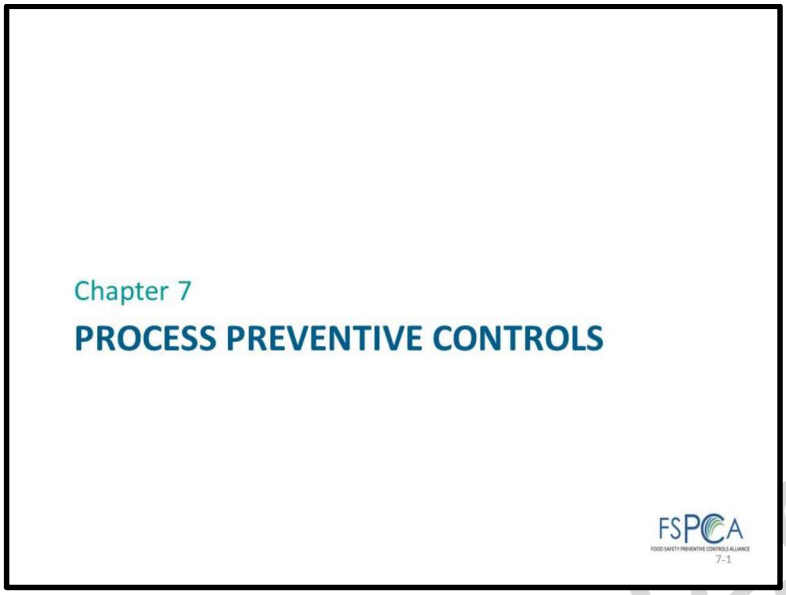
CHAPTER 7. Process Preventive Controls

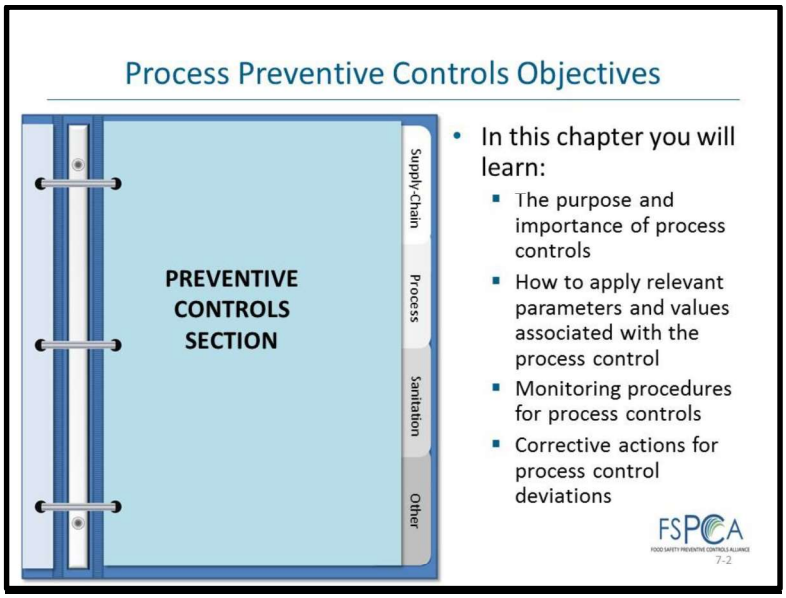


Slide 1

This chapter introduces process controls. These are controls that specifically relate to the procedures, practices, and processes within a facility.

Process controls make up the part of a facility's food safety plan that focuses on controls required at process steps that are critical for the safety of the animal food. Process controls require documentation of parameters and minimum or maximum values associated with the control, monitoring procedures, corrective action procedures and validation that the process controls the hazard.

The requirements for process controls depend on the role of the process control in the food safety system. This chapter provides information on establishing values for processing parameters, how to monitor process controls, and components of corrective actions to be taken for process controls when deviations occur.



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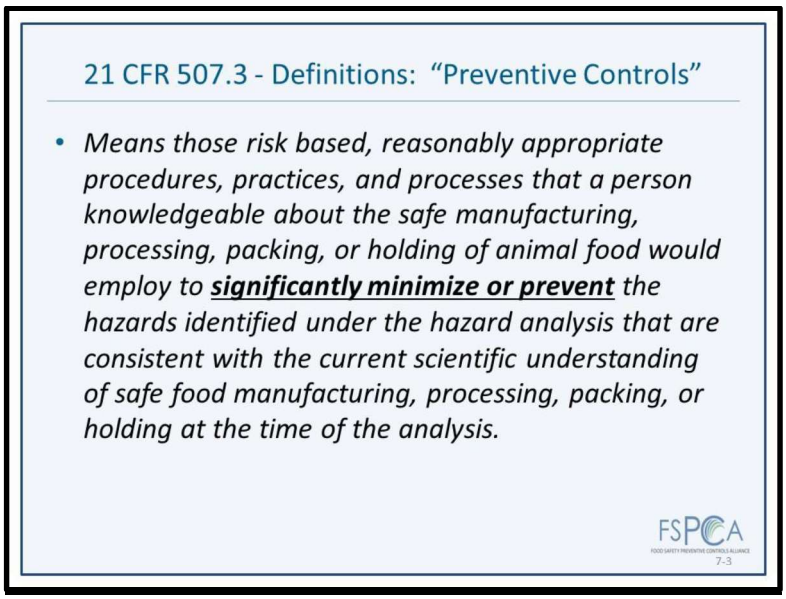
In this chapter, participants will learn 1) the purpose and importance of process controls, 2) how to apply relevant parameters and values associated with the process control, 3) monitoring procedures for process controls, and 4) corrective actions for process control deviations.



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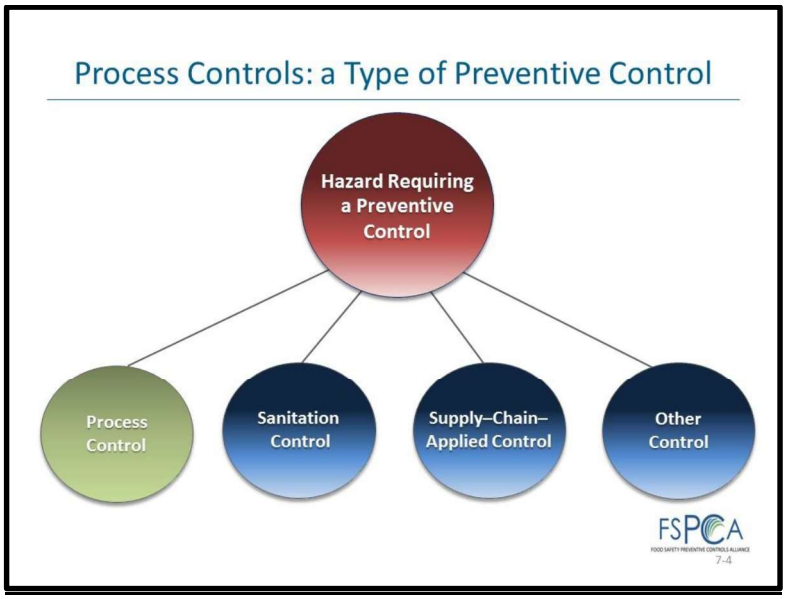
As a reminder, preventive controls are specifically defined. Process controls, as well as all other preventive controls, are included under this definition.



The process for ensuring that a specified minimum temperature is maintained during extrusion, for the purpose of eliminating a potential pathogen, is an example of a written preventive control.

Documents demonstrating regular temperature checks and thermometer calibrations are examples of implementation records.

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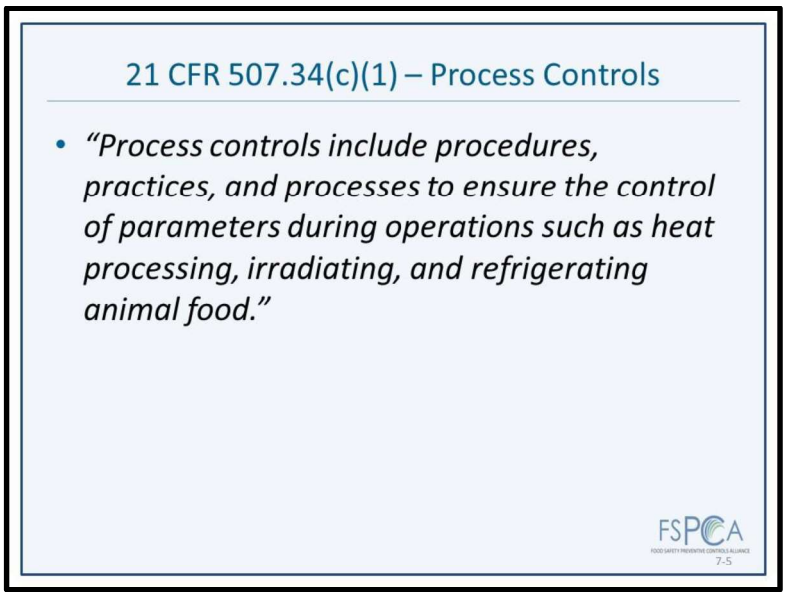
21 CFR 507.34 introduces preventive controls, and can be found on page 56345 of Appendix 1. This section explains that preventive controls are to be identified and implemented in order to significantly minimize or prevent any hazard that was identified in the hazard analysis as being a hazard requiring a preventive control. Preventive controls are required to provide assurance that the animal food manufactured, processed, packed, or held by a facility will not become adulterated.

Preventive controls are required at critical control points, as well as anywhere else that may be appropriate in order to ensure animal food safety. Some facilities or some class participants may be familiar with the concept of a critical control point, or CCP, if they have any experience with Hazard Analysis Critical Control Point (HACCP) plans.

All preventive controls must be written. These written preventive controls are documented in the food safety plan. This includes a description of the process control and its management components such as parameters, monitoring, and corrective actions. Implementation records, which are records that document the implementation of the food safety plan, are also required but are not the same as written preventive controls.

In addition to the process controls covered in this chapter, other preventive control categories include sanitation controls, supply-chain-applied controls, a recall plan, and other preventive controls which may not fall clearly into one of these categories. When selecting a preventive control, ensure that it is appropriate for the facility and the animal food.



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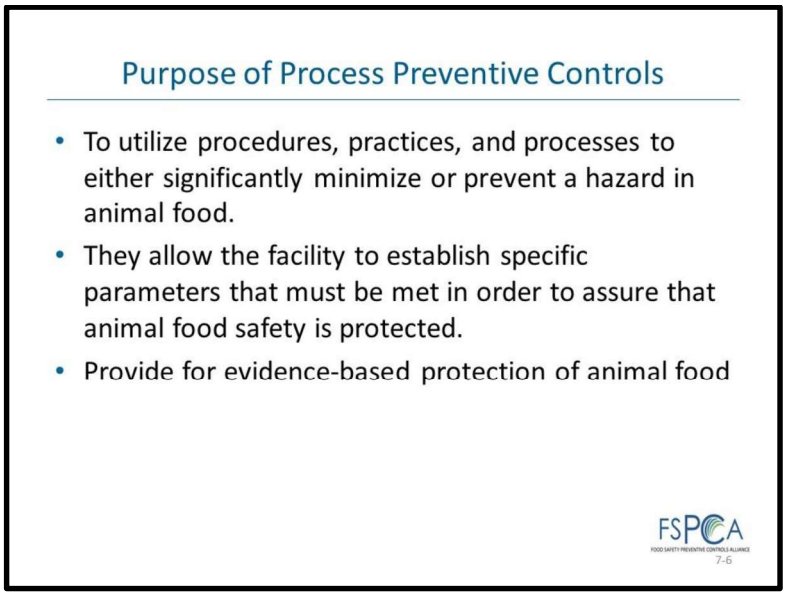
Section 507.34(c)(1) specifically describes process controls as including *"procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food."* In this curriculum, the term "process preventive control" is used interchangeably with "process control" and both terms have the meaning specified in 21 CFR 507.34(c)(1).



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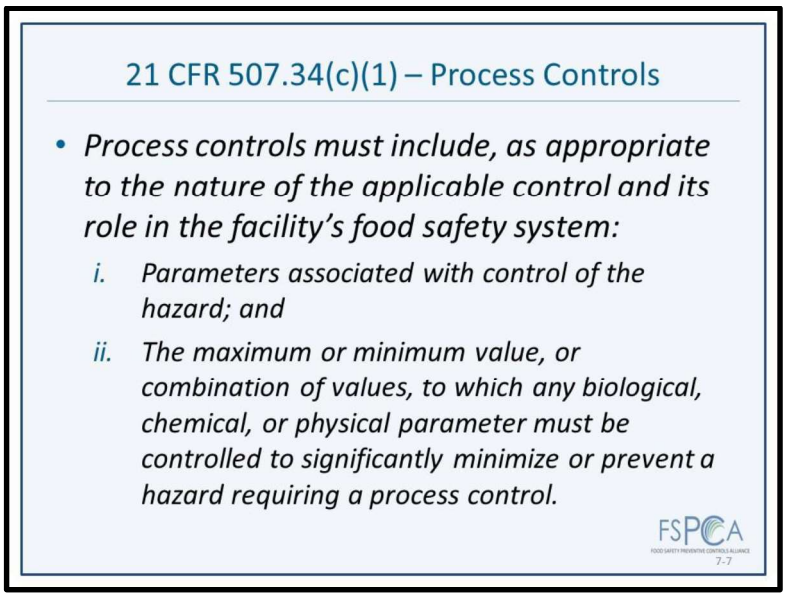
The purpose of process controls is to utilize procedures, practices, and processes to significantly minimize or prevent hazards requiring a preventive control. Implementing a process control includes setting specific parameters that assure the production of safe animal food. Appropriately established parameters are those known to control the hazard(s) of concern based on scientific and/or technical evidence.



Throughout this curriculum, the term "parameter value" will be used. The definition for parameter value is taken from 21 CFR 507.34(c)(1)(ii). For purposes of this curriculum, a parameter value is "*the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.*"

Participants who have completed the human food course may identify a "parameter value" as being the same as a "critical limit." The animal food curriculum chooses to use "parameter value", which more closely follows the rule language.

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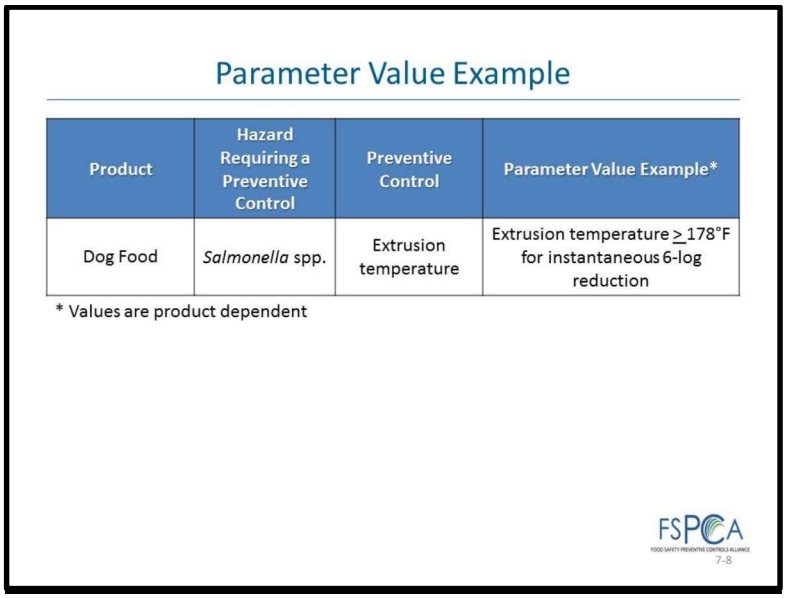
21 CFR 507.34(c)(1) further goes on to specifically describe how parameters are to be identified and utilized. All process controls must include parameters associated with the control of the hazard.

These parameters must be appropriate for the control and its role in the food safety system. In other words, the identified parameters must have an impact on the control of the hazard. As such, adhering to the parameter values will significantly minimize or prevent the presence of the hazard in the animal food.

With this in mind, a maximum or minimum value, or potentially a combination of both, must be established for any parameter associated with a process control. Parameter values should be selected that result in the biological, chemical, or physical hazard being significantly minimized or prevented.



In this example, the parameter value of 178°F is being considered the minimum temperature for instantaneous 6-log reduction of *Salmonella*. The effectiveness of most controls for biological hazards will assess their effectiveness in their ability to destroy pathogens. A 6-log reduction typically reduces pathogens below the threshold of detection by current analytical methods.

A process preventive control relying on a thermal parameter may also need to consider other items, such as time held at the temperature (if applicable) and the animal food matrix.

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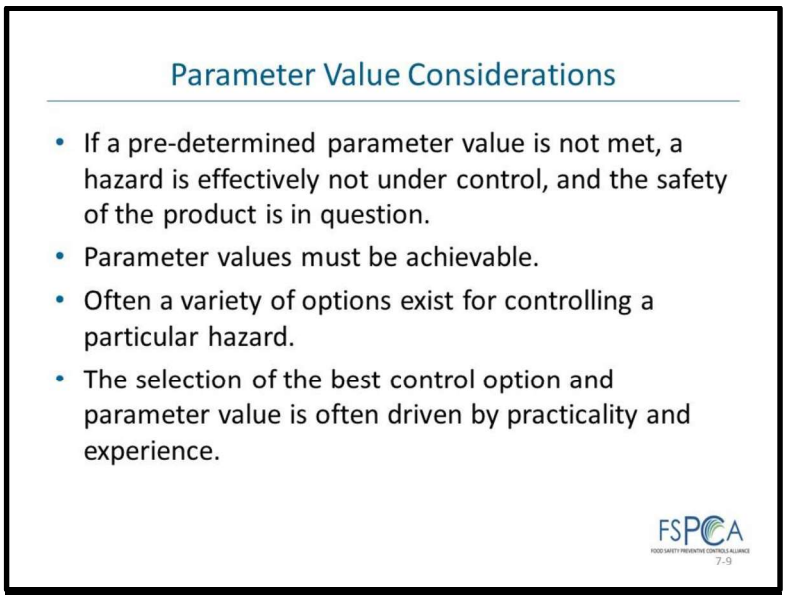
There are different types of parameters, and they must always be specific to the process control and the hazard being addressed. An effective parameter defines what can be measured or observed to demonstrate that the hazard is being controlled. For example, a temperature × time combination may be the parameter value for a thermal processing step. For example, it may be determined that a dog food must be processed at a minimum temperature of 178°F for an instantaneous 6-log reduction of *Salmonella* during a thermal processing step, such as extrusion. In order to reach similar destruction, a lower extrusion temperature may require a longer time at that temperature. The time, temperature, and matrix are all interdependent upon one another to control the hazard.



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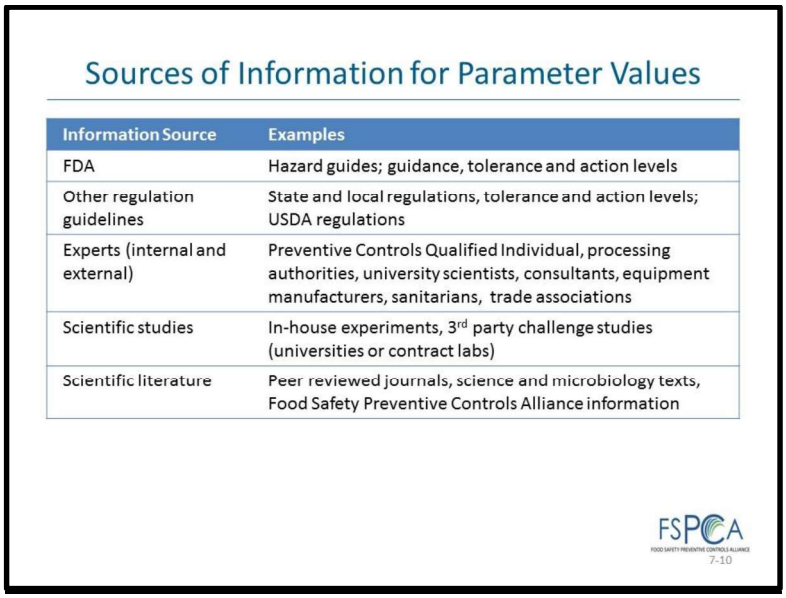
There are a number of considerations involved in establishing parameter values for a process control. A significant amount of thought, and often research, is necessary when setting these values because satisfying the parameter is essential in assuring product safety. Therefore, it is important that the parameter values are based on scientific or technical evidence and can be achieved by the process.

As a process may not realistically be able to maintain an exact value, parameters are often expressed as being equal to, above, or below a reference value. This allows the process control parameter to be met, and gives the option of varying from the exact reference value in order to be more conservative and limit any deviations. This is sometimes referred to as setting an "operating limit," a concept that will be discussed later in the chapter.

Sometimes, different options can be applied to control a specific hazard, as it may be possible to control that hazard at various points within the manufacturing process. For example, a pathogen could be controlled during manufacturing, such as through thermal processing, or control can be applied at the end of manufacturing, such as through irradiation of the finished product.

The PCQI decides the best option, or combination of options, to control the particular hazard, taking into account practical considerations such as the process capabilities in question, how measurements can be made, staff capabilities and other appropriate factors.



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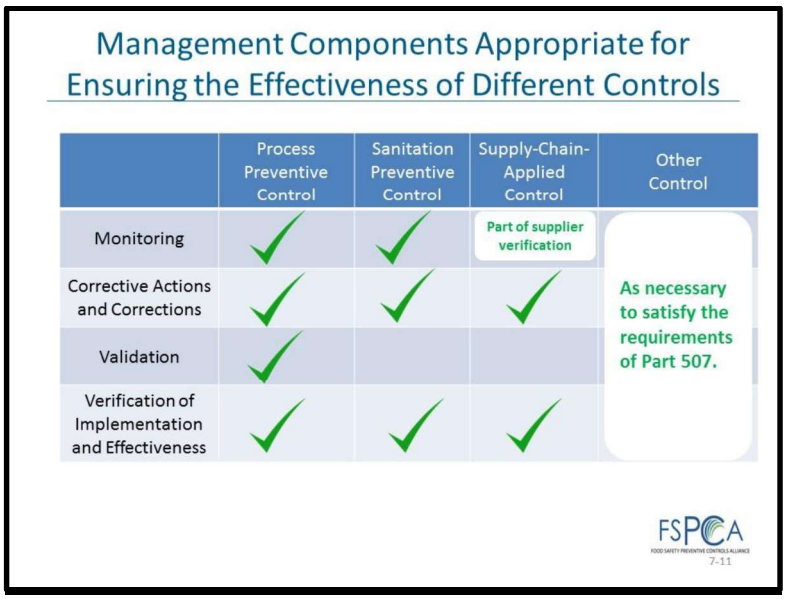
A number of sources of scientific and technical information can be useful in establishing parameter values. FDA and other local, state, and federal government agencies may provide information through technical staff, regulations, guidelines, directives, performance standards, tolerances and action levels. Useful expertise may also come from both internal and external sources. Internally, this might include the PCQI, management, and experienced staff. Externally, information may be gathered from trade associations, process authorities, university and extension scientists, consultants, and equipment manufacturers.

If necessary, scientific studies for specific products can be conducted in-house, at a contract laboratory, or at a university. If a facility chooses to perform a study in-house, make certain to follow defensible methods in the experimental design and analysis.

Information can also be obtained from peer-reviewed scientific literature. However, there may be important differences between the methods used in a published study and those used for the animal food produced and processes employed by a facility. Therefore, care should be taken when using information from these sources to determine specific parameter values.



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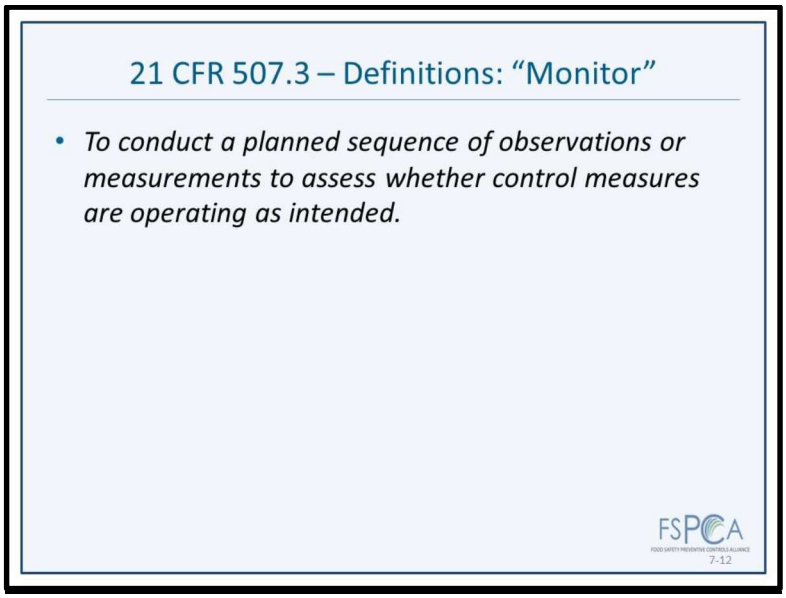
21 CFR 507.39 provides the management components that must be in place for a process control. The management components are used, as appropriate, to ensure the effectiveness of the process control. Process control management components include monitoring, corrective actions and corrections, validation, and verification of implementation and effectiveness. The requirements for these management components were introduced in Chapter 6. The remainder of this chapter focuses on how these components will generally apply to process controls.



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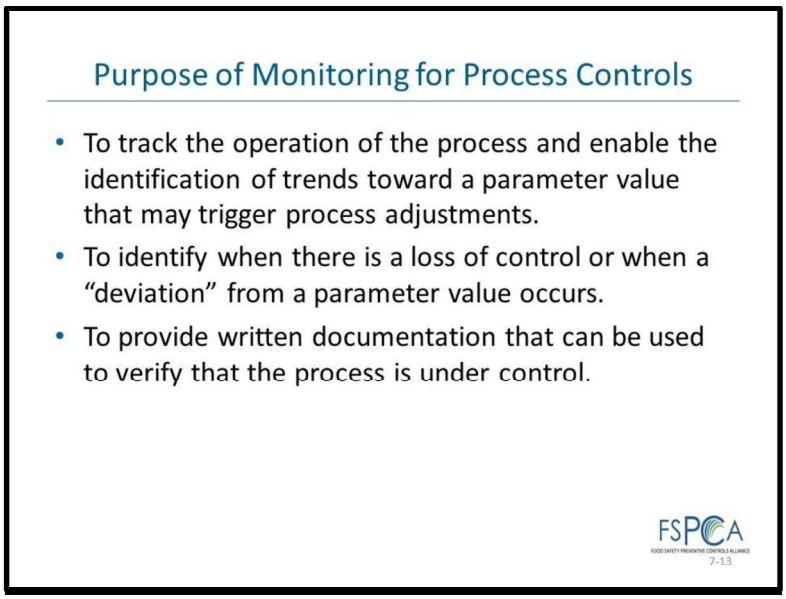
The definition of monitor is *"to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended."*

In essence, monitoring involves the selection of appropriate measurements or observations at a specified frequency. These measurements provide information that is used to evaluate if a process or procedure is meeting the parameters that were set.



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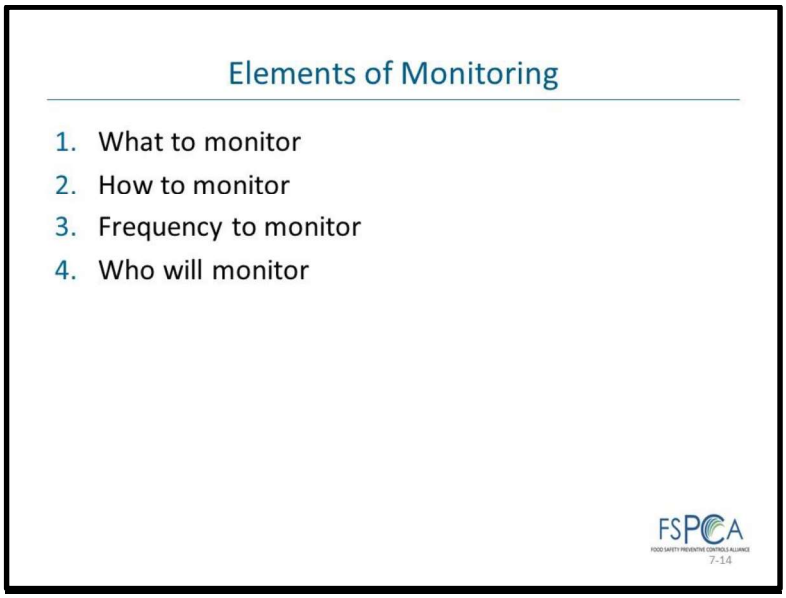
The overall purpose of monitoring a process control is to document that a minimum or maximum value for a parameter has been met. Effective monitoring of all preventive controls ensures that food safety hazards identified in the food safety plan are being controlled. If a parameter value has not been met, monitoring will identify the deviation, which will trigger the need for a corrective action.

Monitoring may also allow for the identification of a trend towards a maximum or minimum parameter value, allowing for adjustments to be made prior to a loss of control that would impact animal food safety. This is called a correction. If adjustments are not made, monitoring will identify that a deviation from a parameter has occurred. In this case, a corrective action is needed. Corrective actions are discussed later in the chapter.

Monitoring procedures must be specific to the process control and the identified hazard. This ensures that the monitoring provides data that can be used to establish a record demonstrating that the process is under control and that the animal food was produced in accordance with the food safety plan.



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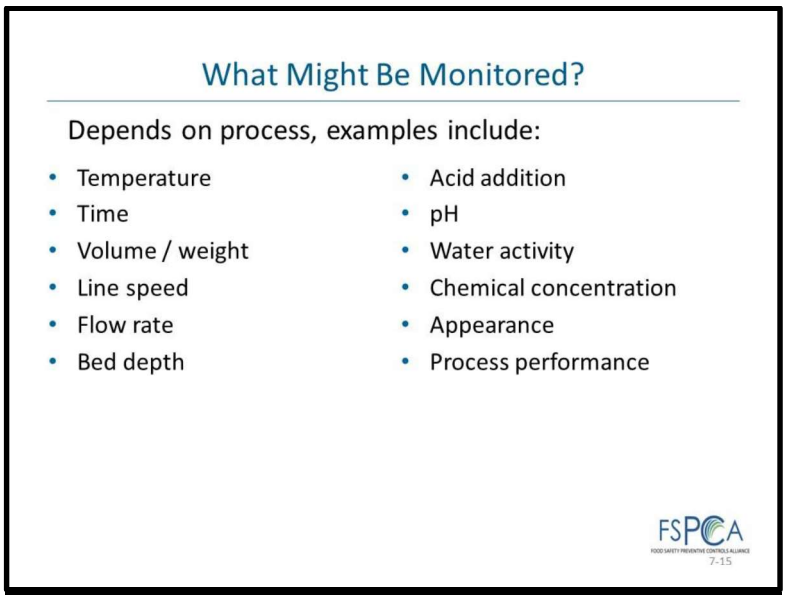
Process control monitoring requires four elements: 1) what measurements or observations will be used to monitor the parameter(s), 2) how will the monitoring be conducted, 3) how often will monitoring occur, and 4) who will do the monitoring.



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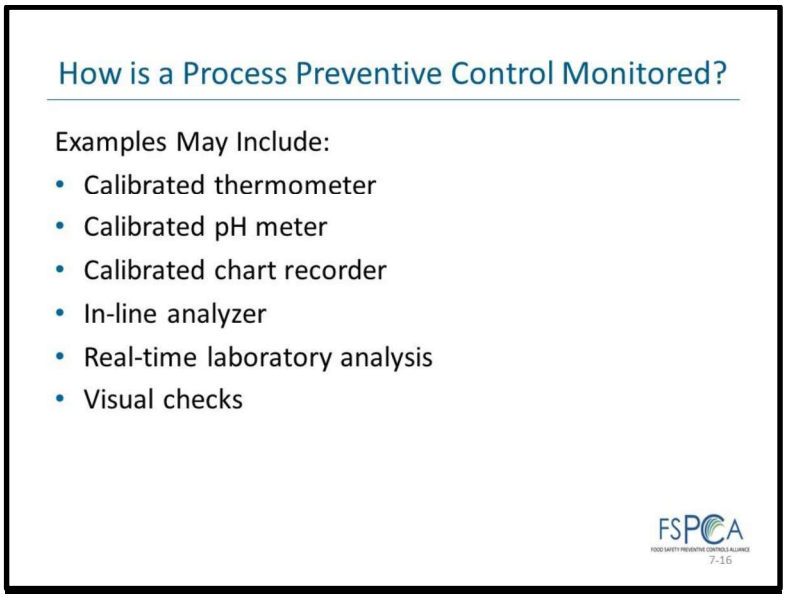
Monitoring process controls depends on the nature of the preventive control and its role in the facility's food safety system. Monitoring may involve measuring either a characteristic of the animal food or a part of the process itself. Examples of monitoring measurements include (but are not limited to):

- Animal food temperature as it passes through a thermal process used as a "pathogen heat-kill step."
- Process parameters such as retention time, line speed, or flow rate if these have been validated to control the hazard either alone or in combination with a temperature measurement.
- Observing that the metal detector is on when metal is a hazard of concern.
- The volume or weight of an ingredient or finished food after production is complete.
- Animal food parameters such as pH, water activity, and nutrient composition.

Visually monitoring the animal food may also be useful, as this can be an indicator of a process failure. Visual monitoring could include observing the appearance of animal food. Based on these observations, additional evaluation may be necessary. Visual observations may provide indication that something is not working correctly with a preventive control; however, they may be most useful in detecting quality concerns with a product, such as color or pellet quality. As discussed in chapter 4, a quality issue may not necessarily constitute a food safety concern and may not result in a *hazard requiring a preventive* control.



Equipment used for measurements must be checked to ensure the process preventive control is effectively monitored.

The calibration of monitoring devices is a verification activity used to ensure that the measurements taken by the monitoring device are accurate and reliable.

Calibration involves comparison against a known calibrated instrument or standards. This ensures that the device is functioning correctly

More information on calibrations can be found on the National Institute of Standards and Technology website: http://www.nist.gov/pml/wmd/labmetrology/calibration.cfm

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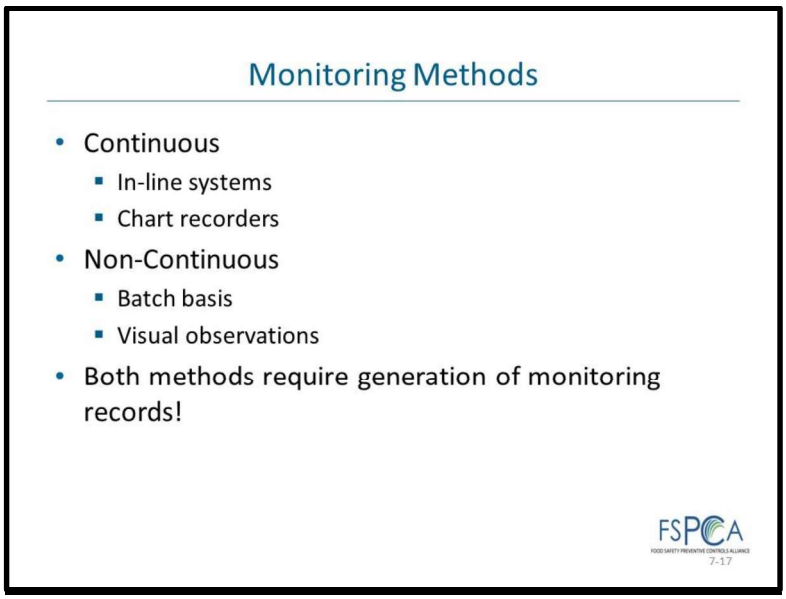
Different methods can be used to monitor parameters associated with process controls.

There are a variety of monitoring instruments that can be used to measure parameters. A facility should ensure that instruments used to monitor a process control are properly calibrated. Examples of monitoring instruments could include thermometers, pH meters, chart recorders, scales, and many other devices.

In-line analysis can be a useful monitoring tool. An example of in-line analysis is metal detection, which is used to locate and isolate metal contamination.

Some rapid testing methods can be performed on site and can then be used for decision making. For example, pH measurements, moisture content, water activity, and other types of tests may have application in a food safety plan. Lengthy analytical tests, such as biological assays, may also be useful for routine monitoring, but pose additional challenges. When such tests are used, test and hold procedures may be necessary to ensure the animal food is safe before it enters into commerce.

Monitoring methods can also involve visual checks. When using visual observation, appropriate parameter values should be selected so that it is clear whether or not the parameter has been violated. Visual checks may not always be suitable for monitoring of process controls, but can be used to ensure that necessary equipment is operating properly, and that the animal food has an appropriate appearance.



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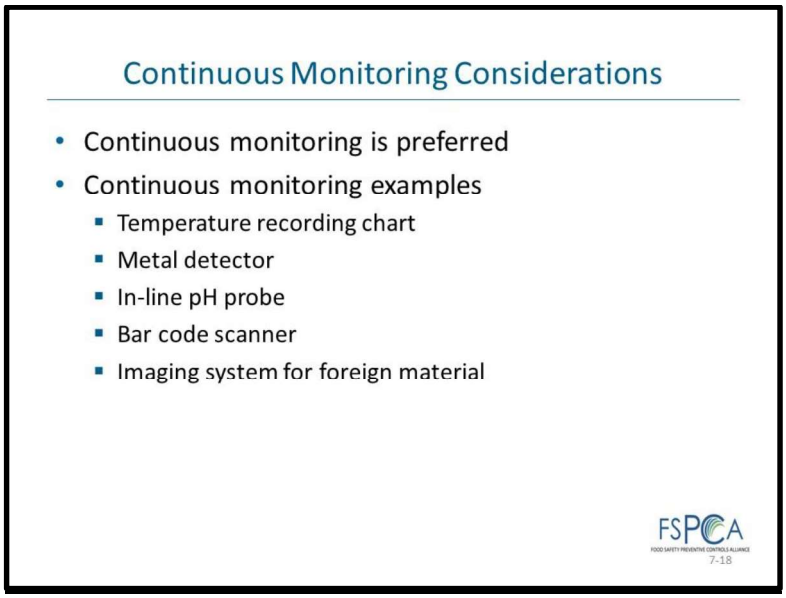
Monitoring frequency depends on the process control and the types of observations and measurements that are needed. Examples of continuous monitoring could include in-line systems or chart recorders. Individual measurements may also be taken or observations made on a less-frequent schedule. This could include testing a product on a per-batch basis or a visual check of a particular process once per shift.

Regardless of whether continuous or non-continuous monitoring is utilized, the frequency should be at regularly scheduled intervals, and a monitoring record must be generated. The monitoring must be appropriate for the animal food, the hazard, and the process control.



While continuous monitoring may be preferred, it is not required.

Continuous monitoring can be performed by a device itself as long as a visual check of the data and/or functionality is also performed to ensure that the device is functioning properly.

Charts run out of ink, pens get stuck, and probes can malfunction; this is why human involvement is necessary, at least periodically.

Continuous monitoring is not feasible in many cases due to cost, process flow, and/or available technology.

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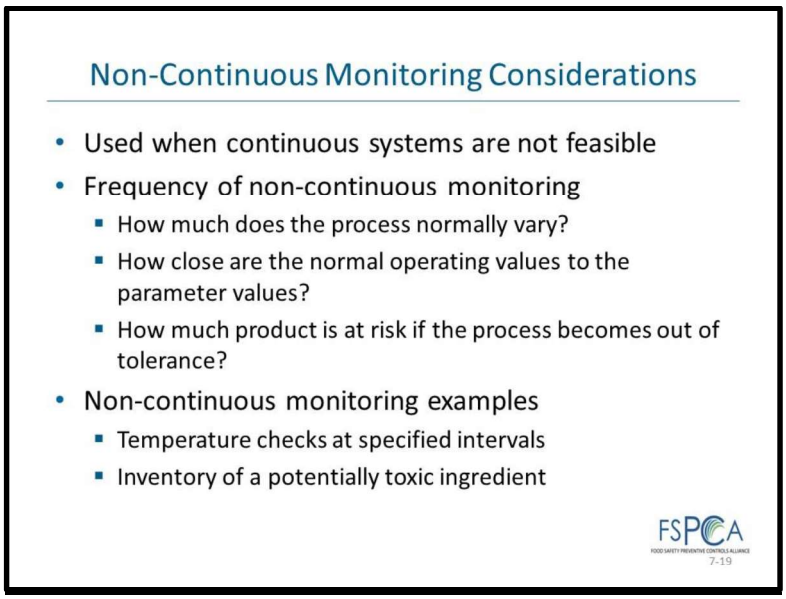
When possible, continuous monitoring procedures are generally preferred. This is because they reduce gaps in recording, as the equipment utilized doesn't forget to collect the data or generate the record. Continuous monitoring is generally performed by an instrument that produces a continuous record. For example, these records can be either affirmative records demonstrating temperature is controlled or "exception records" demonstrating loss of temperature control.

When using continuous monitoring procedures, the record generated from the monitoring needs to be checked by a qualified individual periodically to ensure that the necessary parameters are being met and that the device is operating properly. The length of time between checks is determined by the facility. Keep in mind that the frequency of these checks will directly affect the amount of animal food impacted when a deviation occurs.

Examples of continuous monitoring could include:

- The time and temperature data for a continuous flow extrusion process that may be continuously monitored and recorded on a temperature-recording chart.
- A functioning metal detector that automatically monitors all product that passes through it.
- An imaging system that monitors the production stream, looking for any foreign material that must be removed.

Again, the proper functioning of equipment and any records generated for these types of systems must be monitored by a qualified individual on a pre-determined basis to document that the system is performing as specified in the food safety plan and that deviations have not occurred.



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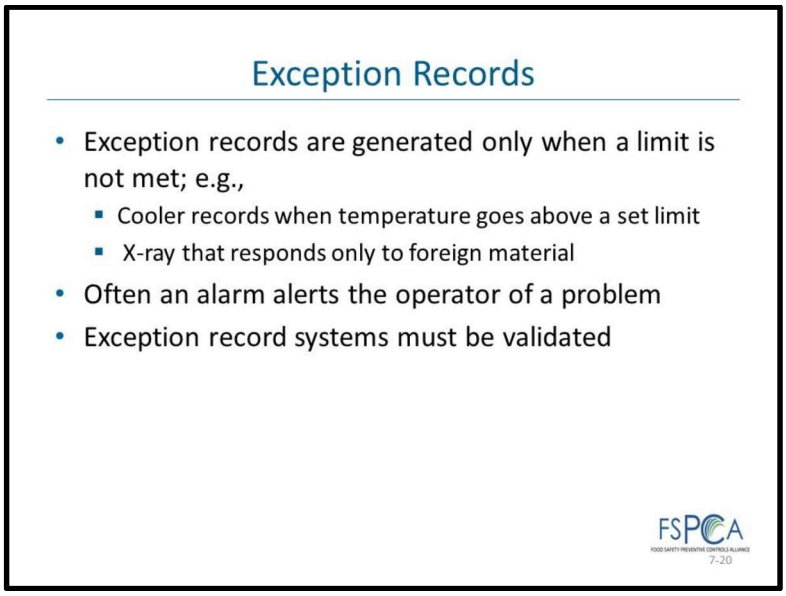
Because continuous monitoring is often infeasible, non-continuous methods are often chosen to monitor process controls.

It is necessary to establish a monitoring interval that ensures that process parameters are met. The frequency of non-continuous monitoring could be influenced by historical knowledge of the animal food and process. Questions that could help determine the frequency include:

- How much does the process normally vary (e.g., how consistent are the data)? If the monitoring data show a great deal of variation, the time between monitoring checks should be short.
- How close are the normal operating values to the parameter values? If the normal values are close to the maximum or minimum allowed value, the time between monitoring checks should be short.
- How much animal food is at risk if a deviation occurs? If a large amount of product is at risk and cannot be reworked, for example, more frequent monitoring may be prudent.

Examples of non-continuous monitoring might include temperature checks of a thermal processing step at specified intervals, or recording the inventory of a potentially toxic ingredient at the end of each production shift.



Exception records are a new concept in the regulation.

Validation is required for exception record systems.

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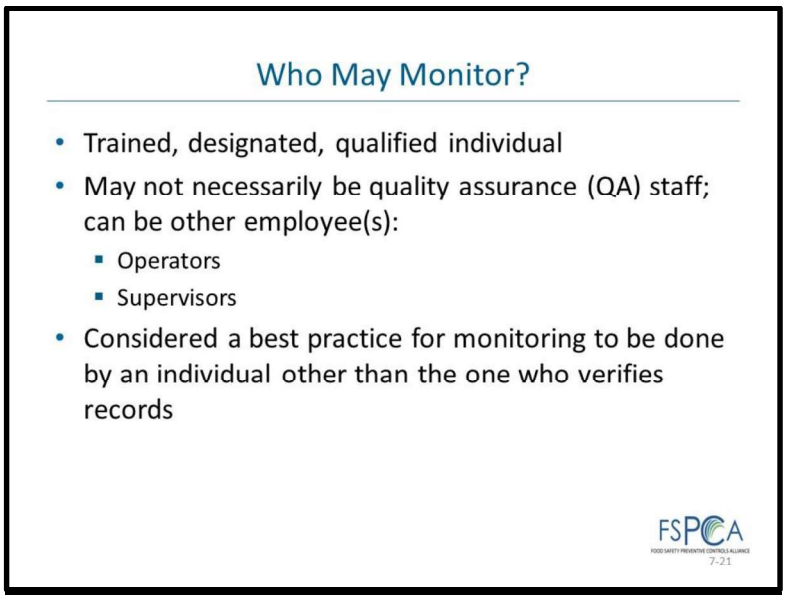
Exception reporting involves automated systems that are designed to alert operators and management only when a deviation (in other words an exception) from the requirement is observed. Automated exception reporting may be more efficient than that performed by operators, which allows for an increase in the frequency of monitoring, which is typically accomplished through continuous monitoring, and reduction of human error.

For example, refrigeration temperature control can notify on exception (e.g., high temperature alarm) and may only record temperatures that exceed the specified temperature. Such systems must be validated and periodically verified to ensure they are working properly. With such systems, monitoring records may not always be necessary, when validation and periodic verification are conducted to ensure that the system is working properly. Therefore, records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled (e.g., a chart recorder) or exception records demonstrating loss of temperature control (e.g., an alarm system that records when a deviation occurs).

If a facility uses "exception records," the facility must have evidence that the system is working as intended, such as a record that the system has been challenged by increasing the temperature to a point at which an "exception record" is generated. Exception records may also be adequate in circumstances other than monitoring of refrigeration temperature, such as monitoring for foreign material with x-rays, which results in a record only when the system detects foreign material. Validation is required.



Individuals who conduct monitoring activities must meet the definition of being *Qualified Individuals.*

Small facilities may have a limited number of people available for monitoring and record review. Thus, a small company may have the same person fill out the monitoring record and also review the record. This may not be ideal, but may be necessary.

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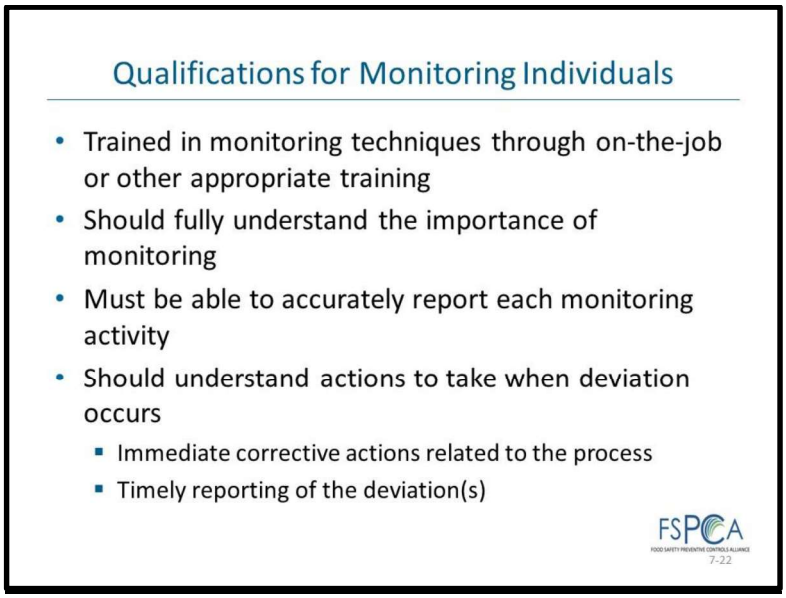
Individuals assigned to monitoring activities should be trained, designated to perform the activity, and must meet the definition of a qualified individual. These individuals may be members of the quality assurance team, but could also be line personnel, equipment operators, supervisors, maintenance personnel, or other qualified staff.

Monitoring by line personnel and equipment operators can be advantageous since they are continuously watching the animal food or equipment. Including production workers in food safety activities helps build a broad base of understanding and commitment to the preventive controls program and a facility's food safety culture.

The qualified individual (who is responsible for monitoring) should respond immediately to all deviations and report them as necessary. This will ensure that process adjustments and corrective actions are made in a timely manner.

All records and documents associated with preventive control monitoring must be signed or initialed by the person doing the monitoring activity, be dated, and, where appropriate, include the time of the monitoring activity recorded.

It is considered good practice for the person doing the monitoring and the person responsible for record review to be different so that errors are not overlooked. However, this is not required, and may be unavoidable in some instances. Also, verification (review of monitoring records) is to be done by (or under the oversight of) a PCQI.



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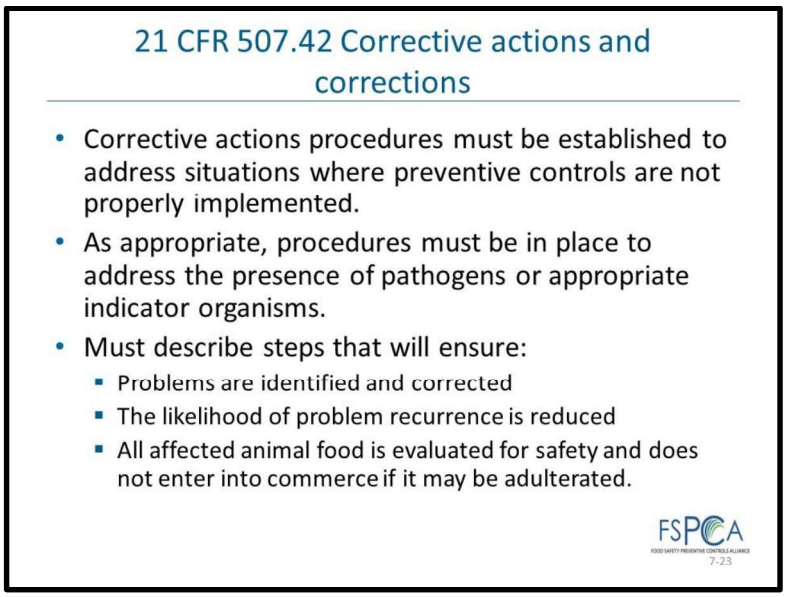
Properly trained ("qualified") personnel must be available at all times that the process control requires monitoring. While monitoring activities may be assigned to a supervisor, make sure this is realistic for the facility. For example, supervisors are sometimes called away for other activities, such as accompanying an inspector during an inspection visit. It is not realistic to expect one person to accompany an inspector and perform monitoring activities at the same time. With this in mind, it is a good practice for monitoring to be conducted by operators who are present at all times during production. The importance of monitoring procedures should be fully explained, and the individual should be trained in the appropriate techniques. In order for the monitoring to be effective, the individual must be able to accurately document the monitoring activity.

A facility may choose to allow the individual responsible for monitoring to take immediate action when a deviation occurs. For example, this could include investigating the cause, documenting any findings, or even shutting down the process without direct involvement from supervisors. Even if a facility chooses not to allow the individual responsible for monitoring to take these actions in the event of a deviation, they should still be aware of what actions may need to be taken and should understand that timely reporting is key.



One specific example of when corrective action procedures is when pathogens or appropriate indicator organisms are present (21 CFR 507.42(a)(1)(i)). Two key biological hazards of concern that may require corrective action or correction are *Salmonella* spp. and *Listeria monocytogenes.*

While this is one situation in which corrective action procedures are required, this is not the only instance that requires corrective action.

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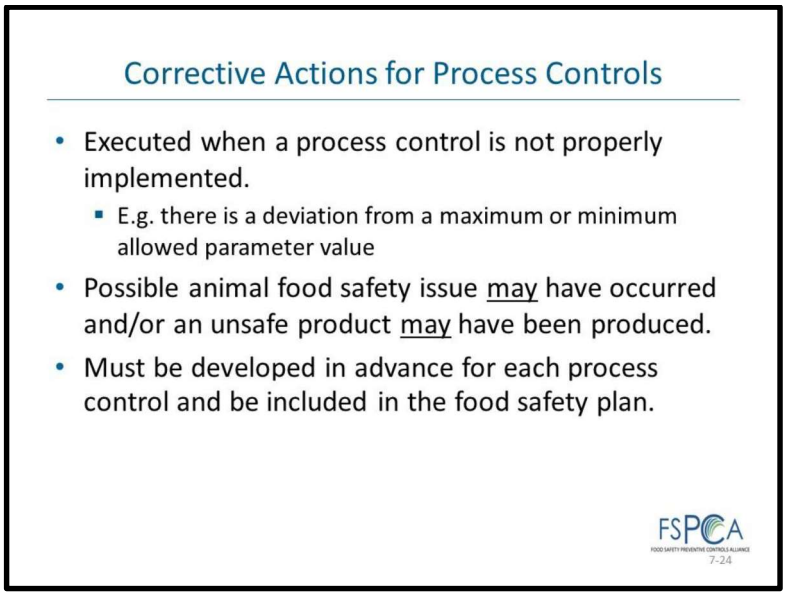
Corrective actions must be established for process controls. The requirements for corrective actions and corrections are discussed in 21 C.F.R. part 507.42 of the rule, which can be found on page 56347 of Appendix 1. The purpose of these procedures is to fix problems with the implementation of preventive controls, and prevent further instances of the identified failure. When something goes wrong, corrective actions or corrections must be performed depending on the hazard, the nature of the preventive control, and the deviation that has occurred.

The rule requires that if a pathogen has been identified as a hazard requiring a preventive control, corrective action procedures must be in place to address its presence. Alternatively, procedures can address the presence of an appropriate indicator organism, if it is detected through product testing or environmental monitoring.

Corrective action procedures must be written, and must describe:

- How problems will be identified and corrected,
- How the likelihood of problem recurrence will be reduced, and
- What steps will be taken to ensure that the animal food is evaluated for safety and will not enter into commerce if it is considered adulterated.



The extent of corrective action depends on a number of factors. If there is repeated failure to meet a parameter value, then specific training, equipment repair, or other corrective action may be necessary to resolve the issue.

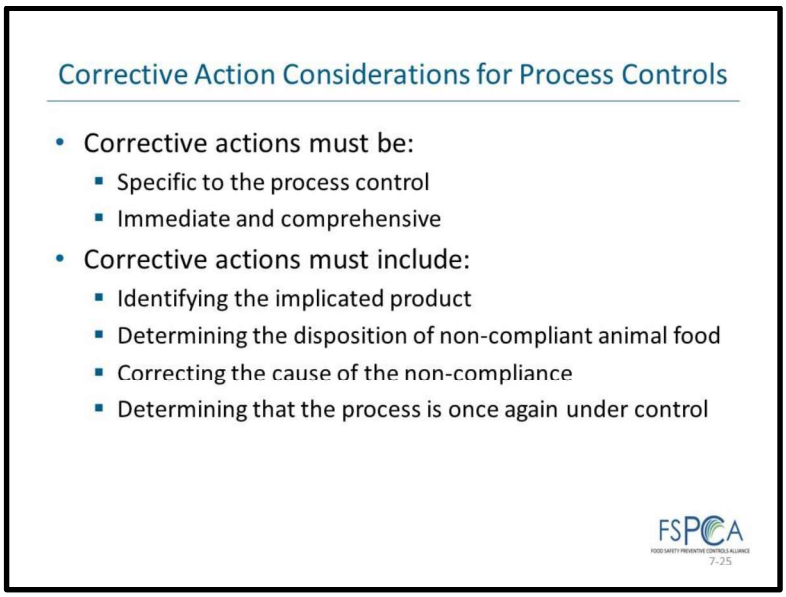
If the root cause of the deviation involves many systems in the facility, revalidation of the entire food safety system may be needed. This might happen if a major maintenance event, such as construction, has resulted in contamination from unknown points.

Slide 24

The need for corrective action arises when a process control is not properly implemented. For instance, a corrective action would be required when there is a deviation from an established maximum and/or minimum parameter value.

A corrective action is necessary any time such a deviation occurs, regardless of whether or not the facility feels that an unsafe animal food has been produced. In other words, corrective actions are independent of perceived food safety. In some cases where a corrective action is required, it may be possible to evaluate the food and make a determination that it is safe. In this case, the corrective action may not necessarily require the disposal of the animal food. However, something must be done to determine why the failure occurred and how it can be prevented in the future.

All corrective action procedures must be developed in advance and be documented in the food safety plan.



When determining the disposition of any non-compliant animal food product, there should be some explanation of the rationale used in estimating the impact of the non-compliance.

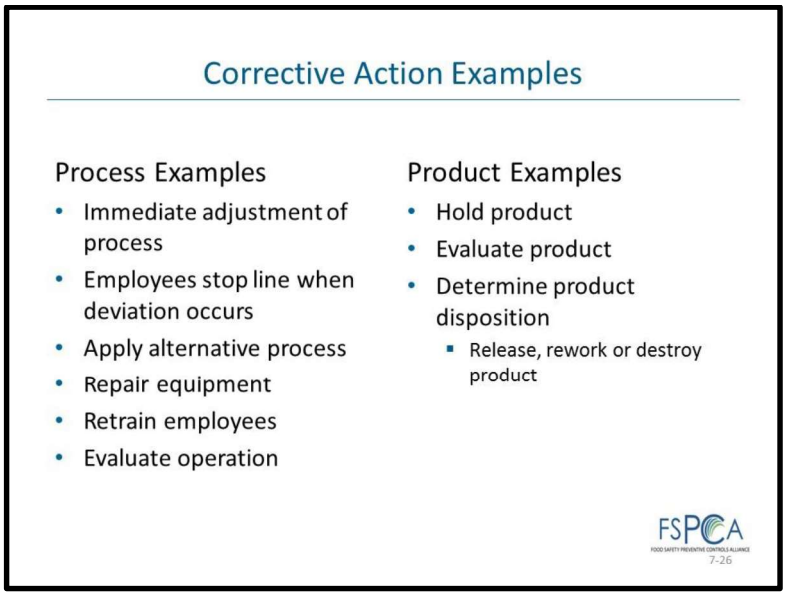
Slide 25

The food safety plan is to be designed to ensure that failures of a process control are rapidly identified and corrected. Predetermined corrective actions provide a "how-to" guide that describes the steps that need to be taken when a preventive control is not properly implemented. The duty of carrying out these procedures must be assigned to one or more individuals who have a thorough understanding of the operation, the animal food(s), and the firm's food safety plan and who have the authority to make decisions.

Corrective actions are to be developed for each process control, considering all of the types of deviations anticipated. For example, assuming a control relies on time and temperature to ensure sufficient pathogen destruction, deviations could occur for either the time or the temperature parameter. Corrective actions would need to be in place to address both possibilities. The timing for corrective actions depends on the monitoring frequency. Corrective actions need to be initiated as soon as the deviation is identified, and must encompass all animal food that could have been affected by the deviation.

When a deviation is detected, the first action is to identify the animal food involved. Implicated product should be segregated and evaluated to determine if a food safety hazard exists. If a hazard exists, the affected animal food must be reworked or destroyed.

Control of the process must also be restored. A corrective action should take care of the immediate problem, as well as provide long-term solutions to reduce the likelihood that the problem will recur. The objective is to re-establish control of the process so that production can start again without further deviations. This may involve equipment repair, employee training and overall evaluation of the process for improvements.



In some situations an animal food may be "cleared" to move off-site, but be put on hold there until the deviation is resolved. This may apply to facilities with limited on-site warehousing.

Slide 26

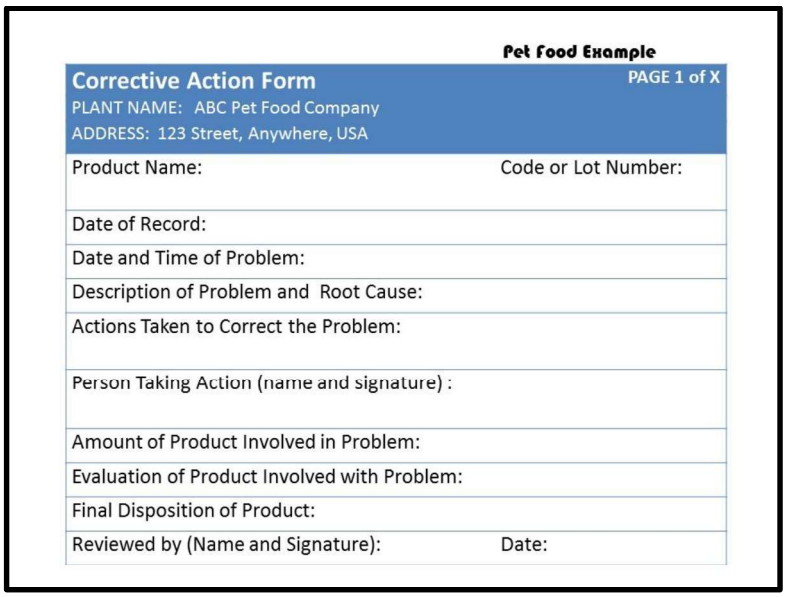
Examples of corrective actions for process controls include those listed here. Sometimes an immediate adjustment of the process can be used to address an out-of-control event. In other cases, an immediate adjustment during processing may not be a feasible solution. An example of this might be a batch process where in- and out-of-control animal food cannot be separated.

As previously mentioned, it may be appropriate for an employee to stop the line. This requires empowerment of the employee to take the action.

In some situations, an alternative process may have been validated to be effective at controlling the hazard. If this is the case, such a process may be implemented as a corrective action. For example, if a temperature drops below the parameter value, an alternative process that involves longer time at a lower temperature may be applied, provided it has been validated.

Other examples of corrective actions might include equipment repairs, or retraining employees on proper procedures. In some situations, an evaluation of the entire operation may be required to ensure that the operation is capable of producing the animal food under conditions that are essential for animal food safety.

When a deviation from required parameters occurs, however brief, corrective actions are to include an evaluation of all affected animal food for safety. The affected animal food must be evaluated for safety prior to determining the appropriate disposition.

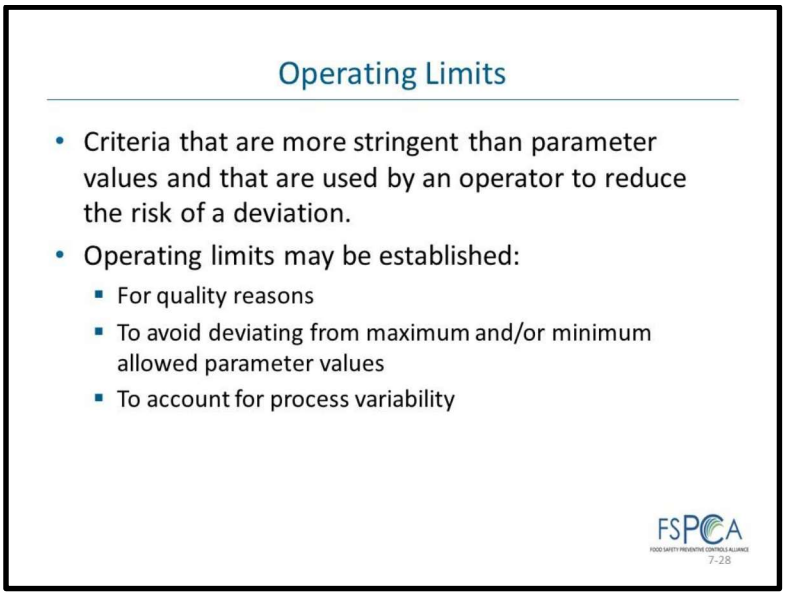


Pet Food Example

Corrective Action Form PLANT NAME: ABC Pet Food Company ADDRESS: 123 Street, Anywhere, USA	PAGE 1 of X
Product Name:	Code or Lot Number:
Date of Record:	
Date and Time of Problem:	
Description of Problem and Root Cause:	
Actions Taken to Correct the Problem:	
Person Taking Action (name and signature) :	
Amount of Product Involved in Problem:	
Evaluation of Product Involved with Problem:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date:

Slide 27

This is an example of a Corrective Action Form, which a facility may choose to include in its food safety plan. In some situations, corrective action activities may take place in a short period of time. In other more complicated situations, corrective action activities may take place over several days. It is important to have an accurate record of all corrective actions in order to assure that the animal food is safe. For example, failure to adequately document when the incident started and ended can lead to an expanded recall affecting a substantial amount of animal food that would otherwise have been unaffected. Keep in mind this adage: if you don't write it down, it never happened.

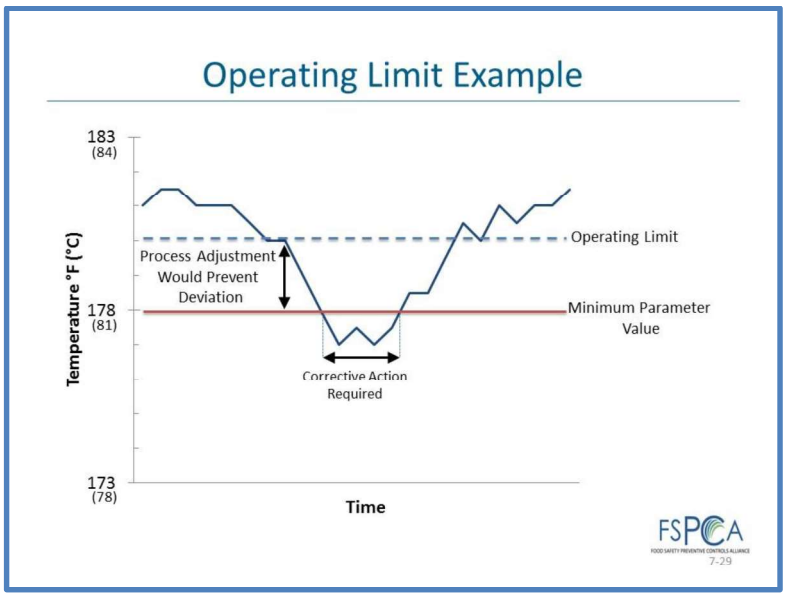


Slide 28

The use of an operating limit may allow for the detection of a potential problem before a process control deviation. This is because the value for the operating limit can be more conservative than the minimum or maximum established parameter values. The process may be adjusted when the operating limit is not met but is still within the established parameters, thus avoiding the need to take corrective action. Operating limits are not required by the rule, but are a good example of a tool that may be used alongside a process control.

Operating limits may be established:

- For quality reasons – for example, higher final temperatures than are needed to kill pathogens may enhance the physical properties of the animal food.
- To avoid deviating from maximum and/or minimum allowed parameter values; or
- To account for normal variability – for example, any batching process will have some variation in weight; an appropriate operating limit can warn operators if the process is approaching a deviation amount that would be considered out-of-control.



Slide 29

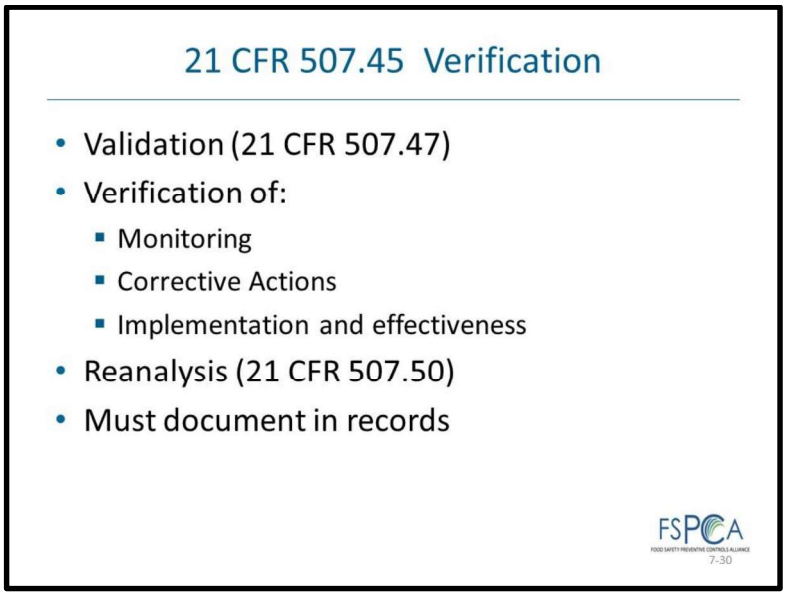
The example above illustrates two important points:

1) Operating limits and process adjustments, and
2) Parameter values and corrective actions

In this example of a cooking process, a minimum parameter value is established at 178°F (81°C). In the slide, the temperature of the process fell below the minimum value.

The facility in this example chose not to set an operating limit. Setting an operating limit (180°F (82°C)) above the minimum value could have alerted an operator to make a process adjustment to bring the temperature back above the operating limit prior to the temperature going below the set minimum parameter value. If an adjustment is made before the temperature drops below the minimum parameter value, no corrective action would be required. However, in this example, an adjustment was not made until after the temperature dropped below 178°F (81°C), thus appropriate corrective actions must be taken and a corrective action record must be generated.

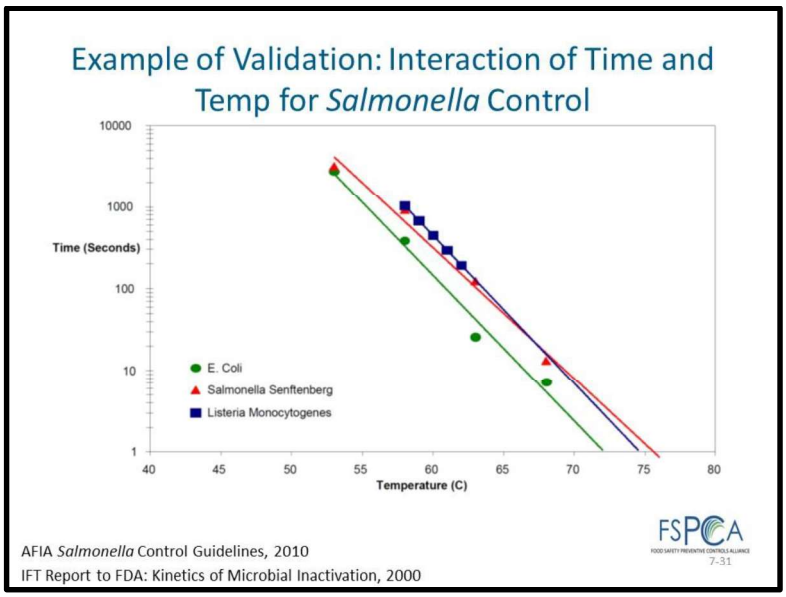
The discussion of operating limits is relevant to the definition of the term "correction." A correction might occur when a process fails to meet the operating limit, but is still within the established maximum and/or minimum parameters associated with the process control. As discussed briefly in chapter 6, 21 CFR 507.42(c)(2) provides the conditions for when a correction, rather than a corrective action, may be appropriate. A corrective action may not be necessary if *"You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety."*



Slide 30

In addition to monitoring and corrective actions, verification is a required management component for process controls. Verification is used to make sure that preventive controls are working as the facility intended to control a hazard. Verification includes validation of the chosen control to assure that it is capable of significantly minimizing or preventing the identified hazard requiring a preventive control. The next slide will discuss an example of validating a process control.

There must be verification that monitoring is being conducted, that appropriate decisions about corrective actions are being made, and that the control is being consistently implemented and is effective in addressing the hazard. A facility must be able to verify that reanalysis of the food safety plan is being conducted as required by the rule, meaning at least once every 3 years and as appropriate when there is a significant process change, new information about a hazard becomes available, or a food safety failure occurs. As with all preventive control management components, these verifications must be documented in records.



There is not strenuous data for all undesirable microorganisms in all matrices. Scientific data, including human food research, can be used as helpful reference points. However, the time × temperature combinations may need to be validated in specific matrices and/or processing systems.

The information referenced in this slide include:

- American Feed Industry Association (AFIA). 2010. *Salmonella* Control Guidelines. http://www.afia.org/resources.asp
- Institute of Food Technologists (IFT). 2000. Kinetics of Microbial Inactivation for Alternative Food Processing Technologies. http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm100158.htm

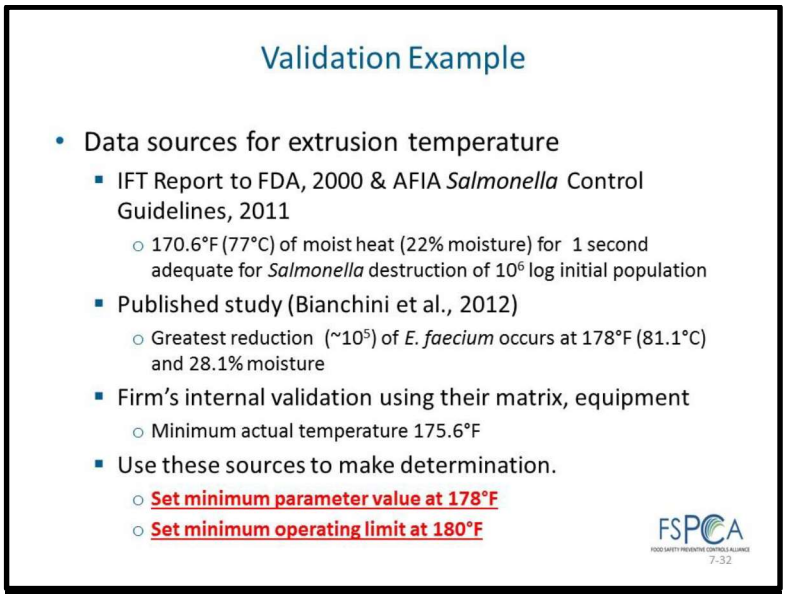
Slide 31

Scientific data may be used to demonstrate how a chosen preventive control is capable of significantly minimizing or preventing a hazard. This slide is an example of scientific data that a facility could use to validate their manufacturing process.

The chart, which is from the American Feed Industry Association's *Salmonella* Control Guidelines and is data derived from a report from the Institute of Food Technologists, illustrates the time and temperature combination at which there is a 6-log reduction in E. Coli (green circles), *Salmonella Senftenberg* (red triangles), and *Listeria monocytogenes* (blue squares). The x-axis is the temperature in Celsius, while the y-axis is a logarithmic scale of time in seconds.

As the temperature increases, the length of time required for a 6-log reduction of the hazard is reduced. For example, a 10^6-log reduction of *Salmonella Senftenberg* requires approximately 1,000 s, or over 16.5-minutes, of thermal processing time when processed at 58°C. Alternatively, the same 10^6-log reduction of the hazard requires approximately 10 s of thermal processing time when processed at 68°C. This line can be extrapolated to predict a 10^6-log reduction can occur instantaneously when the product is heated to 76°C. Note that this study referenced only one serotype of *Salmonella* in a single matrix.

If a facility were to choose to use a thermal processing step as a preventive control for pathogens, data like this could be utilized as validation that certain time and temperature combinations will destroy an undesirable microorganism. Importantly, the facility would also need to consider any unique aspects of their animal food or manufacturing that could impact the time and temperature needed to adequately destroy any pathogens that may be present.



When specific examples, such as scientific literature and internal testing, are used for validation of a preventive control, copies of the literature or supporting records from internal testing must be maintained by the facility. The information could be included in the food safety plan or alternately a reference to location of the documentation could be included in the food safety plan.

In addition to the two previously-cited references, the Bianchini et al. (2012) literature can be found at:

Bianchini, A., Stratton, J., Weier, S., Hartter, T., Plattner, B., Rokey, G.., and Eskridge, A. M. (2012). Validation of extrusion as a killing step for Enterococcus faecium in a balanced carbohydrate-protein meal by using a response surface design. Journal of Food Protection, 75(9), 1646-1653.

Slide 32

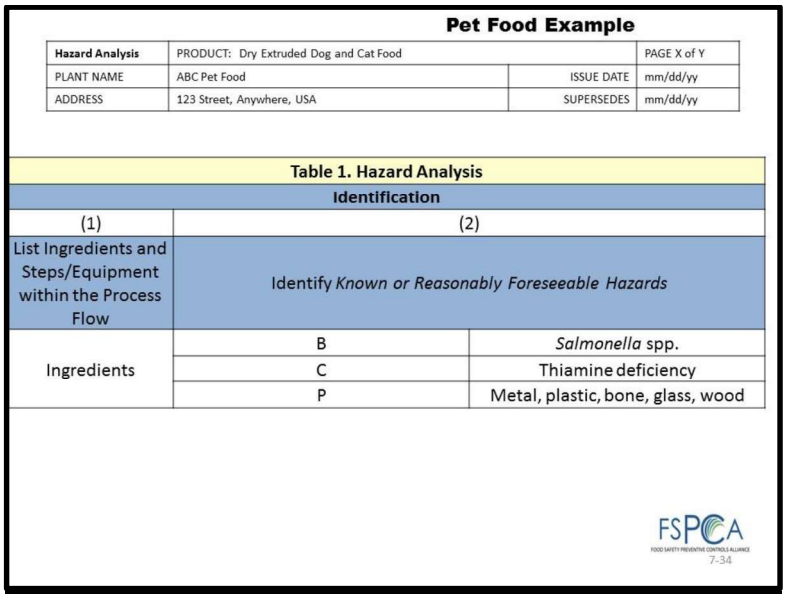
This validation example for control of *Salmonella* relies on three different sources. The first examples are published reports, namely the IFT Report to FDA in 2000 and the AFIA *Salmonella* control guidelines. The second source is a peer-reviewed study published by Bianchini et al. in 2012. The third source is the firm's own internal process data that showed the minimum actual temperature to destroy *Salmonella*, with their specific matrix and equipment was 175.6° F. With this in mind, the firm decides to set a minimum parameter value of 178° F, and an operating limit of 180° F. Setting the operating value above the parameter value is not a requirement, but is a good practice.

Each of these sources could be used as acceptable validation for the process control for the control of *Salmonella*. As previously stated, a facility would need to ensure that the sources are comparable to the animal food and manufacturing processes utilized by that facility. Different animal food matrices and manufacturing environments may alter the specific time or temperature needed to destroy pathogens.

Slide 33

The following slides provide an example of how a processing preventive control may be utilized in an animal food safety plan.

Keep in mind that the example plans are used only for the purpose of instruction, and do not constitute full, working plans, and that the specific examples provided do not necessarily identify hazards requiring a preventive control in all facilities.



Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

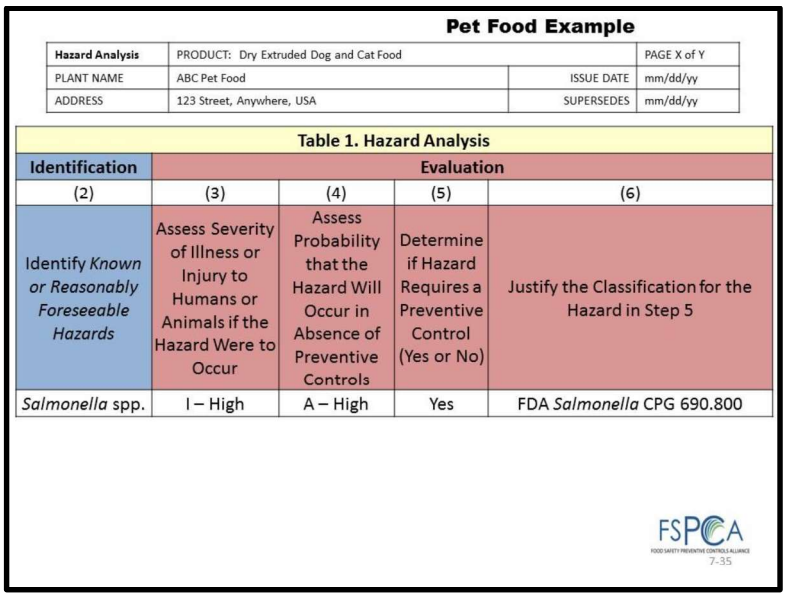
Table 1. Hazard Analysis

Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify *Known or Reasonably Foreseeable Hazards*	
Ingredients	B	*Salmonella* spp.
	C	Thiamine deficiency
	P	Metal, plastic, bone, glass, wood

FSPCA
7-34

Slide 34

In the example plan, *Salmonella* has been identified as a known or reasonably foreseeable biological hazard. This hazard could enter the facility along with received ingredients.



Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

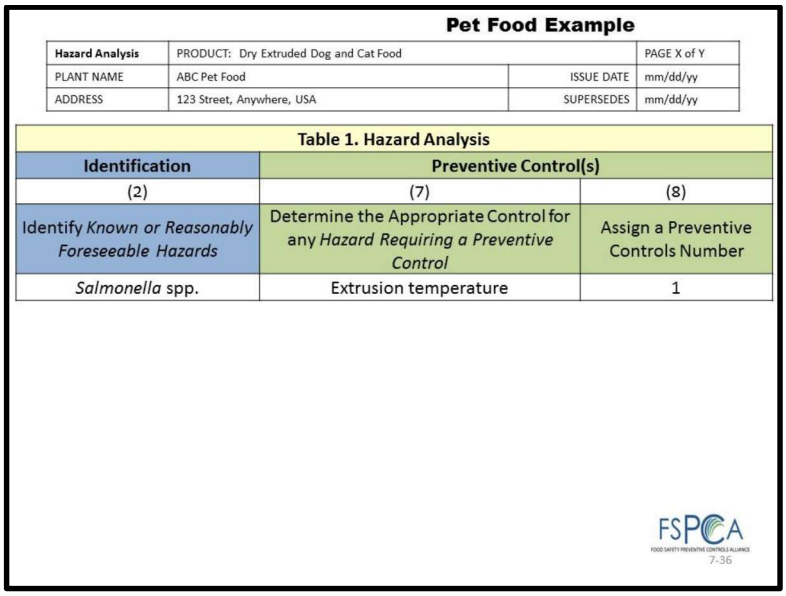
Table 1. Hazard Analysis

Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify *Known or Reasonably Foreseeable Hazards*	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
Salmonella spp.	I – High	A – High	Yes	FDA *Salmonella* CPG 690.800

FSPCA
7-35

Slide 35

In Chapter 5, the determination of severity and probability was discussed. Because *Salmonella* can potentially cause illness in both animals and humans, and because pet foods are direct human contact foods with a zero tolerance level for the pathogen according to the FDA Compliance Policy Guide, it was determined that the hazard requires a preventive control.



Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

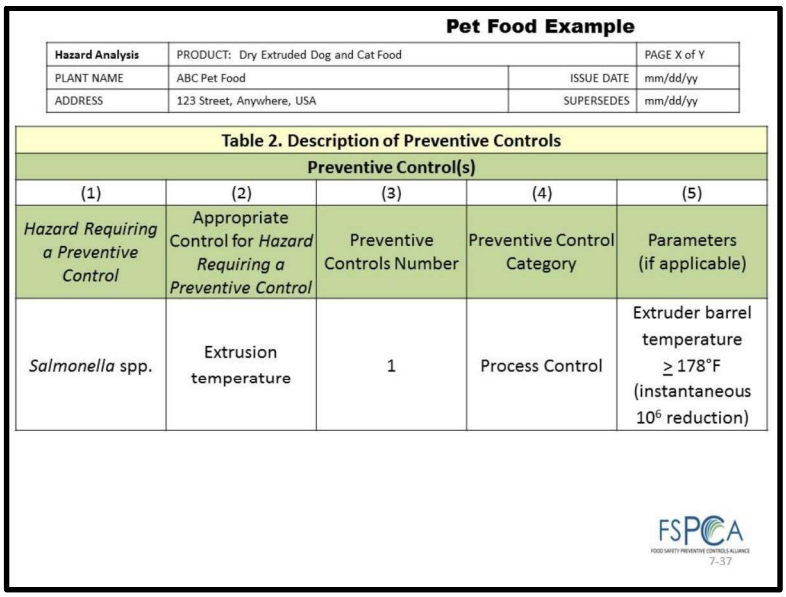
Table 1. Hazard Analysis

Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify *Known or Reasonably Foreseeable Hazards*	Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Controls Number
Salmonella spp.	Extrusion temperature	1

FSPCA
7-36

Slide 36

Salmonella is a heat-sensitive pathogen that can be destroyed at particular time and temperature combinations. The extrusion process used to manufacture dry dog and cat foods operates within temperature parameters sufficient to kill *Salmonella*, and is therefore chosen as the preventive control for the hazard. This is the first preventive control identified in the example food safety plan.



Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 2. Description of Preventive Controls

Preventive Control(s)				
(1)	(2)	(3)	(4)	(5)
Hazard Requiring a Preventive Control	Appropriate Control for *Hazard Requiring a Preventive Control*	Preventive Controls Number	Preventive Control Category	Parameters (if applicable)
Salmonella spp.	Extrusion temperature	1	Process Control	Extruder barrel temperature ≥ 178°F (instantaneous 10^6 reduction)

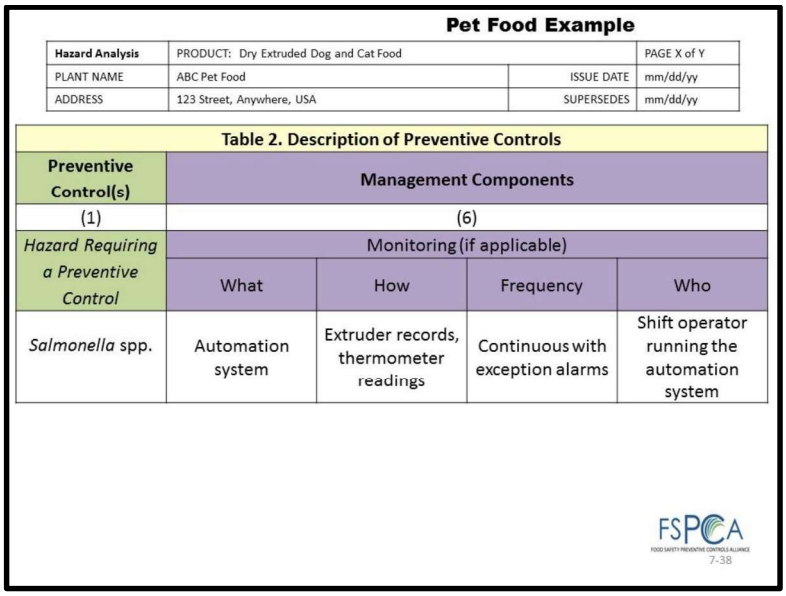
FSPCA

7-37

Slide 37

Table 2 of the food safety plan describes the preventive controls and any applicable management components, which are shown on the next slide.

In this example, the facility's internal testing confirms that a minimum acceptable temperature to destroy *Salmonella*, given their specific process and matrix, is 178°F. This parameter agrees with external validation sources. Thus, the parameter for the process control is that all animal food must be extruded at temperatures exceeding 178°F. As one mechanism to ensure that the animal food is continually extruded above the minimum temperature, the facility chooses to set an operating limit of 180°F.



Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

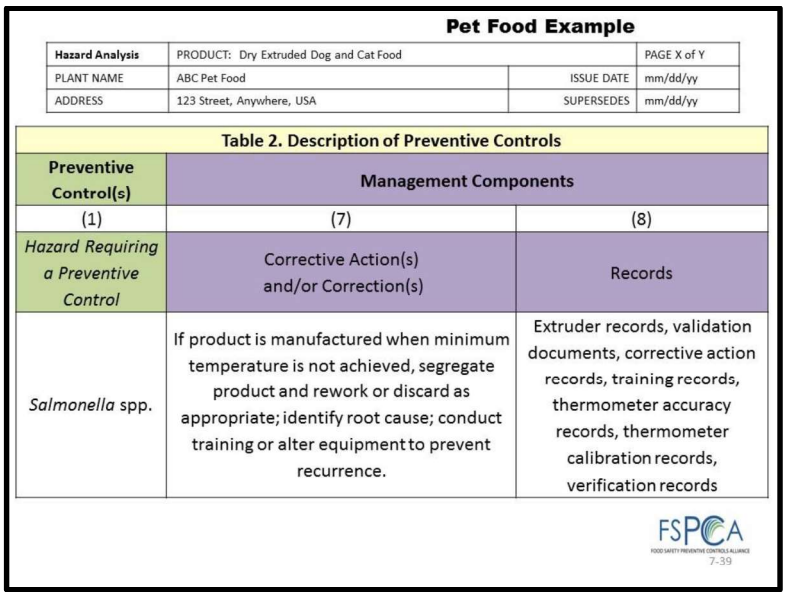
Table 2. Description of Preventive Controls

Preventive Control(s)	Management Components			
(1)	(6)			
Hazard Requiring a Preventive Control	Monitoring (if applicable)			
	What	How	Frequency	Who
Salmonella spp.	Automation system	Extruder records, thermometer readings	Continuous with exception alarms	Shift operator running the automation system

FSPCA
7-38

Slide 38

In order to assure the preventive control is properly implemented, the automation system used to operate the equipment is monitored. This can be done in real-time by viewing temperature readings to monitor that the temperature does not fall below the minimum parameter value of 178°F. Process records will also be reviewed at the end of each shift by the extruder operator in order to verify that the temperature parameter was met for all extruded dog and cat food produced during the shift.



Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 2. Description of Preventive Controls

Preventive Control(s)	Management Components	
(1)	(7)	(8)
Hazard Requiring a Preventive Control	Corrective Action(s) and/or Correction(s)	Records
Salmonella spp.	If product is manufactured when minimum temperature is not achieved, segregate product and rework or discard as appropriate; identify root cause; conduct training or alter equipment to prevent recurrence.	Extruder records, validation documents, corrective action records, training records, thermometer accuracy records, thermometer calibration records, verification records

FSPCA

7-39

Slide 39

Column 7 identifies the corrective actions the facility will utilize if the minimum temperature falls below 178°F. If the minimum temperature is not achieved, the extruded dog and cat food will be segregated and held for rework or will be discarded as appropriate. The cause of the deviation should be identified. If the cause was operator related, retraining will be conducted. If the cause was process related, changes will be made to equipment or controls as necessary to prevent recurrence.

Records generated for this process control include process records (such as extruder records), training records, and verification records.

Pet Food Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	X / Y / 2015
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	X / Y / 2015

Table 3. Description of Preventive Control Verification Activities

Activity	Description of Activity
Type of Validation	○ IFT Report to FDA: Kinetics of Microbial Inactivation, 2000 ○ AFIA *Salmonella* Control Guidelines, 2010 ○ Bianchini et al. in 2012. ○ Internal process data: minimum required temperature = 175.6 F
Assurance Monitoring and Corrective Actions/Corrections are Completed as Directed	Monitoring and corrective action records will be reviewed within 7 working days. Instances exceeding 7 days includes justification.
Type of Verification of Implementation and Effectiveness	Daily checks to confirm thermometer accuracy Quarterly calibration of thermometers Test and hold procedures per SOP 506.3
Reanalysis of Food Safety Plan	Every three years, or as necessary when there are changes to the process, new information becomes available, or it is determined that any of the preventive controls are ineffective in controlling the hazard.

Slide 40

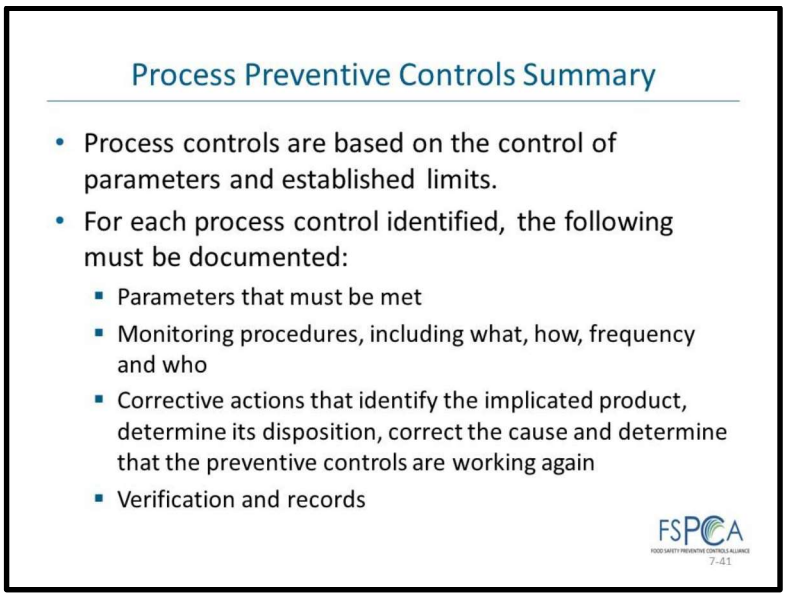
Verification activities include record review, establishing appropriate validation, and reanalysis.

In this example, all monitoring and corrective action records are reviewed within seven working days by (or under the oversight of) the PCQI. If the review time-frame must exceed seven working days, a written justification is provided by the PCQI.

Validation for the process control is listed, and corresponds to the resources described earlier in this chapter.

Thermometers will be checked for accuracy daily and will be calibrated quarterly. Because process records are reviewed at the end of a shift, test-and-hold procedures are used to assure all products shipped have met the established parameters for the process control.

A reanalysis of the plan is conducted every three years, as necessary when changes occur, or when it is determined that a preventive control is ineffective.



Slide 41

Process controls focus on processing steps where control can be applied to significantly minimize or prevent hazards requiring a preventive control. Maximum and/or minimum parameter values must be established to effectively control a food safety hazard. Monitoring procedures are required to ensure that the process control effectively addresses the hazard. Such procedures must specify what will be monitored, how it will take place, how often it will be done and who will do it. Corrective actions must be in place that describe what to do when parameters are not met and the process is considered to be ineffective in controlling the hazard. Finally, verification must be conducted to ensure that management components are appropriately used, that the process control is being properly implemented, and that the hazard is effectively controlled.