

Let’s see what you remember about what you just learned.
Welcome to Module 5, Limiting the Degree of Access. This module will explain limiting the degree of access to the food.

After completing this module, you will be able to:
1. Explain personnel- and operations-based mitigation strategies that reduce access to food;
2. Explain how the use of authorized personnel will reduce access to food;
3. Explain technology-assisted mitigation strategies that reduce access to food; and
4. Deduce which strategies best protect the actionable process steps.

Mitigation strategies designed to reduce an inside attacker’s access to a product can take many forms, but all strategies perform the same essential function—significantly reducing or preventing physical access to the product at the actionable process step. Access-based mitigation strategies can be personnel-based or operations-based strategies that prevent an attacker from accessing the food like taking advantage of multiple people at a production step, sometimes called the buddy system, or something physical in nature, like using locks or seals. Let examine each of these options.
Personnel-based mitigation strategies are specific actions conducted by personnel to significantly minimize or prevent significant vulnerabilities at actionable process steps. Personnel-based mitigation strategies that can reduce accessibility involve establishing who is authorized to be present at an actionable process step and restricting the area to only those people. Authorized personnel are individuals who have been granted permission to be in a specific area and have a need to be present based on their job function. Authorized employees would also be responsible for excluding unauthorized persons from the area. We will talk more about this in upcoming slides.

You should establish who should be authorized to be in a particular area based on a deliberative evaluation of the actionable process step, the specific job function requiring human presence, and the number of workers needed to perform the function. You should also evaluate the skill set of the workers in this area, their seniority, and their level of responsibility. Other factors that may contribute to their trustworthiness for working in a sensitive area of the facility can be taken into consideration such as information gathered during background checks or employee vetting. For example, you may authorize senior or long-term employees to work at an actionable process step because they have established their trustworthiness over time. You may also identify workers that need additional vetting before being assigned to an actionable process step, such as recently hired employees or those performing less critical job functions.
Module 5: Limiting the Degree of Access

Examples of Personnel-Based Mitigation Strategies Transcript

Limiting access to an actionable process step to only authorized personnel can reduce the number of people in a sensitive area and significantly minimize the accessibility to the product. Typically, personnel-based mitigation strategies that restrict access to an area would be designed around an existing, facility-wide security measure of positively identifying people in the facility and employing some practice to easily identify workers who are authorized to work in the area in question. For example, a facility may have an actionable process step with a mitigation strategy designed to restrict access to only those employees whose job function is to oversee the actionable process step. The facility identifies these individuals by issuing them color-coded uniforms, hard hats, or badges, enabling management and other staff to easily determine if they are authorized to be in the area. If an unauthorized person enters the area, they would be immediately identifiable due to the lack of distinct uniform or badge, and should be removed from the area by the authorized individuals. Implementation of the access restriction includes the requirement to recognize and remove unauthorized individuals and this is essential to these types of mitigation strategies. When you rely on workers to implement a mitigation strategy that restricts access of an area to authorized employees, proper training of employees on the consistent and proper implementation of this mitigation strategy is critical.

Examples of Operations-Based Mitigation Strategies Transcript

Operations-based mitigation strategies are changes to, or the continuing implementation of, a specific operational action that is not inherent to the process step and that is designed to mitigate a significant vulnerability at an actionable process step. They differ from personnel-based mitigation strategies in that they are not directly focused on employees but rather on the processes within a facility. How can you differentiate between when an operation is just an operation or when it can also be a mitigation strategy? Think of it like this, a specific operation is a mitigation strategy if absent its consistent and proper implementation, a significant vulnerability would not be significantly minimized or prevented. Changes in normal operational activities can serve as mitigation strategies to reduce the ability of an attacker to access the food and introduce a contaminant to the product. For example, reducing staging time of ingredients and rework can reduce an attacker’s ability to introduce a contaminant. Any time ingredients or rework are stored or staged in unsecured containers, there is a potential opportunity for an attacker to add a contaminant into the ingredient or rework material. Reducing the time ingredients and rework materials are staged in unsecured containers reduces the time ingredients are potentially accessible for an attacker to adulterate the ingredient or rework material. Another operations-based mitigation strategy to reduce access is to, if practical, relocate the staging or short-term storage of partially-used, open ingredient containers to a secure, limited-access part of the facility. Moving the location where this activity is conducted to an area that already has restricted access, significantly reduces the accessibility of an attacker to the open containers.
Module 5: Limiting the Degree of Access

Technology-Assisted Mitigation Strategies That Reduce Access Transcript

Technology-assisted mitigation strategies generally rely on the implementation of some physical access barrier, tamper-evident seal or other mechanism that would prevent access to someone intending to adulterate the food without leaving detectable evidence. The word technology may sometimes bring to mind something complicated or expensive. Technology-assisted mitigation strategies are not limited to electronic systems. They can be very simple such as locks, shields, or protective barriers.

Examples of Technology-Assisted Mitigation Strategies That Reduce Access Transcript

The most illustrative and intuitive example of a technology-assisted mitigation strategy that reduces access is that of a lock on a hatch, inspection port, or lid of an actionable process step. Additional examples of technology-assisted mitigation strategies to reduce access to the food include using tamper-evident tape or seals to reseal ingredient storage containers when tamper-evident packaging has been opened (e.g., for staging, handling, or ingredient sampling); restricting access to the area around an actionable process step with locking gates, doors, or other barriers where only authorized persons can open the barrier by using specially-issued keys or other authority-based access mechanisms such as radio-frequency identification cards, swipe cards, or biometric locking mechanisms; securing loading/unloading hoses in locking cabinets or by securing the hose opening with tamper-evident caps or seals; blocking access pathways to vulnerable points by using ladder cages, locking gangway gates, or implementing other barriers to reduce access to food and equipment; employing seals on a shipping conveyance to reduce the likelihood that the shipping conveyance is accessed during transport.
Module 5: Limiting the Degree of Access

Selecting Mitigation Strategies That Reduce Access Transcript

Taking the vulnerability of the actionable process step into consideration, combined with what you just learned about personnel-based, operations-based, and technology-assisted mitigation strategies, you now have sufficient knowledge to identify the most appropriate mitigation strategies to reduce accessibility. The facility has the flexibility to decide which mitigation strategy or combination of strategies are appropriate based on the facility-specific environment and the significant vulnerability at the actionable process step. Let's apply these lessons by going through a scenario together. Then you will be given an opportunity to think through a scenario on your own.

Now let's do an exercise.

Module 5: Limiting the Degree of Access

Mitigation Strategy Selection Exercise – Limiting the Degree of Access Disclaimer Transcript

Scenarios in this exercise are examples of potential situations that may be encountered in some facilities but are not based on any specific facility or product. They are intended to assist you in your decision-making with respect to identification and explanation of appropriate mitigation strategies and have been simplified for training purposes. Scenarios are designed to prompt thoughtful consideration for identifying and explaining mitigation strategies, though they may not have all the information you would need in a real world environment. Additionally, explanations for the mitigation strategies in this exercise provide you with examples of thought processes and justifications for the selection of specific mitigation strategies in these fictitious scenarios only. When developing mitigation strategies for your own facility, you must choose and explain mitigation strategies that are appropriate for your facility.
Mitigation Strategy Selection Exercise – Limiting the Degree of Access Example Scenario

Transcript

Let's imagine that a facility identified the primary ingredient storage tank as an actionable process step because of the public health impact that would occur if the tank were successfully contaminated, the presence of physical access via a hatch, and the likelihood that an inside attacker could successfully contaminate the food in the tank without being detected or the contamination being discovered. The VA identified that the unsecured access hatch at the top of the tank provided unrestricted access to the ingredient in the tank and would enable an attacker to intentionally contaminate the food. The facility, in considering mitigation strategies, concludes that there is no legitimate need to open the hatch when liquid food is in the tank and locking the hatch would be a simple, cost effective way of significantly reducing accessibility to the ingredient in the tank and would significantly minimize or prevent the significant vulnerability identified in the vulnerability assessment.

Mitigation Strategy Selection Exercise – Limiting the Degree of Access Example Scenario

Transcript

The facility specifies that the security office will hold the keys to the lock and will allow access to the keys only for those persons with good reason and approval from the facility security manager or food defense coordinator. The facility's food defense plan should identify the lock on the hatch as the mitigation strategy and explain that the lock on the hatch renders the food in the tank inaccessible to an attacker, including an inside attacker, thereby significantly reducing the vulnerability present at this actionable process step.
Module 5: Limiting the Degree of Access

Mitigation Strategy Selection Exercise – Limiting the Degree of Access Scenario Transcript

Please watch the video discussing the example scenario carefully. When the video is done, click next to continue to the exercise, where you will determine the best mitigation strategy or combination of strategies for the actionable process step.

Your facility makes ground black pepper and recently completed a vulnerability assessment for this product. The VA identified one actionable process step, grinding. This was determined to be an actionable process step because the grinding process grinds a large volume of whole peppercorns and during this step a significant degree of mixing occurs, so if a contaminant were added at this step, it would be evenly distributed throughout the product. The grinder is located on the main production floor in a high traffic area with accessibility by most production employees. Additionally, the whole peppercorns are manually added to the grinder through an accessible hatch. The grinding operation can be performed by several members of the production team including temporary and contracted workers, but the grinder is generally accessible to anyone in the area—including people not part of the production staff, such as front office workers, delivery personnel, and members of the cleaning team. The grinder has a hatch lid on the top of the equipment that can be opened during operation, but the standard procedure is to add the whole peppercorns to the grinder until the desired amount is reached and then for the lid to be closed while the grinder is in operation. The hatch on the top of the grinder is the only access point to the food.

As the qualified individual assigned to identify and explain mitigation strategies, you have been brought in to determine the most practical mitigation strategy or combination of strategies and to write the explanations. On the next screen is a brief list of potential mitigation strategies for this actionable process step. Please consider each choice and evaluate why it is, or is not, a suitable mitigation strategy for this actionable process step. Additionally, for the strategies that are suitable, consider how you would tailor it/them to this step.

Mitigation Strategies

We asked you to consider each of the five choices provided and evaluate whether it was, or was not, a suitable mitigation strategy for that actionable process step. Your response to Item 1, Restrict grinder operation to authorized personnel, is displayed on the left of the screen and FDA's recommendation is displayed on the right.

FDA recommends that this may be an appropriate mitigation strategy for this actionable process step. One of the reasons the grinder was identified as an actionable process step is because it is readily accessible, potentially allowing an attacker to gain access to the grinder while it is in operation. Restricting the grinding operation to a limited number of pre-identified authorized personnel will reduce the number of people allowed to access the grinder and could significantly reduce the accessibility to the food. Visual aids, such as colored hard hats, color-coded uniforms or visually displayed badges, can assist facilities with quickly identifying the authorized individuals. If you choose to use this strategy, the visual aid or other method of identifying authorized personnel should be part of your tailored mitigation strategy and your explanation.
Mitigation Strategy Selection Exercise – Limiting the Degree of Access – Item 1 Transcript

We asked you to consider each of the five choices provided and evaluate whether it was, or was not, a suitable mitigation strategy for that actionable process step. Your response to Item 1, Restrict grinder operation to authorized personnel, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that this may be an appropriate mitigation strategy for this actionable process step. One of the reasons the grinder was identified as an actionable process step is because it is readily accessible, potentially allowing an attacker to gain access to the food while it is in operation. Restricting the grinding operation to a limited number of pre-identified authorized personnel will reduce the number of people allowed to access the grinder and could significantly reduce the accessibility to the food. Visual aids, such as colored hard hats, color-coded uniforms or visually displayed badges, can assist facilities with quickly identifying the authorized individuals. If you choose to use this strategy, the visual aid or other method of identifying authorized personnel should be part of your tailored mitigation strategy and your explanation.

Mitigation Strategy Selection Exercise – Limiting the Degree of Access – Item 2 Transcript

Your response to Item 2, use a lock on the hatch to the grinder to limit access to the grinder while it is operating, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that this may be an appropriate mitigation strategy for this actionable process step. One of the reasons the grinder was identified as an actionable process step is because it is readily accessible, potentially allowing an attacker to gain access to the food while it is in operation. Requiring the hatch on the grinder to be locked during operation will prevent an attacker from adding a contaminant during the grinding process. Additional information may be useful in the mitigation strategy explanation, such as the type of lock used, and who has access to the lock’s controls or keys.

Mitigation Strategy Selection Exercise – Limiting the Degree of Access – Item 3 Transcript

Your response to Item 3, clean and sanitize the grinder before and after use, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that while this strategy may work as mitigation strategy for some facilities, in this facility the grinder is located on the main production floor where many people have access to the grinder during its use. Cleaning and sanitizing the grinder before and after use is important for food safety reasons, but it would only protect the food from an intentional contamination if the contaminant was added before the grinder was cleaned. If the grinder is open and accessible after cleaning, a contaminant could be added to the grinder which would then contaminate the product when pepper is reintroduced to the grinder and operations resume. Unless cleaning is conducted immediately prior to reintroducing product, the grinder may sit open and accessible for a period of time allowing an opportunity for an attacker to introduce a contaminant. The cleaning and sanitizing practice may need to be altered to serve as a mitigation strategy in its own right, but if used in conjunction with other mitigation strategies, such as previous choices 1 or 2, “restrict grinder operation to authorized personnel” or “use a lock on the hatch to the grinder to limit access to the grinder while it is operating,” these strategies could work synergistically to significantly minimize or prevent the significant vulnerabilities associated with the grinder.
### Mitigation Strategy Selection Exercise - Limiting the Degree of Access - Item 3 Transcript

Your response to Item 3, clean and sanitize the grinder before and after use, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that while this strategy may work as a mitigation strategy for some facilities, in this facility the grinder is located on the main production floor where many people have access to the grinder during its use. Cleaning and sanitizing the grinder before and after use is important for food safety reasons, but it would only protect the food from intentional contamination if the contaminant was added before the grinder was cleaned. If the grinder is open and accessible after cleaning, a contaminant could be added to the grinder which would then contaminate the product when pepper is reintroduced to the grinder and operations resume. Unless cleaning is conducted immediately prior to reintroducing product, the grinder may sit open and accessible for a period of time allowing an opportunity for an attacker to introduce a contaminant. The cleaning and sanitizing practice may need to be altered to serve as a mitigation strategy in its own right, but if used in conjunction with other mitigation strategies, such as previous choices 1 or 2, “restrict grinder operation to authorized personnel” or “use a lock on the hatch to the grinder to limit access to the grinder while it is operating,” these strategies could work synergistically to significantly minimize or prevent the significant vulnerabilities associated with the grinder.

### Mitigation Strategy Selection Exercise - Limiting the Degree of Access - Item 4 Transcript

Your response to Item 4, require workers using the grinder to wash their hands prior to working with product, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that requiring workers to engage in proper hand washing is a prudent food safety measure that may protect against unintentional contamination of the food. However, handwashing does not prevent the actions of an inside attacker who intends to contaminate the food to cause widespread public health harm. This would not be a suitable mitigation strategy to protect the grinder from intentional adulteration.

### Mitigation Strategy Selection Exercise - Limiting the Degree of Access - Item 5 Transcript

Your response to Item 5, Use a closed, in-line, self-contained grinder that will not allow access, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that this mitigation strategy would address the accessibility of the grinder and significantly reduce the significant vulnerability associated with this step, but it may be cost prohibitive or impractical for this operation. If a facility is able to invest in new equipment to mitigate the risk of intentional adulteration at this step, they have the option to do that, but there are other, more practical and cost-effective measures that can be taken to reduce the accessibility to the grinder without having to invest in an entirely new piece of equipment.
Module 5: Limiting the Degree of Access

Mitigation Strategy Selection Exercise – Limiting the Degree of Access Summary Transcript

In this exercise you were given information about an actionable process step and asked to consider five different mitigation strategies and whether or not they would be appropriate for this scenario. As stated in the discussions, some of the strategies may be practical and others may not. This example shows you that there are various ways of reducing the significant vulnerability. In your facility, you must take many factors into consideration to choose the best mitigation strategy or combination of strategies that work for your unique situation, and you must be able to explain how the chosen strategy(ies) are reducing the significant vulnerability at each actionable process step.

Module 5: Summary Transcript

You have now completed Module 5.

Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:
1. Explain personnel- and operations-based mitigation strategies that reduce access to food;
2. Explain how the use of authorized personnel will reduce access to food;
3. Explain technology-assisted mitigation strategies that reduce access to food; and
4. Deduce which strategies best protect the actionable process steps.

Let's see what you remember about what you just learned.
Module 5: Limiting the Degree of Access

You have now completed Module 5. Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:
1. Explain personnel- and operations-based mitigation strategies that reduce access to food;
2. Explain how the use of authorized personnel will reduce access to food;
3. Explain technology-assisted mitigation strategies that reduce access to food; and
4. Deduce which strategies best protect the actionable process steps.

Let's see what you remember about what you just learned.

Resources

- Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types
- FDA Fact Sheet for the IA Rule
- FDA Technical Assistance Network (TAN)
- Food Defense Mitigation Strategies Database (FDMSD)
- FSPCA Intentional Adulteration Training and Materials
- IA Rule
- IA Rule Overview Course

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Welcome to Module 6 "Reducing the Likelihood of a Successful Contamination"

After completing this module, you will be able to:

1. Explain personnel- and operations-based mitigation strategies that reduce the likelihood of successful contamination.
2. Explain technology-assisted mitigation strategies that reduce the likelihood of successful contamination.
3. Deduce which strategies best protect the actionable process steps.
A Successful Contamination

- A "successful contamination" is one where the attacker successfully introduces a sufficient quantity of contaminant to achieve wide scale public health harm.
- Examples of factors negatively affecting successful contamination include:
  - Being caught in the act.
  - Not being able to introduce a sufficient volume of contaminant.
  - The contaminant being detected prior to causing wide scale public health harm, and
  - Not having enough time to introduce the contaminant.

Mitigation Strategies to Reduce the Likelihood of a Successful Contamination

- You can significantly minimize or prevent significant vulnerabilities by using mitigation strategies that reduce or eliminate the ability of an attacker to introduce a contaminant into the product in such a manner as to achieve wide scale public health harm.
- Examples of these mitigation strategies include:
  - Increased observation of an actionable process step so an attacker’s actions would be evident,
  - Strategies that make the ability to carry and introduce a contaminant extremely challenging or impossible, and
  - Strategies that would require the attacker to undertake improbable or impossible actions in order to carry out the attack.
Mitigation strategies that reduce the ability of an attacker to introduce a contaminant into the product can be broken down into those strategies that:

- focus on managing personnel behavior or process operations, and
- are technology-assisted.

Personnel-based mitigation strategies that reduce the likelihood of a successful contamination usually rely on increased observation.

Operations-based mitigation strategies usually rely on procedures that aid in the removal or detection of contaminants, or procedures that would make the introduction of contaminants difficult or unrealistic.
Examples of Personnel- and Operations-Based Mitigation Strategies to Reduce the Likelihood of a Successful Contamination

- Peer monitoring.
- Moving highly vulnerable points, steps or procedures to easily observable areas.
- Flushing equipment or running a discard batch prior to resuming production after equipment has been idle and accessible would eject an intentionally introduced contaminant from the system and prevent it from adulterating the food.
- Requiring workers at actionable process steps to wear uniforms or clothing without pockets or other means of concealing items.
- Altering existing operations, such as visual inspection procedures.

Technology-Assisted Mitigation Strategies that Reduce the Likelihood of Successful Contamination

- Technology-assisted mitigation strategies that reduce the likelihood of successful contamination use strategies that rely on technology to detect suspect activity.
- For example:
  - An alarm mechanism that notifies personnel that a mixing tank, which is typically not opened during operation, has been accessed.
  - Motion detection equipment that notifies a supervisor(s) when a person enters a secure area around an actionable process step.
  - Use of sensors or other similar technologies to detect whether there is a difference in the volume, mass, or density of ingredients that are added to a product to ensure that no additional material is added and that an ingredient is not replaced, in part, by a contaminant.
You may also use technology-assisted mitigation strategies to enhance human supervision or observation of actionable process steps.

For example:

- Using closed-circuit TV systems or other monitoring devices that can support management or security staff observation of actionable process steps.
- Using mirrors to enhance visibility.

Taking APSs into consideration, in conjunction with what you learned about personnel-based and technology-assisted mitigation strategies, you now have sufficient knowledge to identify the most appropriate mitigation strategies to reduce the likelihood of a successful contamination.

Mitigation strategies can be:

- personnel-based
- operation-based
- technology-assisted
- a combination of these

The facility has the flexibility to decide which mitigation strategy or combination strategies are appropriate based on the facility-specific environment and the significant vulnerability at the actionable process step.
Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination Disclaimer

Scenarios in this exercise are examples of potential situations that may be encountered in some facilities but are not based on any specific facility or product. They are intended to assist you in your decision-making with respect to identification and explanation of appropriate mitigation strategies and have been simplified for training purposes.

The scenarios are designed to prompt thoughtful consideration for identifying and explaining mitigation strategies, although they may not have all the information you would need in a real-world environment. Additionally, explanations for the mitigation strategies in this exercise provide you with examples of thought processes and justifications for the selection of specific mitigation strategies in these fictitious scenarios only.

When developing mitigation strategies for your own facility, you must choose and explain mitigation strategies that are appropriate for your facility.

For example:

- A facility’s VA identifies the receiving of bulk liquid ingredients as an APS because the step involves the opening of venting and sampling hatches on the transport conveyance. An inside attacker could successfully contaminate the liquid ingredients without detection because there is often nobody else around when the hatches are opened.
  
  - The facility can implement a mitigation strategy of increased observation of unloading by having the worker who reviews shipping documentation witness the opening of the transport conveyance and the attachment of transfer hoses and or pumping equipment.

  - Increased observation at the APS significantly reduces the ability of an attacker to bring a contaminant into the area, and introduce it to the food during the opening of venting or sampling hatches on the tanker truck without being detected.
Module 6: Reducing the Likelihood of a Successful Contamination

Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination Example Scenario

In this exercise, you were given information about an actionable process step and asked to consider five different mitigation strategies and whether or not they would be appropriate for this scenario. As stated in the discussions, some of the strategies may be practical and others may not. This example shows you that there are various ways of reducing the significant vulnerability. In your facility, you must take many factors into consideration to choose the best mitigation strategy or combination of strategies that work for your unique situation, and you must be able to explain how the chosen strategy(ies) are reducing the significant vulnerability at each actionable process step.
You have now completed Module 6.

In this module, you learned to:

1. Explain personnel and operations-based mitigation strategies that reduce the likelihood of a successful contamination.
2. Explain technology-assisted mitigation strategies that reduce the likelihood of a successful contamination.
3. Deduce which strategies best protect the actionable process steps.
A Successful Contamination Transcript

A "successful contamination" is one where the attacker successfully introduces a sufficient quantity of contaminant to achieve wide scale public health harm.

Examples of factors negatively affecting successful contamination include:

- Being caught in the act,
- Not being able to introduce a sufficient volume of contaminant,
- The contaminant being detected prior to causing wide scale public health harm, and
- Not having enough time to introduce the contaminant.

Mitigation Strategies to Reduce the Likelihood of a Successful Contamination Transcript

For contamination to be considered successful, it would require the introduction of a contaminant into the product so that it results in wide scale public health harm. One way to reduce or eliminate significant vulnerabilities at actionable process steps is to reduce the ability of an inside attacker to introduce a contaminant into the product without being detected. These types of mitigation strategies may be appropriate in situations where reducing access to the food is not feasible, would be cost prohibitive, or poses challenges to the operation of the facility. These types of mitigation strategies can rely on increased observation of an actionable process step so that an inside attacker's actions would be visible and, thus, prevented or stopped. Or they can include strategies that make the carry and introduction of a contaminant extremely challenging or impossible. Some mitigation strategies would require the inside attacker to undertake improbable or impossible actions to carry out the attack therefore reducing or eliminating the significant vulnerability.
Module 6: Reducing the Likelihood of a Successful Contamination

Mitigation Strategies to Reduce the Likelihood of a Successful Contamination
(continued) Transcript

Like mitigation strategies that reduce access, mitigation strategies that reduce the ability of an inside attacker to introduce a contaminant into the product also can generally be broken down into those strategies that focus on managing personnel behavior or process operations and those that are technology-assisted. Now let’s individually examine personnel-based, operations-based and technology-assisted mitigation strategies that can reduce the likelihood of a successful contamination.

Personnel- and Operations-Based Mitigation Strategies to Reduce the Likelihood of a Successful Contamination Transcript

Personnel-based mitigation strategies that reduce the ability of an inside attacker to adulterate a product typically include strategies that increase observation of a significantly vulnerable area so that an attacker’s actions would be easily detected. Generally, increased observation is aided by adequate lighting, and/or removing visual obstructions to obtain clear lines of sight. It is not expected that you will redesign processing lines or make other major structural changes to eliminate visual obstructions. More often, facilities may choose to move easily movable objects that are blocking lines of sight and using personnel for visual observation of the actionable process step. Operations-based mitigation strategies that reduce the ability of an inside attacker to adulterate a product typically include strategies that will clean equipment or otherwise flush out a contaminant that could have been placed in or on equipment such as hoses or vats. Let’s talk about some examples of personnel- and operations-based mitigation strategies to reduce the likelihood of a successful contamination.
Module 6: Reducing the Likelihood of a Successful Contamination

Examples of Personnel- and Operations-Based Mitigation Strategies That Reduce the Likelihood of Successful Contamination Transcript

One personnel-based mitigation strategy is to use the buddy system at an actionable process step by requiring at least two staff members to be in the area during operations to reduce the opportunity for an attacker to discreetly introduce a contaminant into the food. In addition to increasing visibility and observation of an attacker’s actions once they have accessed the actionable process step, using the buddy system can make it more difficult for an attacker to bring the contaminant into the area. Requiring two people at an actionable process step does not necessarily require hiring additional personnel. Rather, it may be possible to incorporate the buddy system into the existing job functions of workers in the area. Other personnel- and operations-based strategies that can reduce an attacker’s ability to successfully adulterate the food include: increasing the supervision of highly vulnerable activities; moving highly vulnerable activities to easily observable areas; requiring workers at actionable process steps to wear uniforms or clothing without pockets or other means of concealing items; implementing procedures where workers are required to check in with a supervisor or security personnel before entering highly vulnerable areas to ensure workers are not carrying a potential contaminant; enhancing visual inspection procedures to ensure that a contaminant has not been introduced into a tank, mixer, or other piece of equipment prior to adding food; using clean-in-place equipment, flushing equipment, or running a discard batch prior to resuming production after equipment has been idle and accessible to rid the equipment of a potential contaminant.

Technology-Assisted Mitigation Strategies that Reduce the Likelihood of Successful Contamination Transcript

Technology-assisted mitigation strategies that reduce the ability of an inside attacker to introduce a contaminant to the product typically include measures that would detect an attacker’s actions, alert management of a problem, and thereby prevent an attacker’s actions from resulting in public health harm. This includes strategies that alert management when a person accesses an actionable process step or unusual activity occurs. Alerts, notifications, alarms, and other similar measures can make a suspicious action noticeable, thereby enabling workers or supervisors in the area to investigate the action and disrupt an attempted intentional contamination of the food. For example, an alarm could notify personnel in a control room that a mixing tank, which is typically not opened during operation, has been accessed. Similarly, motion detection equipment could notify supervisors or security personnel when a person enters a secure area around an actionable process step. You could also use sensors and other similar technologies to detect whether there is a difference in the volume, mass, or density of ingredients that are added to a product to ensure that no additional material is added and that an ingredient is not replaced, in part, by a contaminant.
Technology-Assisted Mitigation Strategies that Reduce the Likelihood of Successful Contamination (continued) Transcript

You may also use technology-assisted mitigation strategies to enhance human supervision of actionable process steps. For example, using closed-circuit television (CCTV) systems or other monitoring devices, can support observation of highly vulnerable areas and actionable process steps. The mitigation strategy in this case is the act of observation and CCTV or other technologies, facilitates the increased observation. Continuous or dedicated monitoring of the CCTV or cameras would not be required. The important thing is that the observation is being elevated such that the significant vulnerability is being mitigated. Another example is to use mirrors to enhance visibility.

Selecting Mitigation Strategies that Reduce the Likelihood of a Successful Contamination Transcript

Taking the vulnerability of the actionable process step into consideration, in conjunction with what you learned about personnel-based and technology-assisted mitigation strategies, you now have sufficient knowledge to identify the most appropriate mitigation strategies to reduce the likelihood of a successful contamination. Again, let's go through a scenario together and then you will be given an opportunity to think through a scenario on your own.

Now let's complete another exercise.
Module 6: Reducing the Likelihood of a Successful Contamination

Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination

Scenarios in this exercise are examples of potential situations that may be encountered in some facilities but are not based on any specific facility or product. They are intended to assist you in your decision-making with respect to identification and explanation of appropriate mitigation strategies and have been simplified for training purposes. Scenarios are designed to prompt thoughtful consideration for identifying and explaining mitigation strategies, though they may not have all the information you would need in a real-world environment. Additionally, explanations for the mitigation strategies in this exercise provide you with examples of thought processes and justifications for the selection of specific mitigation strategies in these fictitious scenarios only. When developing mitigation strategies for your own facility, you must choose and explain mitigation strategies that are appropriate for your facility.

Before starting the exercise, click "next" to watch a video of an example scenario.

Let's imagine that a facility's VA identified the receiving of bulk liquid ingredients as an actionable process step. The facility identified the opening of venting and sampling hatches on the transport conveyance as being significantly vulnerable as it provides an opportunity for an inside attacker to successfully contaminate the liquid ingredients without detection because there is often nobody else around when the hatches are opened. To address this, the facility implements a mitigation strategy of increasing observation of unloading operations by having the worker responsible for reviewing shipping documentation witness the opening of the transport conveyance and the attachment of transfer hoses and pumping equipment. This increases the level of observation of the activity at this actionable process step, thereby significantly reducing the ability of an attacker to bring a contaminant into the area and introducing it to the food during the opening of venting or sampling hatches on the tanker truck without being detected.
Module 6: Reducing the Likelihood of a Successful Contamination

Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination Scenario Transcript

Let's imagine that a facility's VA identified the receiving of bulk liquid ingredients as an actionable process step. The facility identified the opening of venting and sampling hatches on the transport conveyance as being significantly vulnerable as it provides an opportunity for an inside attacker to successfully contaminate the liquid ingredients without detection because there is often nobody else around when the hatches are opened. To address this, the facility implements a mitigation strategy of increasing observation of unloading operations by having the worker responsible for reviewing shipping documentation witness the opening of the transport conveyance and the attachment of transfer hoses and pumping equipment. This increases the level of observation of the activity at this actionable process step, thereby significantly reducing the ability of an attacker to bring a contaminant into the area and introducing it to the food during the opening of venting or sampling hatches on the tanker truck without being detected.

Module 6: Reducing the Likelihood of a Successful Contamination

Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination Scenario Transcript

Please watch the video discussing the example scenario carefully. When the video is done, click next to continue to the exercise, where you will determine the best mitigation strategy or combination of strategies for the actionable process step.

Your facility makes cold pressed almond cranberry energy bars and recently completed a vulnerability assessment for this product. The VA identified several actionable process steps. For this exercise, we are going to focus on the actionable process step of measuring ingredients. This step was determined to be an actionable process step because ingredients are open and accessible while they are being measured and during staging prior to their introduction into the mixer. This step contains a significant vulnerability and requires mitigation strategies because a contaminant could be intentionally introduced into a small amount of ingredient and would then be distributed into a larger volume of food in later processing steps. This step occurs within a dedicated room due to your facility’s food safety allergen control program. Typically, one employee performs this job function at a time, with a total of five employees who perform this job during different shifts. There is one supervisor who oversees the employees at this step, but this person is frequently not in the dedicated room because they also supervise other processing steps within the facility. The facility currently has workers stationed in a control room overseeing processing operations and the facility already uses closed-circuit television systems for observation of external entrances and some processing equipment.

As the qualified individual assigned to identify and explain mitigation strategies, you have been brought in to determine the most practical mitigation strategy or combination of strategies and to write the accompanying explanations. On the next screen is a brief list of potential mitigation strategies for this actionable process step. Please consider each choice and evaluate why it is, or is not, a suitable mitigation strategy for this actionable process step. Additionally, for the strategies that are suitable, consider how you would tailor it/them to this step.

We asked you to consider each of the five choices provided and evaluate whether it was, or was not, a suitable mitigation strategy for that actionable process step. Your response to Item 1, increase supervision of this process step by moving the measuring and staging of ingredients to the main production floor, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that while this may work as mitigation strategy for some facilities with this type of processing step, in this facility the step was purposefully placed in a dedicated room as part of their allergen controls program, and this reduced access to the step. If you chose to use this mitigation strategy you will be increasing supervision to this step therefore making it more difficult for an attacker to successfully contaminate the ingredients without being seen, but moving this step to the main production floor will increase access to this step since more employees, contractors, visitors, etc. will be in the same area as the ingredient measuring and staging. You may also have to re-evaluate the food safety implications of moving this step due to your facility’s allergen program. For these reasons, this may not be the most practical mitigation strategy for this actionable process step.
Module 6: Reducing the Likelihood of a Successful Contamination

**Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination – Item 1 Transcript**

We asked you to consider each of the five choices provided and evaluate whether it was, or was not, a suitable mitigation strategy for that actionable process step. Your response to Item 1, increase supervision of this process step by moving the measuring and staging of ingredients to the main production floor, is displayed on the left of the screen and FDA's recommendation is displayed on the right.

FDA recommends that while this may work as a mitigation strategy for some facilities with this type of processing step, in this facility the step was purposefully placed in a dedicated room as part of their allergen controls program, and this reduced access to the step. If you chose to use this mitigation strategy you will be increasing supervision to this step therefore making it more difficult for an attacker to successfully contaminate the ingredients without being seen, but moving this step to the main production floor will increase access to this step since more employees, contractors, visitors, etc. will be in the same area as the ingredient measuring and staging. You may also have to re-evaluate the food safety implications of moving this step due to your facility's allergen program. For these reasons, this may not be the most practical mitigation strategy for this actionable process step.

**Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination – Item 2 Transcript**

Your response to Item 2, use closed-circuit television (CCTV) systems to support increased observation of this measuring ingredients step, is displayed on the left of the screen and FDA's recommendation is displayed on the right.

FDA recommends that this may be an appropriate mitigation strategy for this actionable process step. The scenario mentioned that there were workers in a control room who oversee the operation of various processing equipment. They could also be tasked with observing activity in the ingredient measuring room via a CCTV monitor. This strategy would help reduce the likelihood of successful contamination because the step would have elevated observation and the workers observing this step would notice the suspicious actions of an attacker.

**Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination – Item 3 Transcript**

Your response to Item 3, use pre-measured food ingredients to minimize weighing/measuring vulnerabilities, is displayed on the left of the screen and FDA's recommendation is displayed on the right.

FDA recommends that this mitigation strategy would reduce the likelihood of a successful contamination at this measuring step, but it may be cost prohibitive or impractical to use pre-measured packaged ingredients in this case. If a facility is able to invest in pre-measured ingredients to mitigate the risk of intentional adulteration at this step, they have the option to do that, but for this example there are other, more practical and cost-effective measures that can be taken to reduce the likelihood of a successful contamination without having to invest in new ingredients or ingredient packaging.
Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination – Item 3 Transcript

Your response to Item 3, use pre-measured food ingredients to minimize weighing/measuring vulnerabilities, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that according to the scenario, typically only one employee performs this job function at a time, with a total of five employees who rotate this duty. There is one supervisor who oversees the employees at this step, but this person is frequently not in the dedicated room when the ingredients are being measured. You may investigate possibly using two employees to measure ingredients at the same time so that there is always observation in this area. Consider that using two employees might mean that measuring ingredients could take less time but it might also mean unnecessarily taking an employee from another job function. For some facilities this may be a simple, practical mitigation strategy to reduce the likelihood of a successful contamination and other facilities may find using two employees at this step to be burdensome and inefficient.

Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination – Item 4 Transcript

Your response to Item 4, use the buddy system when measuring ingredients, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that according to the scenario, typically only one employee performs this job function at a time, with a total of five employees who rotate this duty. There is one supervisor who oversees the employees at this step, but this person is frequently not in the dedicated room when the ingredients are being measured. You may investigate possibly using two employees to measure ingredients at the same time so that there is always observation in this area. Consider that using two employees might mean that measuring ingredients could take less time but it might also mean unnecessarily taking an employee from another job function. For some facilities this may be a simple, practical mitigation strategy to reduce the likelihood of a successful contamination and other facilities may find using two employees at this step to be burdensome and inefficient.

Mitigation Strategy Selection Exercise – Reducing the Likelihood of a Successful Contamination – Item 5 Transcript

Your response to Item 5, restrict access to this room to authorized personnel only when ingredients are being measured, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that since this room is already dedicated for the allergen program reasons, a mitigation strategy that only specific people are authorized to access the room and installing a lock on the door that only the authorized personnel can open could significantly reduce the vulnerability of the ingredient measuring step. To reduce the likelihood of a successful contamination, authorized workers who measure ingredients could be required to be senior or long-time employees who have established themselves to be particularly trustworthy to work in a significantly vulnerable area. This strategy could also be coupled with another strategy that reduces the likelihood of a successful contamination such as prohibiting outside materials from being brought into this room, or using the buddy system as recommended previously in choice 4.
Module 6: Reducing the Likelihood of a Successful Contamination

Mitigation Strategy Selection Exercise - Reducing the Likelihood of a Successful Contamination Summary Transcript

In this exercise, you were given information about an actionable process step and asked to consider five different mitigation strategies and whether or not they would be appropriate for this scenario. As stated in the discussions, some of the strategies may be practical and others may not. This example shows you that there are various ways of reducing the significant vulnerability. In your facility, you must take many factors into consideration to choose the best mitigation strategy or combination of strategies that work for your unique situation, and you must be able to explain how the chosen strategy(ies) are reducing the significant vulnerability at each actionable process step.

Module 6: Reducing the Likelihood of a Successful Contamination

Module 6: Summary Transcript

You have now completed Module 6.

Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:
1. Explain personnel- and operations-based mitigation strategies that reduce the likelihood of a successful contamination;
2. Explain technology-assisted mitigation strategies that reduce the likelihood of a successful contamination; and
3. Deduce which strategies best protect the actionable process steps.

Let's see what you remember about what you just learned.
You have now completed Module 6. Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:

1. Explain personnel- and operations-based mitigation strategies that reduce the likelihood of a successful contamination;
2. Explain technology-assisted mitigation strategies that reduce the likelihood of a successful contamination; and
3. Deduce which strategies best protect the actionable process steps.

Let's see what you remember about what you just learned.

Resources

- Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types
- FDA Fact Sheet for the IA Rule
- FDA Technical Assistance Network (TAN)
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Module 7: Considering Existing Facility Practices

Welcome and Introduction

Welcome to Module 7: “Considering Existing Facility Practices”

After completing this module, you will be able to:

1. Explain existing measures.
2. Give examples of existing measures.
3. Describe facility-wide security measures.
4. Differentiate between facility-wide security measures and mitigation strategies.
5. Explain how existing measures factor into the protection of food.
What Are Existing Measures?

- Existing measures are those practices that are actively applied at a process step and are not integral to operation of the process step.
- Existing measures are applied for other purposes, but can be credited as mitigation strategies.
- Existing measures may originate from other programs such as sanitation procedures, occupational safety procedures, supplier assurance programs, or quality control.

Examples of Existing Measures

- Examples of existing measures include:
  - Buddy system for employee safety.
  - Visually inspecting equipment prior to use for sanitation purposes.
  - Running a discard batch/flushing for quality control purposes prior to resuming production after equipment has been idle and accessible would eject an intentionally introduced contaminant from the system and prevent it from adulterating the food.
  - Positively identifying drivers, visually inspecting seals on shipments, and confirming the accuracy of the shipment for supplier assurance programs.
Facility-Wide Security Measures

- Facility-wide security measures are general, non-targeted, protective measures that are implemented at the facility-wide level to protect personnel, property, or product.
- Such broadly-applied measures may include physical security, personnel security, securing hazardous materials, management practices, and crisis management planning.
  - They may also be described as existing measures if they are at an actionable process step, but they are considered facility-wide security measures if implemented in a broader sense.
  - A facility-wide security measure could be identified as a mitigation strategy if it specifically addresses a significant vulnerability at an actionable process step.
  - Such a measure, if serving as a mitigation strategy, would need to have corresponding management components.

Facility-Wide Security Measures Are Different Than Mitigation Strategies

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<th>Facility-Wide Security Measures</th>
<th>Mitigation Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility- or company-level measures that are broadly applied</td>
<td>Specific measures applied at an actionable process step</td>
</tr>
<tr>
<td>Do not rely on a VA to inform identification</td>
<td>Rely on a VA to inform their identification</td>
</tr>
<tr>
<td>Almost universally applicable</td>
<td>Tailored to address an identified significant vulnerability</td>
</tr>
<tr>
<td>Not required, though still recommended</td>
<td>Required under the IA rule</td>
</tr>
<tr>
<td>Often do not have management components</td>
<td>Require mitigation strategy management components</td>
</tr>
<tr>
<td>May be implemented for a variety of reasons</td>
<td>Essential to significantly minimize or prevent significant vulnerabilities</td>
</tr>
</tbody>
</table>
Use of Facility-Wide Security Measures

- When used in a focused manner, existing facility-wide security measures can serve as mitigation strategies at actionable process steps.
- For example, a facility may have a facility-wide prohibition against personal materials in food production areas and this can be used as a mitigation strategy for an actionable process step.
  - Since the prohibition against personal materials at the actionable process step is a mitigation strategy, it must have associated management components.

How Existing Measures Factor Into the Protection of Food

- Existing measures, including facility-wide security measures, should be evaluated to determine if they could serve as mitigation strategies in their current form, or whether they need to be altered, or used in conjunction with other mitigation strategies to significantly reduce the vulnerabilities.
- If existing measures are being used as mitigation strategies, they must be identified in the food defense plan as mitigation strategies with accompanying explanation and food defense management components.
Factoring Existing Measures Into the Protection of Food

- Taking APSs into consideration, in conjunction with what you learned about existing measures, you now have sufficient knowledge to consider and adapt existing facility practices into mitigation strategies.
- For the last time, let’s go through a scenario together and then you will be given an opportunity to think through a scenario on your own.

Consideration of Existing Facility Practices Disclaimer

Scenarios in this exercise are examples of potential situations that may be encountered in some facilities but are not based on any specific facility or product. They are intended to assist you in your decision-making with respect to identification and explanation of appropriate mitigation strategies and have been simplified for training purposes. Scenarios are designed to prompt thoughtful consideration for identifying and explaining mitigation strategies, though may not have all the information you would need in a real-world environment. Additionally, explanations for the mitigation strategies in this exercise provide you with examples of thought processes and justifications for the selection of specific mitigation strategies in these fictitious scenarios only. When developing mitigation strategies for your own facility, you must choose and explain mitigation strategies that are appropriate for your facility.
Considering Existing Facility Practices Example Scenario

- A facility's VA identifies a process step where breading coating is applied to food as an APS because the hopper that feeds the breader allows:
  - significant physical access to the product, and
  - sufficient likelihood that an inside attacker could successfully contaminate the food.
- The facility chooses to implement a mitigation strategy restricting access only to specific employees who directly work at or supervise the breading step.

- Through normal facility-wide security measures, all employees are given badges for security and white hard hats for safety.
- Building on this existing facility-wide security measure and safety practice, the mitigation strategy includes:
  - A requirement that those authorized employees wear special red hard hats and that their employee ID badges identify their job function.
- This mitigation strategy allows other authorized workers, supervisors, management, and security personnel to easily determine whether persons in the breader area are authorized.
Considering Existing Facility Practices Example Scenario

- The mitigation strategy also requires:
  - Workers who are permitted access to the breading area have:
    - at least 4 years experience with the company,
    - no disciplinary or job performance issues during that time, and
    - approval from company human resources and security offices.
  - Authorized workers immediately escort any unauthorized person out of the area, and notify security personnel or management of the intrusion.

- Training on proper implementation of the mitigation strategy teaches workers how to address the access restriction.
- The facility details this mitigation strategy in its food defense plan and provides an explanation that:
  - this mitigation strategy significantly reduces the ability of an inside attacker to enter the area and if unauthorized persons are found they are easily detected and removed, and
  - the additional vetting of employees authorized to be in the breading area appropriately considers an inside attacker by ensuring that workers in this area have demonstrated responsibility and trustworthiness.
Module 7: Considering Existing Facility Practices

Consideration of Existing Facility Practices Scenario

Consideration of Existing Facility Practices Scenario

Mitigation Strategy

Selection Exercise

In this exercise, you were given some information about actionable process steps and asked to consider three different facility-wide security measures or existing measures and whether or not they should be considered during the evaluation of the appropriate mitigation strategies. As stated in the discussions, some of the existing facility practices could be used as mitigation strategies on their own, some need to be tailored to the actionable process step, and others may need completely different mitigation strategies altogether. In your facility, you should consider your existing practices, the environment around the actionable process step, and the nature of the vulnerability at that point to choose the best mitigation strategy or combination of strategies that work for your unique situation. Remember, if you identify an existing facility practice that can be used as a mitigation strategy, that strategy must be written in the food defense plan, and you must be able to explain how the chosen strategies are reducing the significant vulnerability at that actionable process step.
Mitigation Strategies

You have now completed Module 7.

In this module, you learned to:

1. Explain existing measures.
2. Give examples of existing measures.
3. Describe facility-wide security measures.
4. Differentiate between facility-wide security measures and mitigation strategies.
5. Explain how existing measures factor into the protection of food.

Let's see what you remember about what you just learned.

Course Summary

- Mitigation strategies are risk-based, reasonably appropriate measures applied at actionable process steps that significantly minimize or prevent acts of intentional adulteration.
- You have the ability to choose the most appropriate mitigation strategy or combination of strategies for your facility.
- Mitigation strategies can be technology-based, personnel-based, or operations-based strategies to limit access and/or to reduce the likelihood of successful contamination.
- Existing measures should be considered when identifying potential mitigation strategies.
- Facility-wide security measures, while different from mitigation strategies, can support mitigation strategies or be used as mitigation strategies if they are customized to the actionable process step.
- Mitigation strategies and their explanations must be written in the food defense plan.
Mitigation Strategies are risk-based, reasonably appropriate measures applied at actionable process steps that significantly minimize or prevent acts of intentional adulteration.

- You have the ability to choose the most appropriate mitigation strategy or combination of strategies for your facility.
- Mitigation strategies can rely on technology-based or be personnel-based or operations-based strategies to limit access and/or reduce the likelihood of successful contamination.
- Existing measures should be considered when identifying potential mitigation strategies.
- Facility-wide security measures, while different than mitigation strategies, can support mitigation strategies or be used as mitigation strategies if they are customized to the actionable process step.
- Mitigation strategies and their explanations must be written in the food defense plan.

Mitigation Strategies Final Assessment

- In order to complete this course, you must answer at least 8 questions out of 10 total questions correctly.
- You can only take the final assessment up to 3 times.
- If you must retake the final assessment, please be aware that the question sets will vary.
- You may now close learning Module 7 and begin your final assessment.

Module 7: Considering Existing Facility Practices

Module 7: Welcome and Introduction Transcript

Welcome to Module 7, Considering Existing Facility Practices. This module will explain existing measures and how they factor into the protection of food.

After completing this module, you will be able to:
1. Explain existing measures;
2. Give examples of existing measures;
3. Describe facility-wide security measures;
4. Differentiate between facility-wide security measures and mitigation strategies; and
5. Explain how existing measures factor into the protection of food.
Module 7: Considering Existing Facility Practices

What Are Existing Measures? Transcript

Existing measures are those practices that are actively applied at a process step and are not integral to operation of the process step. For reasons other than food defense (e.g., quality control, worker safety), you may already have certain measures in place at a particular process step that also could serve as mitigation strategies. Generally, such measures are not, by nature, inherent characteristics of the process step’s operation and the VA should not consider these practices when identifying whether the process step is an actionable process step. Rather, you should evaluate these measures when determining whether these practices could serve as a mitigation strategy in their current or altered form and whether you need an additional mitigation strategy to augment the existing practice. While applied for other purposes, if existing measures provide a level of food defense protection for the actionable process step then, they should be considered when you are identifying and explaining mitigation strategies. We will go over how to do this in later slides.

Examples of Existing Measures Transcript

One example of an existing measure that should be considered when identifying mitigation strategies at actionable process steps includes the buddy system. Imagine your cold storage facility uses buddy systems to prevent workplace injury when working in an area. This practice could be identified by the facility as a food defense mitigation strategy if the buddy system is already in use at an actionable process step. Another example could include altering a visual inspection of equipment at an actionable process step. For example, a liquid food storage tank at your facility has an inward opening hatch and when full, the pressure of the liquid prevents the hatch from being opened, rendering the interior of the tank inaccessible. However, when the tank is empty, the hatch may be opened and, therefore, an attacker could add a contaminant. Assume this has been identified as an actionable process step during a VA. It may be part of normal facility practice for a supervisor to conduct a visual check of the storage tank after a cleaning cycle to ensure proper cleaning. The facility may elect to implement a food defense mitigation strategy by altering its visual check procedure so that the supervisor conducts the visual check immediately prior to food being added to the storage tank in addition to after the cleaning, thereby inspecting the tank after it has been empty and accessible for an extended period. Other examples of existing practices that could be mitigation strategies either as is, altered, or in conjunction with other mitigation strategies include:

- Running a discard batch or flushing hoses for quality control purposes, and
- Positively identifying drivers, visually inspecting seals on shipments, and confirming the accuracy of the shipment for supplier assurance programs.
Module 7: Considering Existing Facility Practices

Facility-Wide Security Measures Transcript

Facility-wide security measures are general, non-targeted, protective measures that are implemented at the facility-wide level to protect personnel, property, or product. Such measures may include physical security, personnel security, securing hazardous materials, management practices, and crisis management planning. Just like existing measures, a facility-wide security measure could be identified as a mitigation strategy, if it specifically addresses a significant vulnerability at an actionable process step. Such a measure, if serving as a mitigation strategy, would need to have corresponding management components.

Facility-Wide Security Measures Are Different Than Mitigation Strategies Transcript

Non-targeted, facility-wide security measures, such as locking perimeter doors, requiring visitor sign-in, or using employee identification badges that display the same information for all employees are broadly applied and almost universally applicable. It's important to note, facility-wide security measures do not require a VA to inform their identification and implementation. Mitigation strategies are identified and implemented based on a vulnerability assessment that considers an inside attacker, and are specially tailored to significantly reduce or prevent the significant vulnerabilities associated with actionable process steps. Some facility-wide security measures, such as facility perimeter protections, or facility wide badging procedures are not targeted to provide protection at actionable process steps, particularly from an attacker who has achieved legitimate access to the facility and has a basic understanding of facility operations and the food products under production. However, in many cases mitigation strategies and facility-wide security measures can complement each other and support the facility’s overall food defense system, and you can build mitigation strategies upon foundational and existing facility-wide security measures.
Module 7: Considering Existing Facility Practices

Use of Facility-Wide Security Measures Transcript

How can facility-wide security measures work in collaboration with food defense? When used in a focused manner, existing facility-wide security measures can serve as mitigation strategies at actionable process steps. For example, a facility may have a facility-wide prohibition against personal items in food production areas and this can be used as a mitigation strategy for an actionable process step. Since the prohibition against personal items at the actionable process step is a mitigation strategy, it must have associated management components to ensure its proper implementation, considering the nature of the mitigation strategy and its role in the food defense system.

How Existing Measures Factor Into the Protection of Food Transcript

Generally, existing measures are not by nature inherent characteristics of the process step and should not be taken into consideration during the vulnerability assessment, which determines significant vulnerabilities and actionable process steps. But they can be considered when you are determining appropriate mitigation strategies for your actionable process steps. Existing measures, including facility-wide security measures, should be evaluated to determine if they could serve as mitigation strategies in their current form, or whether they need to be altered, or used in conjunction with other mitigation strategies to significantly reduce the vulnerabilities. For example, a facility might already have a standard operating procedure to prohibit personal items, such as backpacks, in food production areas. In its VA, the facility identifies the process step of flavor addition as an actionable process step then evaluates potential mitigation strategies for the process step of flavor addition, the facility concludes that the existing practice of prohibiting personal items from food production areas contributes to the reduction of a significant vulnerability associated with this step. With this rationale, this facility-wide prohibition against personal materials in food production areas can be used as a mitigation strategy for the actionable process step. The facility would then evaluate if any additional mitigation strategies are needed to significantly reduce any additional components of the significant vulnerability associated with this actionable process step. Your facility may already have multiple policies or procedures in place that you can modify to provide protection against acts of intentional adulteration. When identifying mitigation strategies, we suggest you first consider these existing policies and procedures, because they have the benefit of already being familiar to employees and could reduce costs if fewer new mitigation strategies need to be implemented. When thinking about whether or not an existing measure should be a mitigation strategy think of this: if the actionable process step is dependent upon the existing measure, in whole or in part, for protection, then it should be identified as a mitigation strategy because if the existing measure were not present there would be an unmitigated significant vulnerability. It is important to note that if existing measures are used as mitigation strategies they must be identified in the food defense plan as mitigation strategies, with associated explanations and food defense management components.
Module 7: Considering Existing Facility Practices

Factoring Existing Measures Into the Protection of Food Transcript

Taking the significant vulnerability at the actionable process step into consideration, in conjunction with what you just learned about existing measures, you now have sufficient knowledge to consider and adapt existing facility practices into mitigation strategies. For the last time, let's go through a scenario together and then you will be given an opportunity to think through a scenario on your own.

Now let's complete our last exercise.

Mitigation Strategy Selection Exercise – Consideration of Existing Facility Practices Disclaimer Transcript

Scenarios in this exercise are examples of potential situations that may be encountered in some facilities but are not based on any specific facility or product. They are intended to assist you in your decision-making with respect to identification and explanation of appropriate mitigation strategies and have been simplified for training purposes. Scenarios are designed to prompt thoughtful consideration for identifying and explaining mitigation strategies, though they may not have all the information you would need in a real-world environment. Additionally, explanations for the mitigation strategies in this exercise provide you with examples of thought processes and justifications for the selection of specific mitigation strategies in these fictitious scenarios only. When developing mitigation strategies for your own facility, you must choose and explain mitigation strategies that are appropriate for your facility.
Mitigation Strategy Selection Exercise - Considering Existing Facility Practices Example Scenario Transcript

Let’s imagine a facility identifies a process step where a breaded coating is applied to food as an actionable process step. The facility concludes in its vulnerability assessment that the hopper that feeds the breader at this step allows both significant physical access to the product as well as a sufficient likelihood that an inside attacker could successfully contaminate the food without detection. To mitigate an attacker’s physical access to the product, the facility implements a mitigation strategy that restricts access only to specific employees who directly work at or supervise the breading process step.

Mitigation Strategy Selection Exercise - Considering Existing Facility Practices Example Scenario Transcript

Normal facility-wide security measures dictate that all employees are given badges for security and white hard hats are issued to each employee for safety. Building on this existing facility-wide security measure and the existing safety practice, the facility decides to issue those authorized employees special red hard hats and identifies their job function on their employee identification badges. This allows their fellow authorized workers, supervisors, management, and security personnel to easily determine whether persons in the area surrounding the breader are authorized.
Module 7: Considering Existing Facility Practices

Mitigation Strategy Selection Exercise – Considering Existing Facility Practices Example Scenario Transcript

As part of the mitigation strategy, the facility requires workers who are permitted access to the breading area be with the company for at least 4 years, have no disciplinary or job performance issues during that time, and be approved by company human resources and security offices. The mitigation strategy requires that authorized workers immediately escort any unauthorized person out of the area, and notify security personnel or management of the intrusion.

As part of their training on proper implementation of the mitigation strategy, workers are specifically trained on how to address the access restriction. The facility details this mitigation strategy in its food defense plan and provides rationale in its explanation that this mitigation strategy significantly reduces the ability of an inside attacker to enter the area to contaminate the food and if unauthorized persons are found in the area they are easily detected and removed. The facility also explains that the additional vetting of employees authorized to be in the area around the breader appropriately considers the actions of an inside attacker by ensuring that workers in this highly vulnerable area have consistently demonstrated their responsibility and trustworthiness. This shows how both a facility-wide security measure and an existing measure were both used to significantly reduce the significant vulnerabilities at the breading coating operation.
Module 7: Considering Existing Facility Practices

Mitigation Strategy Selection Exercise – Consideration of Existing Facility Practices Scenario Transcript

Please watch the video discussing the example scenario carefully. When the video is done, click next to continue to the exercise, where you will determine the best mitigation strategy or combination of strategies for the actionable process step.

Three different facilities make fettuccini marinara with broccoli and they each recently completed vulnerability assessments for this product. All of the facilities use the same process, ingredients and equipment for making the fettuccini, but they do have unique facility-wide security measures and existing practices. The VAs all identified the mixing step as an actionable process step. This step was determined to be an actionable process step because multiple ingredients (sauce, spices, cheese, broccoli and pasta) are combined together and mixed in large batches prior to product packaging. If a potential contaminant were successfully added during this mixing step, the contaminant would be dispersed throughout the product. The mixing step is located on the production floor, where many employees have access.

As the qualified individual assigned to identify and explain mitigation strategies, you have been brought in to determine the most practical mitigation strategy or combination of strategies and to write the accompanying explanations. On the next screen is a brief list of potential mitigation strategies for this actionable process step. Please consider each choice and evaluate why it is, or is not, a suitable mitigation strategy for this actionable process step. Additionally, for the strategies that are suitable, consider how you would tailor it/them to this step.

Mitigation Strategies Selection Exercise – Consideration of Existing Facility Practices – Item 1 Transcript

We asked you to consider each of the three choices provided and evaluate whether it was, or was not, a suitable mitigation strategy for that actionable process step. Your response to Item 1, Facility 1 uses trusted, senior employees to work at the mixing step, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that to ensure high-quality standards, this facility requires that a senior-level employee operates the mixer. In this case, the process step would be able to operate with a less senior employee working there (i.e., it is not inherent to the process step), but the facility has implemented the practice of positioning more trusted employees in this area for a business purpose—in this case, quality control. If the presence of the senior-level employee is relied upon by the facility as the protective measure to minimize an otherwise significant vulnerability at the process step, then the presence of this senior-level employee is a mitigation strategy. The mitigation strategy would be that the mixing operation is only performed by authorized personnel of a certain seniority and trustworthiness. This could be a suitable mitigation strategy if the senior-level employee is designated as authorized and is restricting unauthorized persons from accessing the mixer. You would include in your mitigation strategy the criteria for authorized personnel and may want to designate this type of personnel with specific identification or uniforms for easy identification.
Module 7: Considering Existing Facility Practices

Mitigation Strategy Selection Exercise – Consideration of Existing Facility Practices – Item 1 Transcript

We asked you to consider each of the three choices provided and evaluate whether it was, or was not, a suitable mitigation strategy for that actionable process step. Your response to Item 1, Facility 1 uses trusted, senior employees to work at the mixing step, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that to ensure high-quality standards, this facility requires that a senior-level employee operates the mixer. In this case, the process step would be able to operate with a less senior employee working there (i.e., it is not inherent to the process step), but the facility has implemented the practice of positioning more trusted employees in this area for a business purpose—in this case, quality control. If the presence of the senior-level employee is relied upon by the facility as the protective measure to minimize otherwise significant vulnerability at the process step, then the presence of this senior-level employee is a mitigation strategy. The mitigation strategy would be that the mixing operation is only performed by authorized personnel of a certain seniority and trustworthiness. This could be a suitable mitigation strategy if the senior-level employee is designated as authorized and is restricting unauthorized persons from accessing the mixer. You would include in your mitigation strategy the criteria for authorized personnel and may want to designate this type of personnel with specific identification or uniforms for easy identification.

Module 7: Considering Existing Facility Practices

Mitigation Strategy Selection Exercise – Consideration of Existing Facility Practices – Item 2 Transcript

Your response to Item 2, Facility 2 prohibits personal items on the production floor (including the mixing step area), is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that this facility has an existing facility-wide policy of prohibiting items unrelated to food production from food production areas for good manufacturing purposes. In considering mitigation strategies for the mixer, you conclude that this policy contributes to the reduction of a significant vulnerability associated with this mixing step by reducing the ability of an inside attacker to carry enough volume of a contaminant into the mixing area to adulterate the food. With this rationale, this facility-wide prohibition against personal materials in food production areas can serve as a mitigation strategy for the actionable process step. To tailor this existing strategy, the mitigation strategy here would be to prohibit personal items at the mixing step area. This strategy must have associated management components to ensure its proper implementation. Additionally, management components for this mitigation strategy are required only for the implementation of the strategy at the mixing step and not more broadly throughout the facility. This ensures that resources are used in a targeted manner, and not diluted to multiple areas of the facility that are not the most vulnerable. This strategy alone may not reduce the significant vulnerability to an acceptable level and you should determine if any additional mitigation strategies are needed to significantly reduce the significant vulnerability associated with this actionable process step.

Module 7: Considering Existing Facility Practices

Mitigation Strategy Selection Exercise – Consideration of Existing Facility Practices – Item 3 Transcript

Your response to Item 3, Facility 3 cleans the mixer at the end of the day as part of their sanitation procedures. The mixer is open and accessible until the next day’s mixing operations, is displayed on the left of the screen and FDA’s recommendation is displayed on the right.

FDA recommends that you evaluate the facility’s sanitation procedures for the mixer to see if they contribute to reducing the significant vulnerabilities at the mixer. You recognize that since the mixer is left accessible for extended periods after cleaning, therefore providing an opportunity for an attacker to introduce a contaminant into the cleaned mixer, you determine this current sanitation strategy would not be an adequate mitigation strategy since it is not restricting access to the mixer or reducing the ability of an inside attacker to successfully contaminate the mixer. It wouldn’t make sense for this facility to alter its cleaning process to happen immediately before production since that would leave the mixer dirty overnight and lead to food safety issues. This particular existing measure may not work as a mitigation strategy even if it is altered. You may think about instituting a mitigation strategy that requires flushing the equipment just prior to use to expel a contaminant that could have been added to the mixer while it was idle, or implementing a mitigation strategy to secure the mixer after cleaning. You should evaluate if any additional mitigation strategies are needed for when the mixer is in operation, such as those discussed before.
Module 7: Considering Existing Facility Practices

Mitigation Strategy Selection Exercise – Consideration of Existing Facility Practices Summary Transcript

In this exercise you were given some information about actionable process steps and asked to consider three different facility-wide security measures or existing measures and whether or not they should be considered during the evaluation of the appropriate mitigation strategies. As stated in the discussions, some of the existing facility practices could be used as mitigation strategies on their own, some need to be tailored to the actionable process step, and others may need completely different mitigation strategies altogether. In your facility, you should consider your existing practices, the environment around the actionable process step, and the nature of the vulnerability at that point to choose the best mitigation strategy or combination of strategies that work for your unique situation. Remember, if you identify an existing facility practice that can be used as a mitigation strategy, that strategy must be written in the food defense plan and you must be able to explain how the chosen strategies are reducing the significant vulnerability at that actionable process step.

Module 7: Summary Transcript

You have now completed Module 7.

Let’s review what you have learned before you move on to the knowledge checks.

In this module, you learned to:
1. Explain existing measures;
2. Give examples of existing measures;
3. Describe facility-wide security measures;
4. Differentiate between facility-wide security measures and mitigation strategies; and
5. Explain how existing measures factor into the protection of food.

Let’s see what you remember about what you just learned.
Module 7: Considering Existing Facility Practices

Module 7: Summary Transcript

You have now completed Module 7. Let's review what you have learned before you move on to the knowledge checks.

In this module, you learned to:

1. Explain existing measures;
2. Give examples of existing measures;
3. Describe facility-wide security measures;
4. Differentiate between facility-wide security measures and mitigation strategies; and
5. Explain how existing measures factor into the protection of food.

Let's see what you remember about what you just learned.

Course Summary Transcript

In summary, mitigation strategies are risk-based, reasonably appropriate measures applied at actionable process steps that significantly minimize or prevent acts of intentional adulteration. You have the ability to choose the most appropriate mitigation strategy or combination of strategies for your facility since they are facility specific. Mitigation strategies can rely on technology or be personnel- or operations-based strategies to limit access and/or reduce the likelihood of successful contamination. Existing measures should be considered when identifying mitigation strategies. Facility-wide security measures, while different than mitigation strategies, can support mitigation strategies or be used as mitigation strategies if they are customized to the actionable process step. Mitigation strategies and their explanations must be written in the food defense plan.

Course Completion Transcript

You have now successfully completed the Identification & Explanation of Mitigation Strategies training.

Successful completion of this training satisfies the training requirement within the IA rule (21 CFR 121.4(c)(3)(iii)) for an individual to identify and explain mitigation strategies. To undertake any other activities within the IA rule you must take additional training as specified by 21 CFR 121.4.

To print your certificate, exit out of this course and visit the "Transcripts" tab in your learning portal.

Click the "Exit Course" button below to exit this course.
You have now successfully completed the Identification & Explanation of Mitigation Strategies training. Successful completion of this training satisfies the training requirement within the IA rule (21 CFR 121.4(c)(3)(iii)) for an individual to identify and explain mitigation strategies. To undertake any other activities within the IA rule you must take additional training as specified by 21 CFR 121.4.

To print your certificate, exit out of this course and visit the "Transcripts" tab in your learning portal. Click the "Exit Course" button below to exit this course.

Resources
- Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types
- FDA Fact Sheet for the IA Rule
- FDA Technical Assistance Network (TAN)
- Food Defense Mitigation Strategies Database (FDMSD)
- FSPCA Intentional Adulteration Training and Materials
- IA Rule
- IA Rule Overview Course

Help
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Mitigation Strategies