



WATER SPRAY AND  
CASCADE SYSTEMS

REGULATORY ISSUES

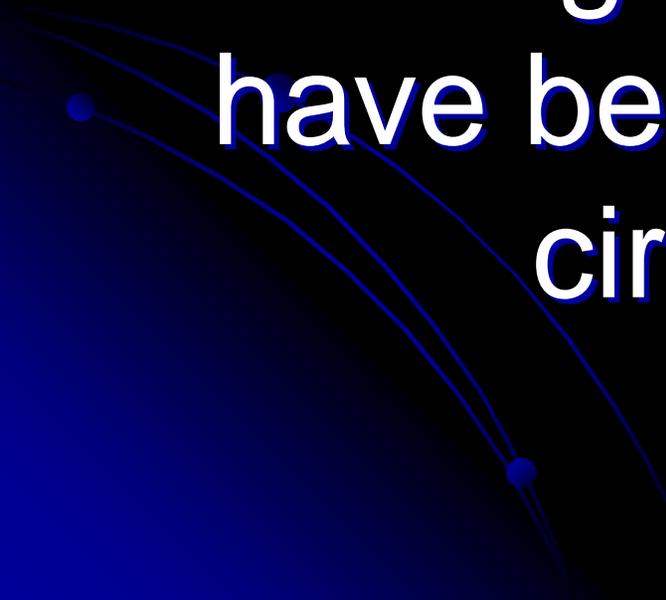
**THIS IS NOT GUIDANCE**

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PRESENTATION IS NOT  
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POSITION.....



# THIS IS NOT GUIDANCE

This presentation describes problems we have seen/are seeing and solutions that have been used in various circumstances.



# TWO PARTS TO REGULATORY OVERSIGHT

**PART 1 - FILING ISSUES**

**PART 2 - INSPECTIONAL  
ISSUES**

**PART 3 - CRISIS STRIKES**

# FILING ISSUES



# Top Reasons LACF Forms get Returned: Water Spray/Cascade

- Firms submit raw TD and HP data with no written summary of the test results expecting FDA to review the data and extract the results.
- Critical information, necessary for review, is not indicated such as 'time-steam-on' or program steps.
- TD has no diagram of where the TC's were placed.

# Top Reasons LACF Forms get Returned: Water Spray/Cascade

- Written summary of TD and HP results consist of very brief explanations of what happened during the test, without a full explanation of the test. Examples:
  - How nesting was considered
  - Fill weights of containers (% over)
  - Initial temperature of ballast during TD

# Top Reasons LACF Forms get Returned: Water Spray/Cascade

- The submissions do not include TD and HP tests to support the product being filed.
- Firms do not submit data which supports temperature distribution for all container types and sizes.
- Firms submit data which does not support the filed retort Come-Up-Temperature.
- The initial temperature of the product/ballast is not taken into consideration when performing TD test.

# Top Reasons LACF Forms get Returned: Water Spray/Cascade

- The TD tests do not include diagrams or photos of the retort showing the temperature sensors and valves.
- The TD test do not include diagrams or photos of the container racking systems including location the temperature sensors during the test.
- Firms who have previously submitted TD or HP data do not identify the SID number of that process form on the filing.

# Top Reasons LACF Forms get Returned: Water Spray/Cascade

- Firms attempt to complete a TD test using less than the optimum number of temperature sensors without explanation.
- Firms do not identify the slowest heating area of the retort.
- The submissions do not contain the raw temperature readings from each probe or at a minimum the min/max readings.

# Top Reasons LACF Forms get Returned: Water Spray/Cascade

- Some firms attempt to use average retort temperatures during TD and HP studies – Please identify and focus on the slowest heating location.
- HP is not conducted where TD identified the slowest heating location.

# Top Reasons LACF Forms get Returned: Water Spray/Cascade

- HP test for one product are applied to products which may have different heating properties.



# Top Reasons LACF Forms get Returned: Water Spray/Cascade

- The maximum residual air for flexible containers is missing.
- The maximum thickness in the retort for flexible containers is missing.
- Data from a very small number of temperature probes (sometimes as few as 1) are submitted in support of HP data.
- The minimum overpressure is not supplied.

# INSPECTIONAL ISSUES & OBSERVATIONS



# INSPECTIONAL ISSUES

**Computers:** Is your computer system validated?  
Does your computer generate any type of record?  
Do you have any documentation of validation?

## **Agitation:**

Is the agitation speed in the scheduled process?  
Is the rotational speed adjusted to that specified in the scheduled process?

# INSPECTIONAL ISSUES

## ***Steam Spreader:***

Are steam spreader holes clear?

Are spreaders in good condition and pointing upward?

## ***Water Drains (Recirculation Inlets):***

Are drains equipped with screens to prevent clogging?

Some drains screens are designed to prevent blockage.

# INSPECTIONAL ISSUES

## *Water Distribution:*

Are the spray nozzles/cascade holes free of debris/obstructions?

Is the filter/screen basket clear of debris/obstructions?

Is there mineral scale/buildup in the system?

Are all the nozzles in place?

Is the flow rate the same as that done in TD study?

# INSPECTIONAL ISSUES

## *Water Distribution:*

What is the pump capacity?

Is it the same type of pump as originally installed?

Is the flow rate indentified / measured as a critical factor?

Are flow rate problems identified as deviations?

# INSPECTIONAL ISSUES

## *Water Distribution:*

Where is the flow rate meter?

Is it accurate? And how do they know?

How do they know the water level?

Is the drain valve tight sealing?

- Is there a water level alarm?

## *Come-Up:*

How is come-up documented?

# INSPECTIONAL ISSUES

## *Come-Up:*

Are they following the come-up procedure utilized in the Temperature Distribution study?

Are all conditions the same?

Container Size/Type?

Water Flow/Circulation Rate?

Temperature?

Time?

Plumbing?

Racks? Stacking configurations?

# INSPECTIONAL ISSUES

## *Come-Up:*

Are come-up steps considered critical on the filing forms?

## *Crates and Racks:*

Are they following positioning configurations from the scheduled processes?

Are racks designed for uniform heat distribution and circulation around product containers?

# INSPECTIONAL ISSUES

## *Crates and Racks:*

Are divider/separators used to prevent shingling/mating/nesting of low profile pouches/containers?

Is nesting/mating/shingling possible?

Was nesting/mating/shingling considered as part of the process establishment?

Any sharp points on racks?

Any collapsed racks?

# INSPECTIONAL ISSUES

## ***Crates and Racks:***

Any repaired racks which could create heat distribution issues?

## ***Pressure Control – Air Inlets:***

Does the scheduled process establish overpressure requirements?

Is overpressure monitored?

Is compressed air inlet baffled/diffused/or heated before contacting containers?

# INSPECTIONAL ISSUES

## *Pressure Control – Air Inlets:*

Is the compressed air inlet the cold spot?

If the air inlet is the cold spot, could a pressure control issue lead to under-processing at that location (due to an unanticipated inflow of air)?

Are pressure drops considered process deviations?

How are they handled?

# **CRISIS STRIKES!**

*("OH #&@%\$!")*

CRISIS STRIKES!!!

*Stay Calm.....*

*Avoid reflex reactions.*



**CRISIS STRIKES!!!**

*Don't Touch  
Anything...*

*Until you have a plan as to what you're  
going to do.*

**CRISIS STRIKES!!!**

*How Are You  
Going to  
Evaluate the  
Deviation?*

*Think about how you can recreate the  
conditions observed.*

CRISIS STRIKES!!!

*Document the  
Conditions...*

Photo's, Process Records, Notes,  
Measurements, etc...

CRISIS STRIKES!!!

*If Necessary,  
Consult Your  
Process  
Authority.*



**CRISIS STRIKES!!!**

*Bracket the  
time period of  
the deviation.*

Identify, contain, retrieve suspect  
product....

**CRISIS STRIKES!!!**

*Think About  
"Corrective &  
Preventative  
Action"*





**YOUR  
QUESTIONS?**

