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Root Cause Analysis

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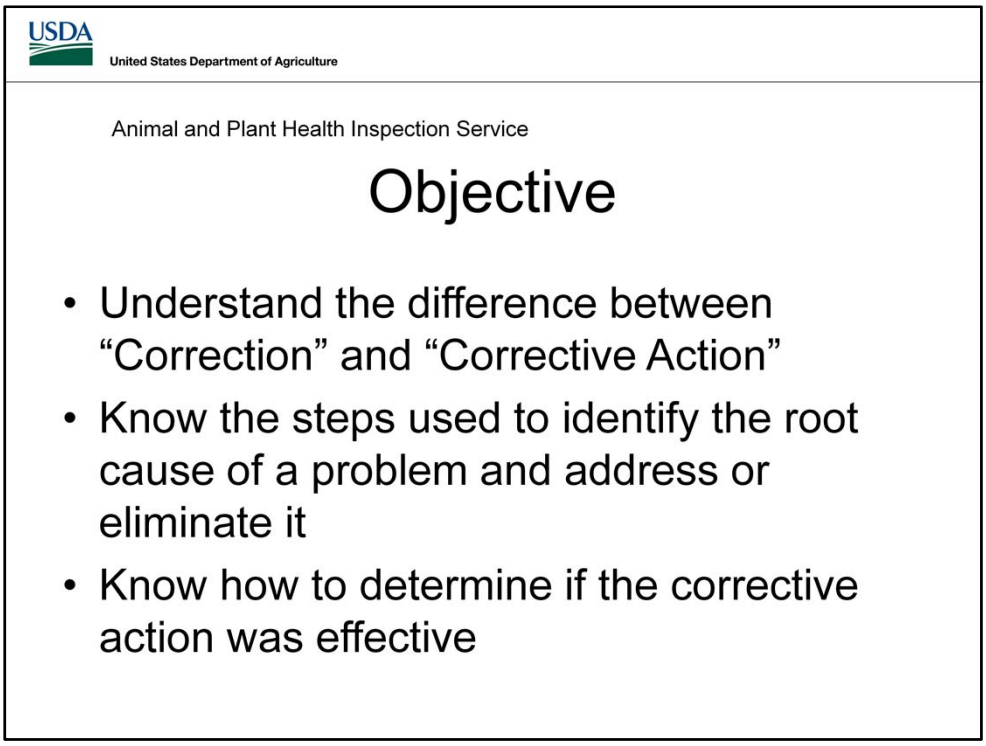
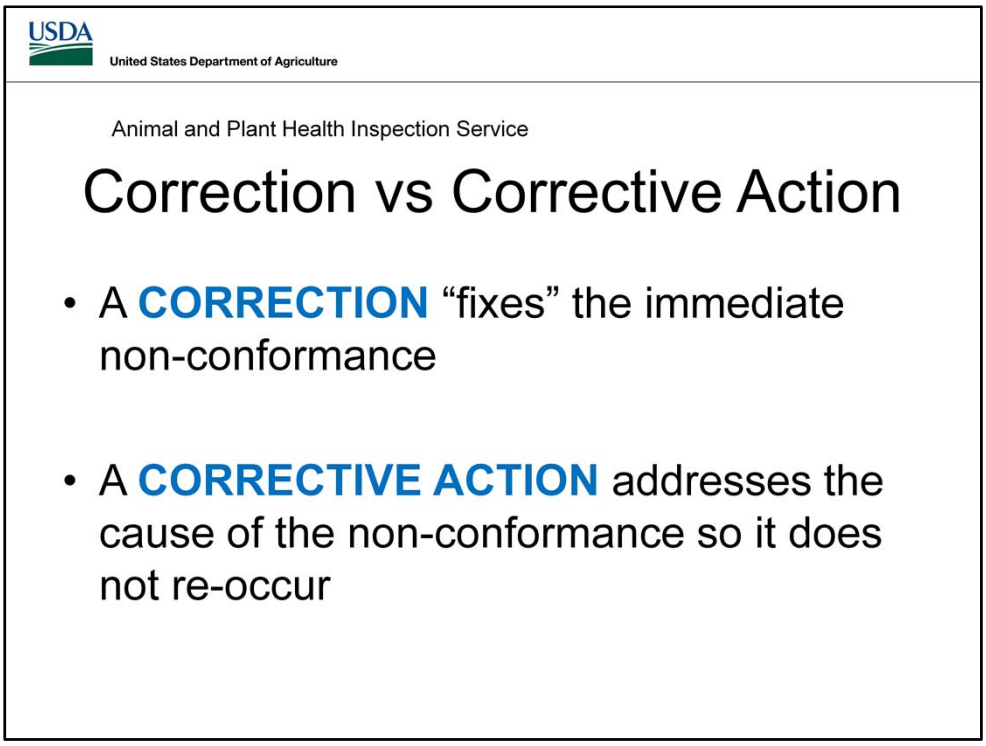


The objective of this presentation is to provide guidance in performing root cause analysis investigations.

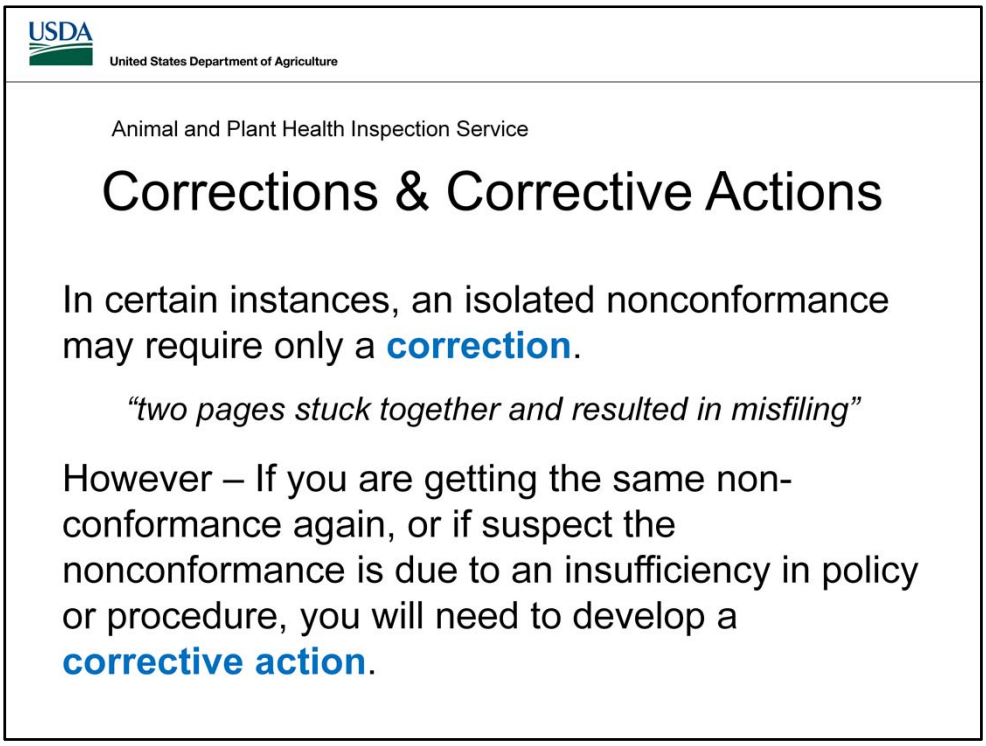
Consistent production and testing of veterinary biological product requires quality management procedures to ensure the uniformity and consistency of the processes.

It is the intent of this presentation to explain the difference between "Correction" and "Corrective Action", to define the steps used to identify the root cause of a problem and address or eliminate it, and to describe how to determine if corrective action was effective



Corrections can stop the bleeding but do necessarily address the reason for a wound.

Corrective actions are put in place to address the **reason** for the bleeding and prevent additional wounds from the occurring from the same cause.

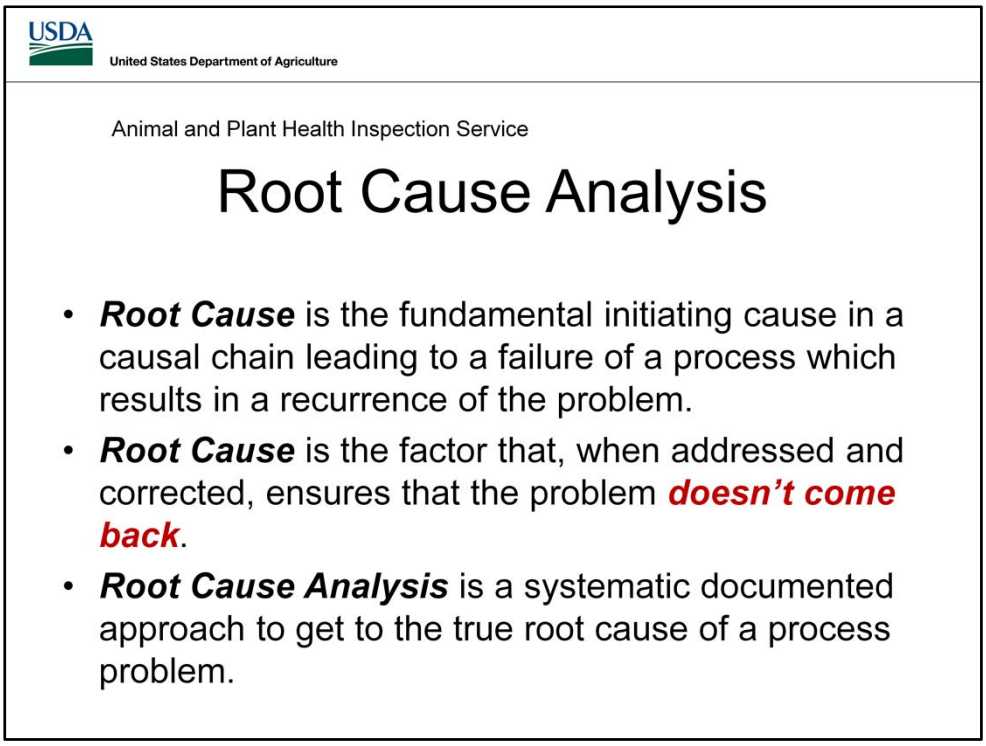


Two pages stuck together may simply mean that next time you need to pay more attention – it may not require the need to implement corrective action.

However deviations may require corrective action.

If the pages continue to stick together or misfiling continues - you should try to determine why it is repeating.

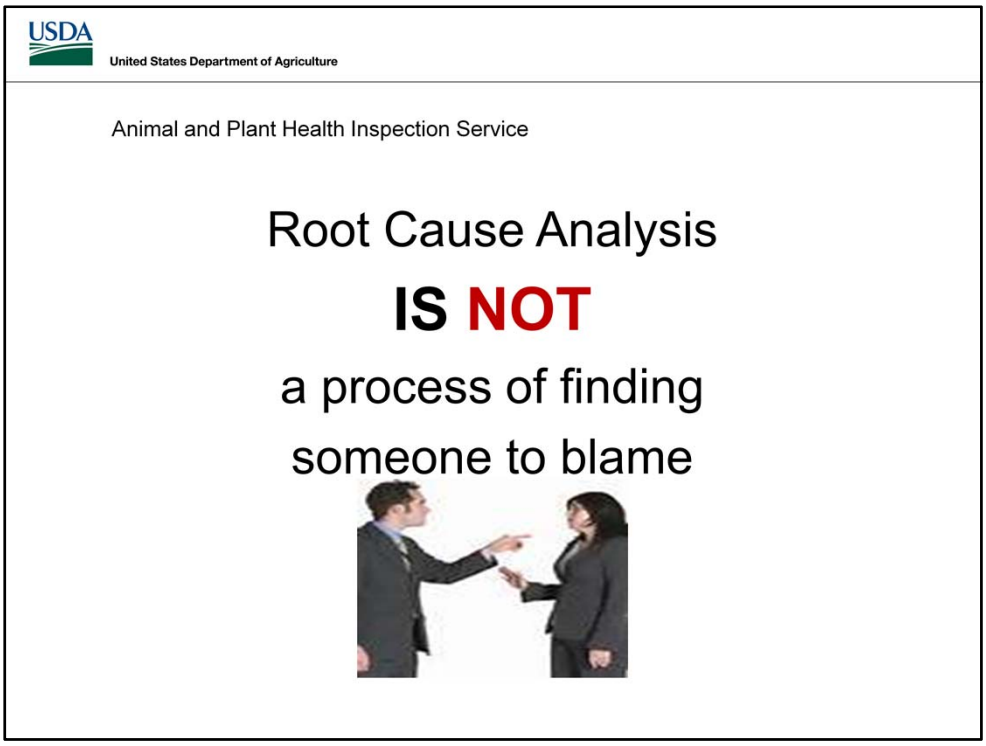
If it continues something else is wrong which is causing it.



If the decision is made that a non-conformance is not just an isolated innocent, the non-conformance should undergo a thorough root cause analysis.

When the true root cause is addressed and corrected, the problem will not come back.

Root Cause Analysis is a documented approach to get to the **true** root cause of a process problem.

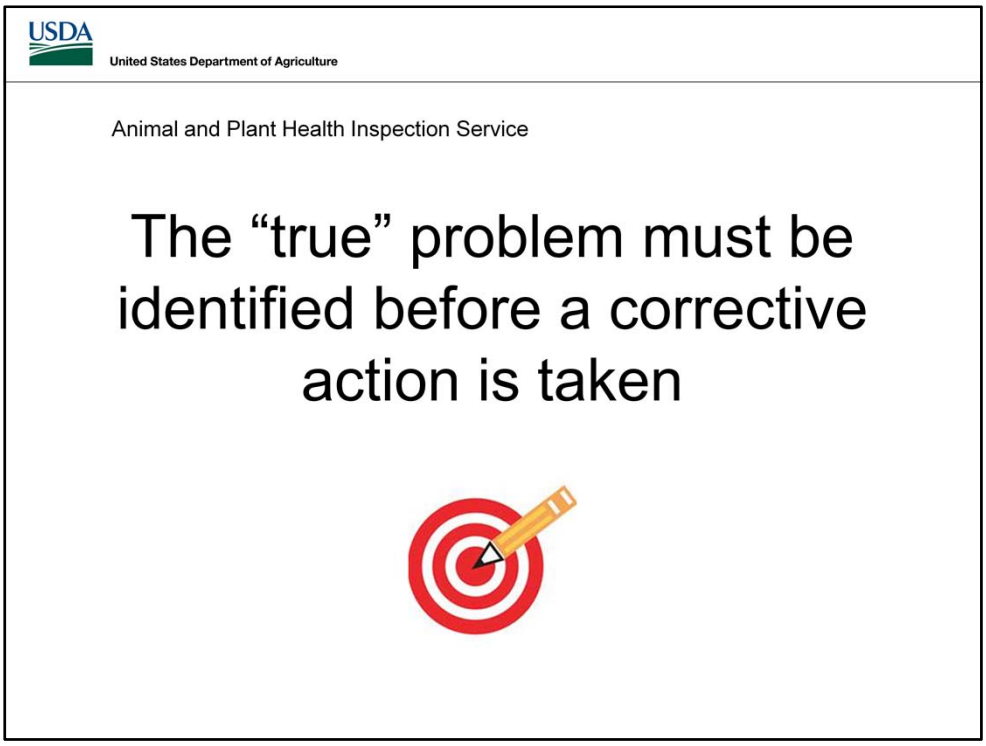


As an example, on the day after the crash of Asiana Airlines Flight 214, while the wreckage was still on the ground, representatives of the airline stated the available evidence suggested the crew was at fault.

Representatives said the pilot in control of the Boeing 777, had little experience flying that kind of plane. Although he had nearly 10,000 hours flying other planes, he only had 43 hours on the 777 aircraft.

Despite this, the NTSB Chair Deborah Hersman said her agency was a long way — perhaps months — from reaching a conclusion on what caused the crash.

While human error may be the root cause; a thorough investigation should first eliminate all other possibilities.

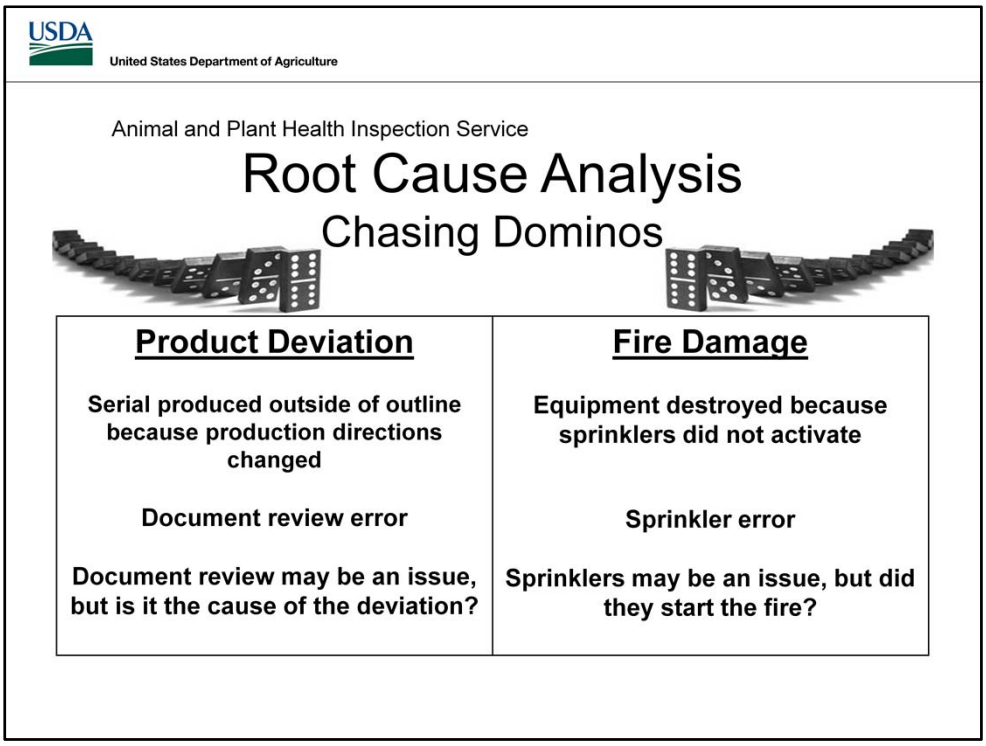


The causal chain should be evaluated to the initiating root cause. The outcome is not likely the root cause.

An underlying factor or root cause can be determined by multilayered “why” questions or some other predefined method.

In our program of regulation of veterinary biologics, the CVB expects manufacturers of veterinary biologics to perform a systematic approach when dealing with non-compliance to requirements.

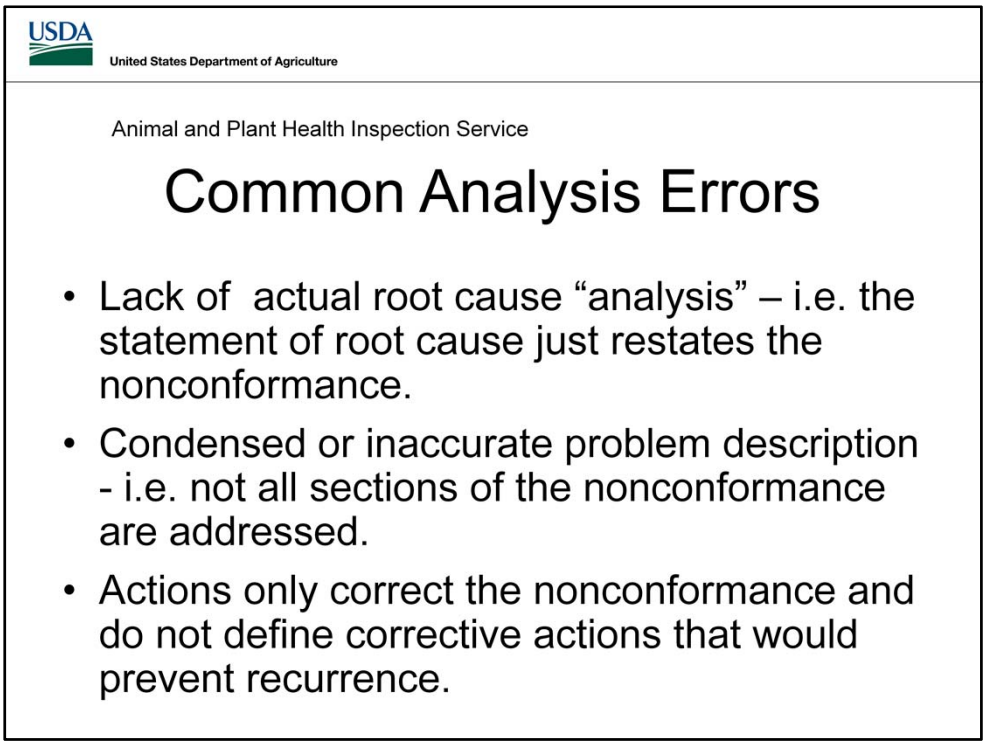
All non-compliance must undergo a root cause analysis along with a corrective/preventive action.



Determining the root cause can be like chasing dominoes. You need to identify what knocked down the first domino, not just the domino that knocked down this domino.

Failure to accurately determine the true root cause is like saying that equipment was destroyed because sprinklers did not activate during a fire.

The sprinklers may have contributed to the damage, but was it the true root cause? What started the fire?



Lack of actual root cause “analysis” - It is common that the immediate cause of **final** outcome is described as the root cause.
Simply restating what happened does not address the action.

Condensed or inaccurate problem description - The conclusion of the investigation should be substantiated with data, credible functional analysis, and impact. All aspects of the non-conformance need to be addressed. Do you know if other areas were affected or could be affected?

Actions only correct the nonconformance and do not define corrective actions - Often the actions described are corrections, not corrective actions. They address the immediate occurrence but do not address the root cause. A proactive evaluation may be necessary to address **all** aspects and finalize the risk assessment to determine if the actions taken will prevent a re-occurrence.

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SYMPTOM APPROACH
VERSUS
ROOT CAUSE ANALYSIS

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System Approach vs Root Cause

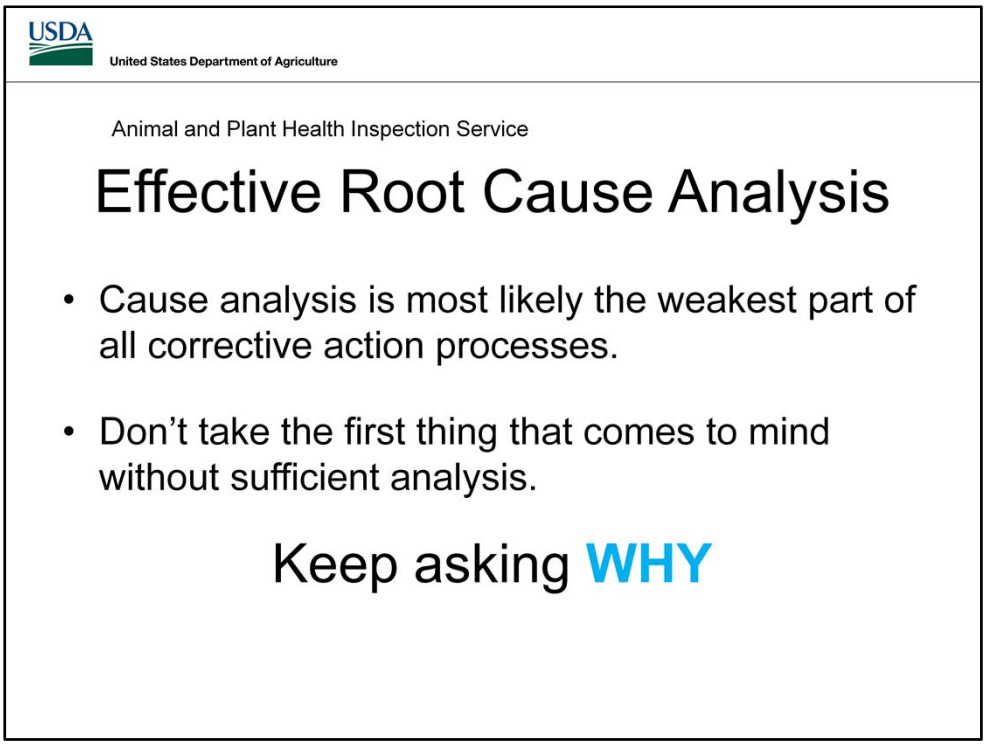
System Approach	Root Cause
"Errors are often a result of worker carelessness."	"Errors are the result of defects in the system. People are only part of the process."
"We need to train and motivate workers to be more careful."	We need to find out why this is happening, and implement mistake proofs so it won't happen again."
"We don't have the time or resources to really get to the bottom of this problem."	"This is critical. We need to fix it for good, or it will come back and burn us."

Don't just put a bandage on the issue – symptoms can be covered or repaired by corrections – they are not the root cause.

Perhaps errors are not always a result of worker carelessness. Is it possible that "Errors are the result of defects in the system and that people are only part of the process."

Rather than simply training or retraining, should we find out why the issue continues to occur?

Rather than choosing not to take the time to investigate, wouldn't it be better to fix the item for good so it does not come back?

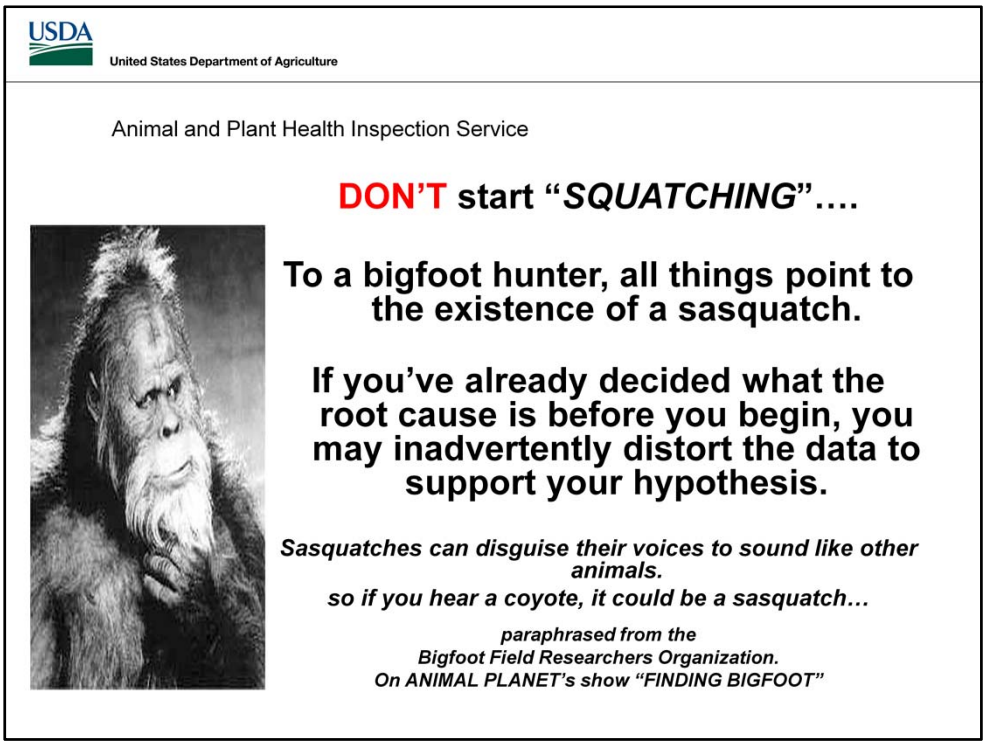


The hardest part of the process can be determining what the problem is.

But you need to get to root before you can take meaningful corrective action.

The approach may be a fishbone type evaluation, "why" evaluation, causal tree, or other means.

Don't be satisfied with the first answer that comes to mind, don't take the easy way out.



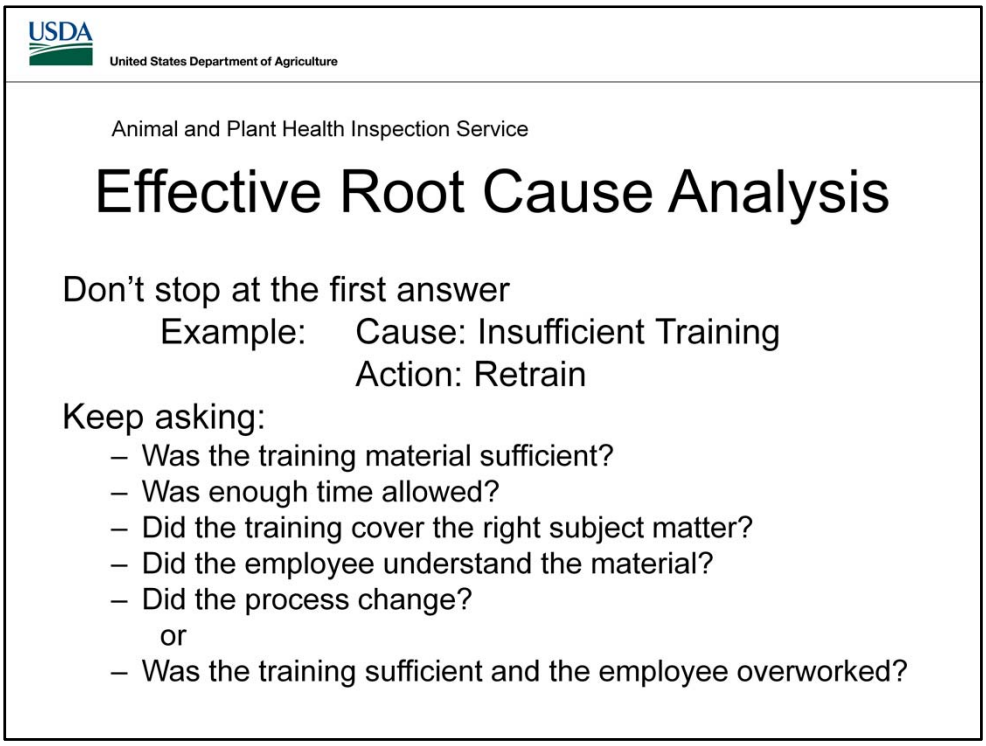
Don't start "squatching" - If you've ever watched Animal Planets "Finding Bigfoot" you've seen an examples of investigations when the investigators have already determined the cause of the occurrence. To them any footprints found are the result of bigfoot.

During one episode a researcher said "*Sasquatches can disguise their voices to sound like other animals. so if you hear a coyote, it could be a sasquatch…"*

If you've already decided what the root cause is before you begin, you may inadvertently distort the data to support your hypothesis.

Begin with an open mind. Don't start looking for bigfoot.

So then how do you get to the answer?



Don't stop at the first reason

As I mentioned earlier, following the crash of Asiana Airlines Flight 214, when it was determined that the pilot had only 43 hours of experience on that type of aircraft, the NTSB Chairman said the agency was a long way from reaching a conclusion on what caused the crash.

She chose to continue asking rather than stopping at the first answer.

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Root Cause Analysis is asking **why** the problem occurred, and then continuing to ask **why** that happened until we reach the fundamental element that failed

As children we continue to ask why. And ask, and ask, and ask…….
As adults we lose that quality.

Albert Einstein once said - “I have no special talents. I am only passionately curious.” (Albert Einstein --- To Carl Seelig – March 11,1952.)

Don’t stop asking why at just because you hit a target

Keep asking until you’ve hit the bulls-eye.

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Examples of missed targets

The employee is the root cause, management cannot be held responsible for the actions of employees.

The root cause as an unclear procedure, a minor change was made to the standard operating procedure.

An employee failed to follow a procedure, the procedure was changed to require another person to verify that they did it right.

Only the QA or QC Department were involved the investigation.

Human error was identified and more training was required.

Here are examples of 5 conclusions and actions the CVB would probably not consider as adequate

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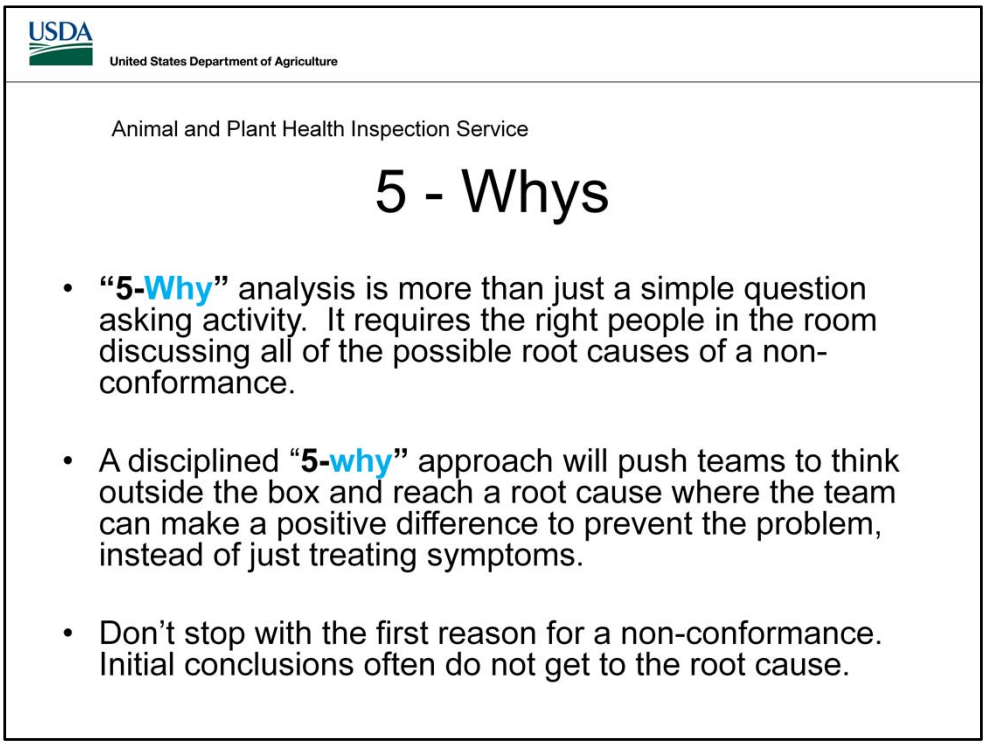


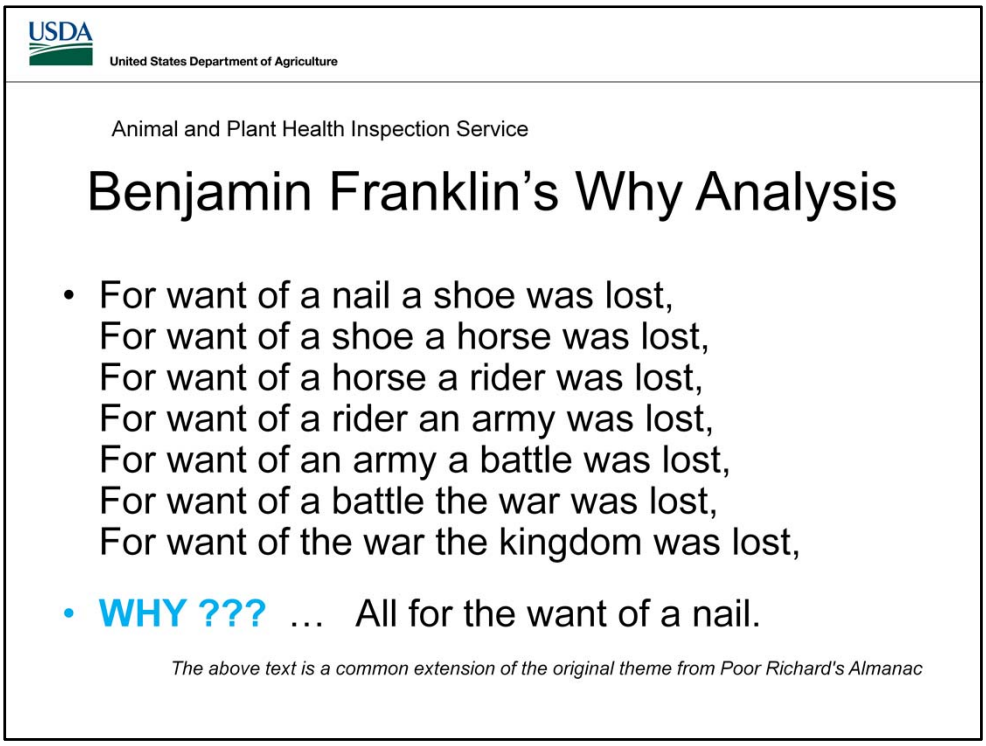
"5-Why" analysis is more than just a simple question asking activity. It requires the right people in the room discussing all of the possible root causes of a non-conformance.

The most effective analysis begins with gathering the right people.

A disciplined "**5-why"** approach will push individuals to think outside the box and reach a root cause where the team can take action to prevent the problem, instead of just treating symptoms.

Its important to discuss the issue with subject matter experts who can answer the "what if's"

It is also important to include people who do not have a vested interest in what the root cause may be - The manufacturers and maintenance crew of a plane wouldn't mind if the root cause of a crash was pilot error. Similarly a production site may believe low potency is the result of a QC testing issue, while QC may believe it's a production issue. All sides must be considered.

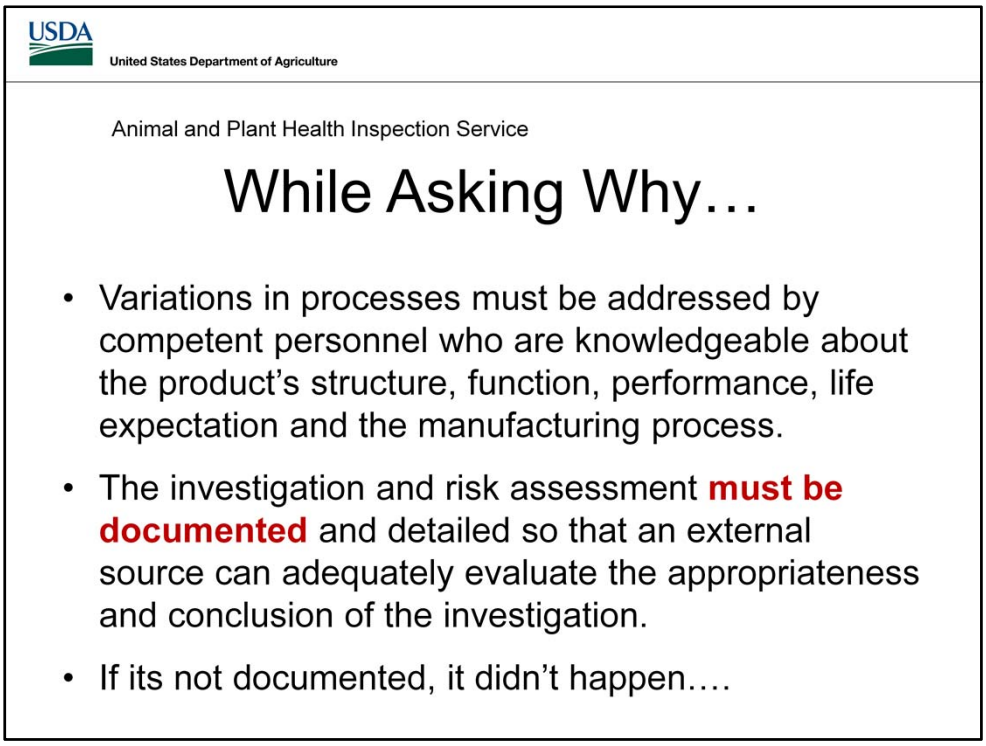


Using the analysis of asking why isn't new …. Ben Franklin published one in Poor Richard's almanac

Each domino knocked down another domino – until the kingdom was lost

Why ? - all for the want of a nail -

Sometimes you need to ask why more than 5 times, but you get the idea.

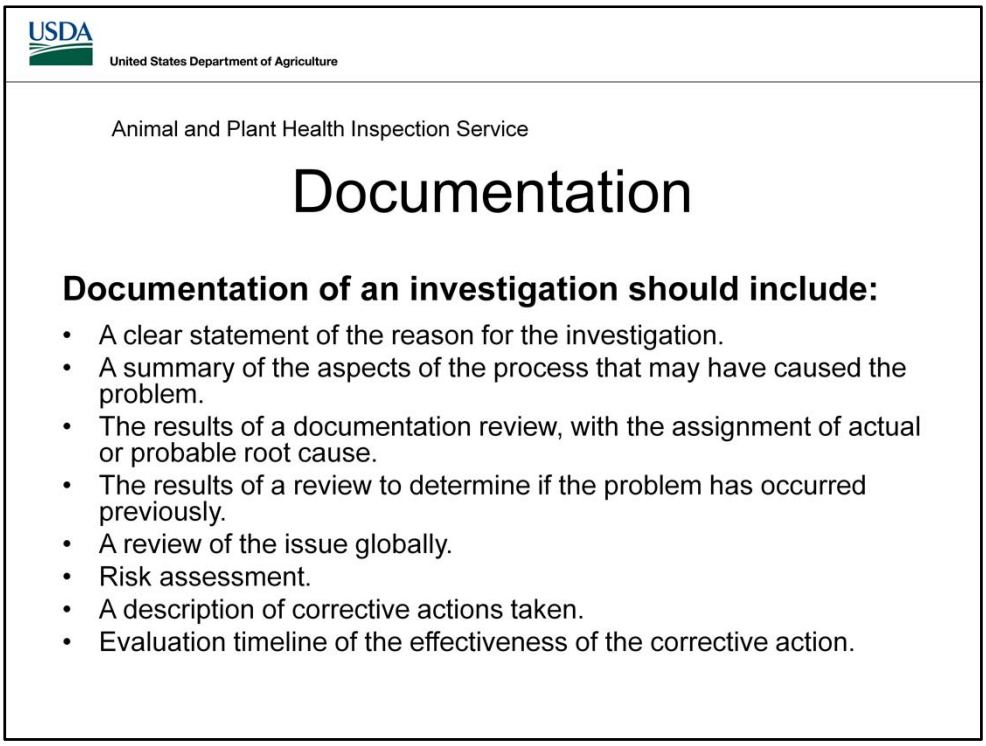


Variations in processes must be addressed by competent personnel who are knowledgeable about the product's structure, function, performance, life expectation and the manufacturing process.

Deviations from accepted scientific approaches must be justified in a manner considered generally acceptable by experts in that field.

The investigation and risk assessment must be documented and detailed so that an external source can adequately evaluate the appropriateness and conclusion of the investigation.

If its not documented, it didn't happen…



Deviations from accepted scientific approaches must be justified in a manner considered generally acceptable by experts in that field.
Proper documentation must include a clear statement of the reason for the investigation.

Do you know what happened?

Have you determined why?

How did you come up with the answer?

Has it happened before?

Has it happened somewhere else?

Is it possible it will it happen again?

What did you do to prevent it?

How do you know what you did will work? Can you prove it?

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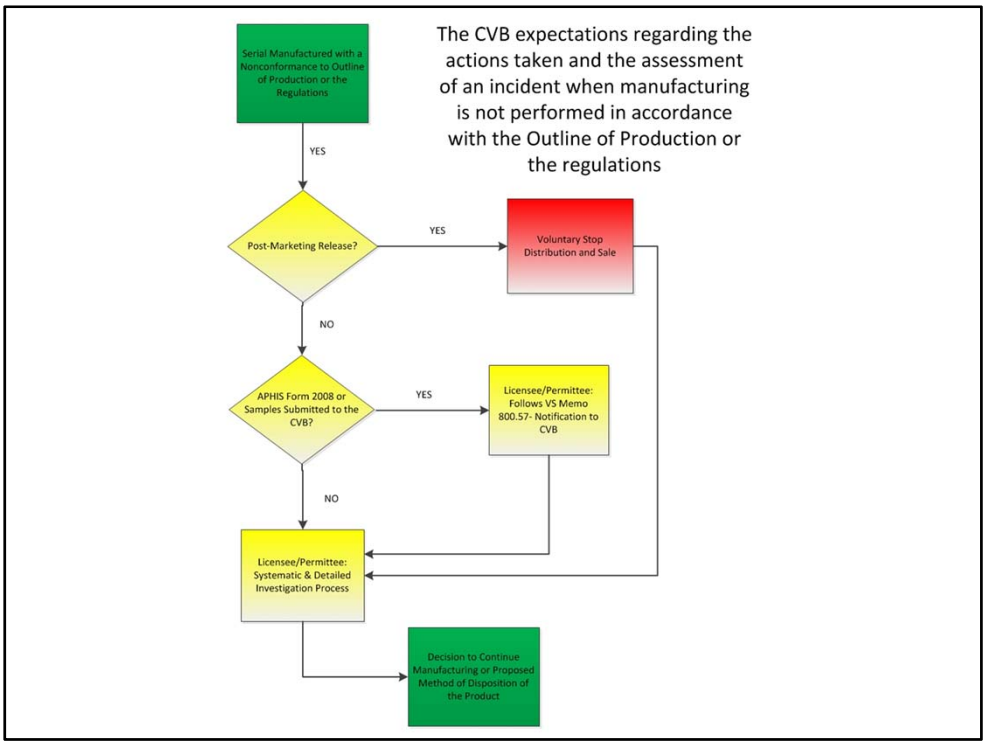
Documentation

Section 6 of the CVB Quality Management System Manual describes steps for a Corrective Action to be performed and documented

- Cite the specific requirement from which the deviation occurred
- Document the relevant information regarding the non-conformance
- Perform a root cause analysis – why and how did it occur
- Explore possible corrective actions and select a corrective action plan
- Monitor the effectiveness of the corrective action plan
- Document the above steps and have it reviewed by management



The flowchart shown outlines the CVB's expectations regarding the actions taken and the assessment of an incident when manufacturing is not performed in accordance with the Outline of Production or the regulations

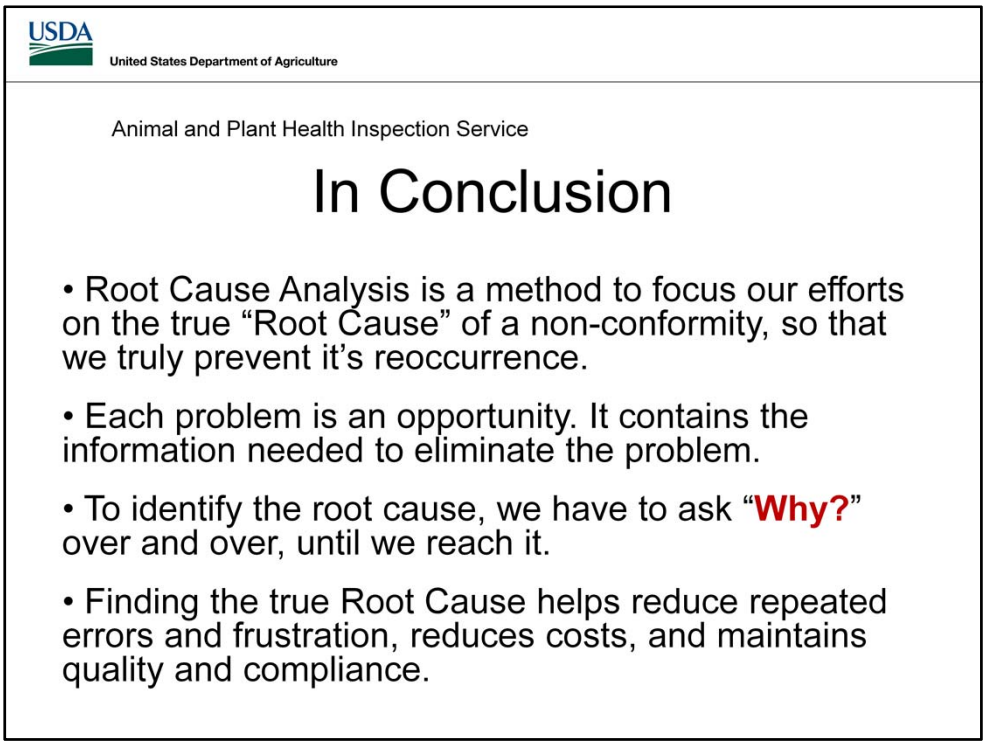
When a non-conformance to the Outline of Production or regulations is discovered, the firm should determine the status of the serial or serials effected.

If submission of the APHIS Form 2008 and/or samples to CVB has occurred, the firm must follow VS Memorandum 800.57 regarding notification of the event to CVB.

Serials which have been released by CVB are subject to Stop Distribution and Sale until an investigation or risk assessment has performed. If the firm chooses not to Voluntarily Stop Distribution and Sale and the CVB determines and adequate assessment has not been performed, the CVB may Mandate Stop Distribution and Sale.

Remember, since the purity, safety, potency, and efficacy of the product are based on the procedures approved in the Outline of Production , contrary to the judicial system where individuals are considered innocent until proven guilty, serials produced outside of the approved Outline of Production are considered to be worthless until proven otherwise.

Once the status of serial has been resolved, and the immediate fire of product effect on the public has been evaluated, the firm can perform a thorough, detailed investigation to evaluate continuation of production, and disposition of product produced.



It is CVB's expectation that the Licensee or Permittee should have a documented systematic approach to dealing with deviations to the Outline of Production, Special Outline or the regulations.

Any deviation, regardless of presumptive minor risk, must undergo the same detailed and documented product marketing risk evaluation.

Deviations discovered following release of products are subject to Stop Distribution and Sale of Product unless/until a risk evaluation has been performed.

All incidents where manufacturing was not performed in accordance with the Outline of Production or regulations must undergo a root cause analysis along with a corrective/preventive action.

The investigation and final quality risk assessment must be documented and detailed so that appropriateness of the conclusion of the investigation can be adequately evaluated.

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THANK YOU