

IFSS Framework – Basic Level Gen Eds
B24 Recalls

Definition: Introductory knowledge, skills, and abilities related to the process of removing a product from commerce.

Topic Area TLO (Terminal Learning Objective): Describe the recall process in regulatory programs.

Topic Area ELOs (Enabling Learning Objective):

- Explain the recall process.
- Explain why recalls are initiated.
- Determine when to recommend that a recall may be necessary.
- Explain agency roles in recalls.
- Identify components in the recall process.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
<p>Definition: Basic knowledge of recalls related to regulatory programs.</p> <p>TLO: Describe the importance of recalls.</p> <p>ELOs:</p> <ul style="list-style-type: none"> • Define key terminology. • Give examples of what could initiate a recall. • Explain the differences between recall classifications. • Describe the importance of interagency and industry collaboration. • Explain the need for communication with stakeholders. • Explain agency’s plan for removing product from the distributions system. • Explain firm’s plan for removing product from the distribution system. • Explain the purpose of 	<ul style="list-style-type: none"> • The regulator can discuss how recalls contribute to maintaining human and animal health. • The regulator can describe the regulator’s agency’s policies for recalls. • The regulator can explain the reasons to initiate a recall: <ul style="list-style-type: none"> a. Enforcement action to keep human and animal food safe b. Remove economic adulteration • The regulator can explain the impact if the product isn’t removed. • The regulator can explain the reasons for a voluntary recall: <ul style="list-style-type: none"> a. Process for allowing the producer to take responsibility for not complying with the requirements

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<p>a market withdrawal.</p> <ul style="list-style-type: none"> • Trace a product through the supply chain. 	
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Unit 2: Risk Assessment	TLO Behavioral Anchors - not all-inclusive
<p>Definition: Process to evaluate information for potential health impact of the product if it remains on the market.</p> <p>TLO: Discuss the importance of risk assessment in product safety assurance.</p> <p>ELOs:</p> <ul style="list-style-type: none"> • Explain the importance of risk assessment to determine if a recall is needed. • Give examples of triggers that could initiate a recall. • Explain how the potential severity of the hazard affects risk. • Explain how probability of exposure affects risk. • Describe how recall classes I, II, III would affect a recall decision. 	

Unit 3: Documentation	TLO Behavioral Anchors - not all-inclusive
<p>Definition: Records needed when conducting a recall.</p> <p>TLO: Explain the importance of documents needed when conducting a recall.</p>	

- The regulator can provide information to aid in decision making:
 - a. To determine the scope of the recall
 - b. To support the risk assessment
- The regulator can conduct recall audit checks:
 - a. Verify unsafe products are off the market.
- The regulator can discuss the role of documentation in validation, tracking, and organization:

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<p>ELOs:</p> <ul style="list-style-type: none"> • Identify documents used to track product movement. • Give examples of documents that should be reviewed. • Identify the documents that need to be collected. • Review documents used to determine the scope of the recall. 	<ul style="list-style-type: none"> a. Defensibility b. Evidence to support a recall
<p>Unit 4: Communications</p>	<p>TLO Behavioral Anchors - not all-inclusive</p>
<p>Definition: Information sharing and messaging strategies between agencies and stakeholders.</p> <p>TLO: Discuss the role of communication during a recall.</p> <p>ELOs:</p> <ul style="list-style-type: none"> • Describe the importance of interagency and industry communication. • Explain how communication is coordinated during a recall. • Identify requirements related to information sharing. • Describe the roles of regulatory agencies in issuing public communications. • Explain the importance of sharing lessons learned from recalls. • Describe media types used to inform stakeholders of a recall. • Describe the criteria of 	<ul style="list-style-type: none"> • The regulator can describe the communication process with stakeholders while conducting a recall: <ul style="list-style-type: none"> a. Articulate the chain of command b. Describe agency’s jurisdiction c. Describe agency’s communication policy • The regulator can inform stakeholders that there is a recall: <ul style="list-style-type: none"> a. Recall alerts b. Inform the regulated population of the necessity c. Adapt communication to the stakeholders d. List the steps to take a recall • The regulator can gather information for a recall: <ul style="list-style-type: none"> a. Ask the right questions and document b. Active listening c. To maintain a better understanding of the situation • The regulator can give examples of agency communication policies. • The regulator can discuss the process of assembling a recall team. • The regulator can explain regulations to substantiate a recall.

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<p>the messaging types that are used during a recall.</p> <ul style="list-style-type: none"> • Explain the criteria for issuing a public health message during a recall. • Explain how sensitive communication should be shared with affected stakeholders. • Explain when sensitive communication would be shared with affected stakeholders. • Describe the agency internal communication process during a recall. • Explain how public health recall messaging would affect international distribution. 	
<p>Unit 5: Recall Process</p>	<p>TLO Behavioral Anchors - not all-inclusive</p>
<p>Definition: The process of removing unsafe products from all points of production, distribution, manufacturing, processing, storage, retail, and consumer ownership.</p> <p>TLO: Explain how the recall process is used to remove unsafe products.</p> <p>ELOs:</p> <ul style="list-style-type: none"> • Describe how the decision is made to initiate a recall. • Describe the process of implementing a recall. • Discuss the importance of notifying the public. • Describe the process of recall validation. 	

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<ul style="list-style-type: none"> • Describe the process of determining if a recall should be initiated. • Describe the process of how a recall would be conducted. • Explain the process of how relevant stakeholders are notified of a recall. • Describe how to verify that a recall has been properly conducted by a firm. 	
<p>Unit 6: Product Disposition</p>	<p>TLO Behavioral Anchors - not all-inclusive</p>
<p>Definition: Ensuring that unsafe products do not reenter the marketplace.</p> <p>TLO: Explain the role of product disposition during a recall.</p> <p>ELOs:</p> <ul style="list-style-type: none"> • Explain the importance of product disposition. • Give examples of reconditioning products. • Explain when a product needs to be destroyed. • Describe coordination that may be needed between agencies for product disposition. • Describe the verification needed to ensure proper product disposition. 	

- The regulator can define what disposition means.
- The regulator can discuss the methods for holding a product.
- The regulator can define methods of disposition.
- The regulator can discuss the importance of documentation.
- The regulator can explain recall effectiveness checks:
 - a. Trace back trace forward
 - b. Collect evidence for disposition validation
- The regulator can explain how to avoid the reintroduction of unsafe product back into the food chain:
 - a. Identify the product and document storage of the product
 - b. Witness and document destruction of product
 - c. Describe the appropriate security measures