

Operational Risk Management

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Slide 1: Operation Risk Management

This is Lesson 4: Operational Risk Management.

Slide 2: Guest Speaker

I'm Martin Bucknavage. Today we're going to continue talking about the risk of intentional contamination and then using the tool of operational risk management as a way to manage that risk of intentional contamination.

Slide 3: Overview

To overview: first, we'll identify the food system. We'll take a look at the different threat assessments and then we'll look at the operational risk management strategy as a way to control those threats within our food system.

Slide 4: Basic Strategy

So for the basic strategy of operational risk management, first we want to identify the food system and its parameters. The food system could be small, it could be what occurs within a processing plant or it could be a larger system; maybe for the harvesting and the distribution of grains such as wheat. Next, we evaluate the threat assessments. Then we conduct a risk assessment against those threats. Then we use operational risk management to determine if those risks need to be handled, if we can put mitigations to reduce those risks or if there are ways to eliminate those risks altogether.

Slide 5: Operational Risk Management Strategy

So first we identify the food system and its parameters. And as I said it could be anything from a small system to a larger, complex system. We have to look at the environment in which the processing occurs or in which the food system occurs; the people that have access to the system whether it's workers or people from the external environment. We look at the types of materials, the raw grains that are coming in and the raw materials that we use; the packaging that we use. We also look at the equipment. It's important to look at equipment, is it internal or external? Transportation, is it an open or closed transportation? Is it done by internal or external people? We look at the product itself. And we also look at the flow diagram.

Slide 6: Operational Risk Management Strategy

One of the most important parts of this is laying out the flow diagram. First we want to make sure that we cover one step back where are all the raw materials coming from? And how are those materials shipped and received by our facility? Then we look at processing. Making sure we cover each of the processing steps

that occur within our facility. Moving onto packaging, the type of packaging that we use for that product and then to distribution. How that product is moved and where it is moved.

Slide 7: Operational Risk Management Strategy

After we've identified our food system and the parameters that occur in that processing, next we will move on to evaluating the threat assessments.

Slide 8: Threat Assessments

In conducting a threat assessment the first thing we have to look at are the types of aggressors. As we discussed earlier in intentional contamination as part of lesson 2, there are a number of different types of aggressors that have to be considered. We have criminals and protesters, terrorists, subversives (people that sneak into our facility), and we have insiders whether it's the compromised insider or even a disgruntled employee.

Slide 9: Threat Assessments

Next we have to look at the tactics that could be used by the aggressors. We can have external attacks with a contaminated product before or after it leaves our facility. We have forced entry where people break into the facility and contaminate either the process or the product. We have covert entry where people dress up as a worker, a supplier, or even a visitor into our facility. And of course we have the 2 insiders which are the insiders compromised by somebody else or we have the disgruntled employee.

Slide 10: Threat Assessments

The next part of doing a threat assessment is looking at the different types of agents that can be used by aggressors whether it's biological, chemical, physical, or radionuclear.

Slide 11: Threat Assessments

The next thing we need to do is take a look at the characteristics of the agents. One is the stability of that agent in the matrix. Can that agent be susceptible to heat if we are heat-processing product? Is that agent susceptible to acid if our product is acidic? Another thing that's important to do is to look at is if that agent is going to stand out and be detected in the matrix before somebody consumes it. So does that agent have a certain color that's different from our product? Have a certain flavor that you can detect? Or especially odor: if that agent provides an odor that would prevent the person from consuming the product.

We have look of the dosage required, if the dosage is something that requires a high dosage of material, can the aggressor that much agent into the facility and contaminate on the level that's needed to provide the required outcome that they're looking for? Is it going to provide a severity? Is it available? Is it something that's available on the market or is it something that somebody has to go out and make? Is it something that you have to bring in overseas? And last

usability. Is it something that somebody can actually handle and get into the facility? So these are different questions that we have to look at what we start to look the agents and determine whether or not it's going to have the impact or provide the impact that the aggressors are looking for.

Slide 12: Threat Assessments

As a reminder from our earlier session, CDC has a threat classification for different biological agents. Of course we have category A agents which are often hard to handle; things such as *Bacillus anthracis* and *Yersinia pestis*. We have category B which includes a lot of our current food safety hazards; things like *Salmonella* and *E. coli*. But also include hazards such as ricin. Then we have our category C which are our up and coming agents which we don't have as much in-depth knowledge about.

Slide 13: Threat Assessments

Next we have our metals. We have heavy metals such as arsenic lead Mercury Valium; we have pesticides, PCBs, a number of different chemicals that can be used to contaminate food. We have radiological agents like cobalt 60, cesium 137, or even worse.

Slide 14: Threat Assessments

With each of the agents, we have to look at the different considerations for those agents. So how accessible is the agent? If we are looking at *Clostridium botulinum* toxin, is it something that that person can get a hold of; is it something that they can go by? Or is it something that they can grow? If they can grow the organism and then extract that toxin. The next thing is how easy is that toxin to dispense? Is it something that can be handled by the aggressor to get it into the food product? Does that agent then get dispersed throughout the food product or if it is an oil, does it start to rise up out of that product? And of course that leads us into the interaction with the food as well as with the process. If the process has a heat step in it and if the aggressors are using an agent that is susceptible to heat or if it's susceptible to something in that product like a preservative or an acid naturally inherent in that food.

The next thing that we have to look at is the toxicity. Can the aggressor provide a sufficient quantity of the agent into the food to get the dose that's required to get the intended effect? So if the aggressor is going to contaminate a 30,000 gallon batch tank with a particular agent and that agent is going to require 3 pounds of product, can that aggressor get 3 pounds of the agent into his satchel or whatever to the food process and dump it in there without being detected?

The other thing that we have to look at is the incubation time, that's really the time from when the person consumes the product until they start to see the effect of the agent. The longer the incubation time, the higher the number of people using it is going to be. So if somebody contaminates milk with a particular agent

and it takes 2 weeks for them to see the symptoms, people can be consuming that milk for 2 weeks until they start to see an issue. And of course another thing that occurs is that when this happens, it makes traceability a lot harder. It's a lot harder to remember what you ate 2 weeks ago. On the other side of the coin, because of this time lag, it decreases the immediate impact and so the aggressor doesn't get that pop in the number of cases all at one time. And another thing that it allows is once it's detected a number of different interventions can be made to prevent the person from becoming ill. In some cases antiserum or some different types of treatment can be given to the individual to lower the impact of the disease.

Slide 15: Threat Assessments

So there are some challenges when we start to do threat assessments using food contamination agents. One is there is a wide variety of agents. Second, it's poorly understood how some of these different agents are going to interact with the food. Are they going to blend well, are they not? We just don't have enough studies to show how each different food product is going to interact these different agents. Along with that, how that's going to affect humans once those products are consumed. Does the food product inhibit some of the absorption of the agents? Especially some of the agents have been more of an issue with inhalation.

Another thing that makes it very difficult is the inability to correctly diagnose the different agents. Many doctors have not seen a lot of these different agents in action. So when somebody comes into the hospital whose been exposed to one of these agents, it often may take days doctors to correctly determine which agent has been used. Another thing is the high variability of reporting and response. This has improved over the last 10 years. So what you're waiting for is: once somebody becomes sick, how fast does it get into the system and how fast can doctors start to react to it once people do become ill? As it is now, it takes a day or two for that information from the state to get to the CDC and for the CDC to start to look through and evaluate and identify different types of trends of different illnesses that occur.

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Once we've gone through and evaluated our threat assessments, now we move onto conducting the risk assessment.

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The steps in the operational risk management strategy identify the hazards associated with all phases of the operation. Assess the risks. Analyze the risk control measures. Make control decisions. Implement those controls. And then supervise, review, and improve on our ability to control those risks.

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So where do we focus our attention? What we look at is the probability of that agent occurring and we look at the severity of it. We want to focus most of our attention on the things that have a high probability of occurring and are going to have a high severity.

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So when we talk about severity, we can go everywhere from negligible, where a contamination event by that agent only has minor effects, all the way to catastrophic where a contamination event by that agent results in numerous deaths.

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Then we have, along with that, the probability of that contamination event occurring. This can go from everywhere from unlikely all the way up to frequent or high probability.

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So again looking at our operational risk assessment matrix, most of our attention is going to be put up in the upper left-hand corner that graph, where the probability of the contamination event is highly likely or likely to occur and the severity of a contamination that is either critical or catastrophic. Things in the right hand bottom corner of the matrix where an event is unlikely and the severity is negligible will not receive much attention or any attention at all.

			PROBABILITY					
			Frequent	Likely	Occasional	Seldom	Unlikely	
			A	B	C	D	E	
SEVERITY	Catastrophic	I	Extremely high					
	Critical	II		High				
	Moderate	III		Medium				
	Negligible	IV		Low				
			Risk Levels					

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So moving back to our steps in the operational risk management, we identify the hazards, we assess the risks of those hazards, we analyze risk control measures, we make control decisions, we implement risk controls, and then we continuously improve on our practices.

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So as an example of operational risk management, let's take a look at a certain scenario. In this scenario, we're going to look at the unloading at the dock by vendor drivers. In this scenario, we will have different drivers with no identifications presented, the trucks are not to be sealed and the dock is going to be open to unauthorized personnel.

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So what kind of risk do we have in our scenario? Certainly the driver can be a threat to the product delivered. We don't have any indication of the individual so anybody can come up and be a threat as far as contaminating food product. And in this they can use a number of different chemical agents. Not having the truck sealed means that that truck can be assessed at any point before the delivery occurs, so that truck can be stopped along the way and somebody could contaminate the product and we would not have an idea if that occurred. Another thing that can occur is that aggressors can enter the docking area contaminate raw materials at that particular point.

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Next we analyze the risk control measures. What are some things that we could put in place to prevent some of the issues that we just discussed? One, using pre-approve shipping carriers. Knowing that our supplier in terms of transportation has some measures in place so that we don't have unknowns or totally unknowns showing up our dock. Another is to have drivers present identification upon arrival. So somebody goes out and makes sure that whoever is delivering the material is who they're supposed to be. Another control measure is to only receive locked or sealed vehicles. Making sure the trucks are locked so no one can access it somewhere along the road. We can restrict access to the docking area so people can't get up and contaminate the product while the product is being unloaded. And then having approved personnel open up the truck and inspect the contents and reconcile the load before that load is empty. So these are different risk control measures that we can put in place to help prevent a contamination event.

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Once we've identified the different control measures we could make, the next thing we have to do is make decisions about which ones we want to put in place. So we ask ourselves "will the measures we've identified actually reduce the risk of contamination event?" And can the measures actually be undertaken or will the cost those measures be so high that there's no way we could put them in place? Once we've gone through the major decisions, we implement those controls. And many of the controls that we've mentioned are things that could put in place with relatively low cost and can have a pretty good success of reducing the risk that we want to.

Once we put these measures in place, then we go through and make sure we are supervising these different measures, making sure that people are checking IDs, making sure that people aren't getting into areas where they don't belong. We review them on a regular basis to see how our performance has been at implementing these different controls, making sure the controls are working the way we want. And then improving upon them, looking at what we need to do down the road to ensure that we're not going to have any contamination event at this particular part of the process.

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Now let's review the operational risk management tools. The first rule is to accept no unnecessary risk. If there's no reason for taking on risk, then don't do it. As an example, say we're storing a particular chemical in our warehouse that could be used to contaminate food that would result in a high severity of illness. Well if we're not using that chemical, why take on the risk of carrying that chemical in the warehouse?

The second: make risk decisions at the appropriate level. One of the things that we want to do is push decision-making as low as we can in the hierarchy of facility management. So if somebody in the loading dock can check those IDs, and we trust that person, that person who should be making the decision versus somebody higher in the organization where we lose time and we could lose corrective action capabilities.

The third: accept risk when benefits outweigh the costs. Certainly we can go around and put a 10-foot fence around our facility. But does that reduce any of the risks? And that's a decision that has to be made. And certainly the cost of putting a chain-link fence or a number of cameras around our facility may not reduce the risk that we need it to. And this cost may be high.

The 4th: integrate risk analysis at all levels within the facility and within our management structure. So the people who are making decisions do know which risks they have to assess, the cost of those risks, and the decisions that they have to make.

Slide 28: Points to Ponder

So the first question that we have is "what limitations does the company have to adopting a risk management strategy?" And we're going to look at this from a risk assessment standpoint. That is, when you start to look at a number of agents, does the facility have the capability of doing a risk management strategy as we discussed?

Slide 29: Points to Ponder

Looking at another question is "what limitations does a company have from adopting a risk management strategy with regard to facilities?" So as we put in

control measures, can we put in any kind of control measures across the facility to prevent any the different types of risks?

Slide 30: Points to Ponder

Then we asked the same question from a personal standpoint. “What kind of limitations does the company have with regard to its personnel?”