The Metrics that matter in Process Control Validations

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AGENDA

1. Background
2. Elements of a Validation Study
3. Validation Approaches
4. Summary

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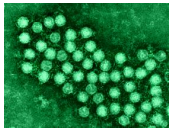
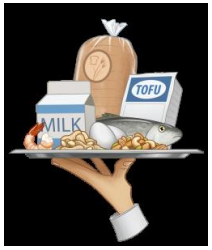
In HACCP hazards are characterized as

Biological hazards



Chemical hazards



Allergens

Mycotoxins

Physical hazards

(Source: StateFoodSafety.com)

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Background – Principles of HACCP

1. **Conduct a hazard analysis**
2. **Identify Critical Control Points**

   Note: For a “critical” control point, ALL product is exposed to this control mechanism.

3. **Establish critical limits** for preventive measures associated with each identified Critical Control Point
4. **Establish Critical Control Point monitoring requirements**

   refers to: Who, what, when, how to ensure control to be able to identify when there is a loss of control

5. **Establish corrective actions** to be taken when monitoring indicates that critical limits are not met
6. **Establish** procedures for identifying that the HACCP system is working correctly - **Verification / Validation**
7. **Establish effective record-keeping procedures**

Background – Definition of „Validation“

Codex Alimentarius “GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES” (2008):

“Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.”

Validation focuses on:

- the collection and evaluation of scientific, technical and observational information to determine whether control measures are capable of achieving their specified purpose in terms of hazard control
- measuring performance against a desired food safety outcome or target, in respect of a required level of hazard control

Examples of existing Regulations / Guidelines

- **Low-Acid canned food regulations / guidelines:** "12D *Clostridium botulinum* cook", FDA 21 CFR 108 (USA)
- **Milk Pasteurization**: Codex Alimentarius (CAC/RCP 57-2004) CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS „The application of heat to milk and liquid milk products aimed at reducing the number of any pathogenic micro-organisms to a level at which they do not constitute a significant health hazard." „As *C. burnettii* is the most heat-resistant non-sporulating pathogen likely to be present in milk, pasteurization is designed to achieve at least a 5 log reduction of C*. burnettii* in whole milk (4% milkfat)."
- **Almond Processing** (USA): 7 CFR 981.442 USDA (minimum 4-log reduction of *Salmonella* bacteria in almonds)
- **Nuts Processing** (USA): GMA " Industry Handbook for the Safe Processing of Nuts" (recommendations for a 5 log reduction of *Salmonella* bacteria on nuts)
- **Juice Processing** (USA): Guidance for Industry: Juice HACCP Hazards and Controls Guidance (The 5-log pathogen reduction requirement in 21 CFR 120.24..)
- **Egg Processing**: International Egg Pasteurisation Manual
- **Meat Processing**: USA - FSIS 64 FR 732, UK – ACMSF

Process Validation

! Even with available guidelines / regulations, a risk assessment should be carried out to determine appropriateness of applied values.

To be considered: target organisms, origins, further contamination / potential growth, prevalence, final products, consumption patterns / exposures

Furthermore, guidelines / regulations are not available for all products:

e.g. cocoa, coconut, spices, seeds, herbs, fruits and vegetables

Elements of a Validation Study

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Elements of a Validation Study - Process

Do you know your process??

Is it…

Described: Operational Procedures & Limits

Controlled: Operational Limits are met (includes reliable measurements & corrective actions)

Reproducible: Trend Analysis shows no drift

Which parameters need to be considered to control a given hazard?

Moisture (Steam, Water additions)

Time (Speed, Type of material flow – laminar – turbulent)

Temperature (even distribution / cold spots)

Pressure / Gas / Irradiation

Weight and potential others (instrument specific)

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Elements of a Validation Study – Food Matrix




Do you know your product??



Intrinsic Product Characteristics and their variability:

- Moisture / Water Activity
- Composition: Fat / Protein / Sugar / Salt / Preservatives
- pH

Physical Product Characteristics and their variability :

- Density / Size
- Surface
- Initial ingoing temperature
- Initial Form (e.g. raw or pre-processed)
- Final Form (e.g. pieces, whole, pastes)

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Elements of a Validation Study – Conditions

Even under variable conditions the process shall control the biological hazard.

Therefore, variabilities of conditions need to be taken into account such as

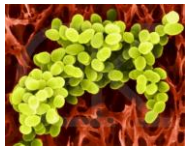
Process variables, e.g.

- control of startup & end of run
- time
- temperatures / temperature distribution
- moisture
- mixing efficiency (surface exposure)
- weight
- Divert / Shutdown features / alarm settings

Product variables, e.g.

- fat / sugar / salt
- water content
- sizes
- Temperature

Elements of a Validation Study – Target Pathogen


- Which biological hazards are considered significant and must be addressed / controlled in the process?

Leads to

What is the **target pathogen** to be controlled by the process?

“target pathogen” referring to the organism(s) which express the highest resistance to the treatment / process used, and thereby controlling those would enable control of others.

- Are prevalence data known for that organisms, i.e. levels / likelihood of occurrence?

- Is there a surrogate available which could be used in the industrial process?

„surrogate“ referring to a non-pathogenic organism, which behaves equivalent / similar to the target pathogen in the process.

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Validation Approaches

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Validation Approaches – processing parameters

Advantages

- ☺ no microbiological laboratory required
- ☺ immediate result readings / discussions
- ☺ Can be easier to perform / repeat – depends on equipment design & monitoring capabilities !

Challenges

- ‼ Validity depends on scientific basis used
- ‼ Critical Parameters need to be measurable in industrial process
- ‼ Equipment needs to be accessible for the validation

Validation Approaches – Surrogate Microorganisms

Advantages

- ☺ direct reading of lethal step effectiveness (log-reductions achieved)
- ☺ validation data based on inoculated material

Challenges

- ‼ Surrogate has to be adequate for the purpose (mimics target pathogen – potentially adaptation to matrix required, introduces no risk)
- ‼ (Heat) resistance of the organism has to be confirmed for each trial
- ‼ No change in product characteristics due to inoculation
- ‼ Requires specific (transport) controls to be put in place
- ‼ Requires microbiological laboratory / external services
- ‼ Consider Variability of method of detection
- ‼ Requires possibility to confine inoculated material

Further Considerations

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Considerations for existing Equipment

Equipment in Food processing has a **long shelf life**

↳ At time of installation might not been considered a control step

Consequence:

☹ No adequate monitoring / control of processing parameters installed that time

☹ No diversion / corrective actions in case of under processing foreseen

☹ Cleanability only designed for quality reasons

☹ Segregation before and after processing often inadequate to ensure food safety

Considerations for existing Equipment

Challenge:

- Validation of such equipment / processes
- Establishing of real critical parameters for food safety
  Example: Is batch weight critical?
- “Retro-Fit”, i.e. re-design & install adequate monitoring sensors in such equipment
- Zoning / Segregation challenges

Considerations for existing Equipment

Examples of potentially required modifications:

✓ Installation of new (Temperature) sensors

✓Evaluation / Determination of product flow

✓Installation of divert mechanisms

✓Evaluation of common equipment pieces after processing to determine cleaning requirements

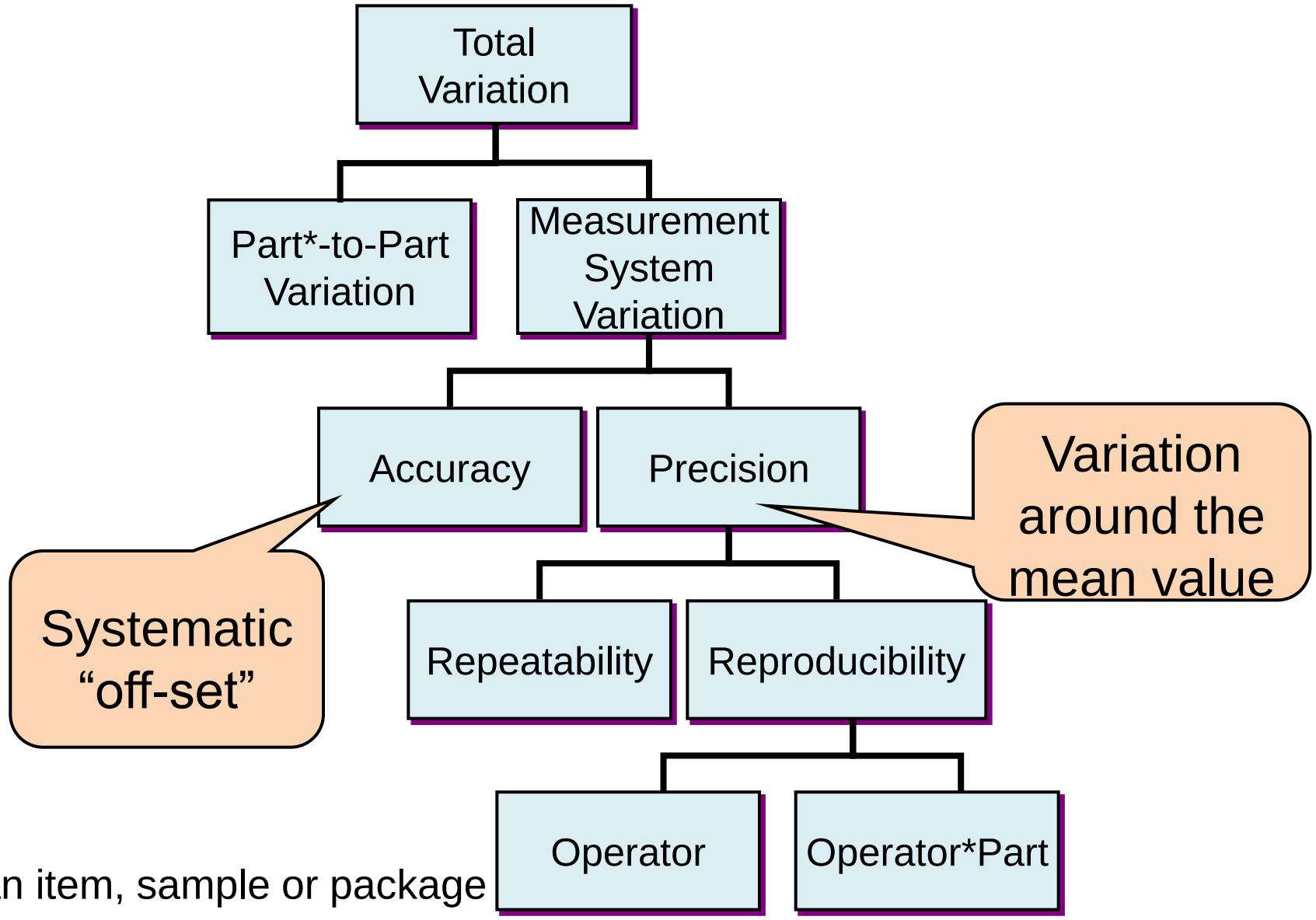
✓Segregation between raw and processed goods

Considerations for NEW Equipment

Get The Design Right!

Statistical Considerations

Sources of Variation



* Part can be an item, sample or package

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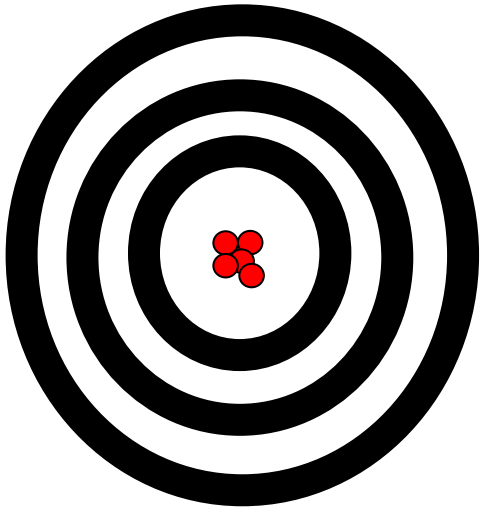
Statistical Considerations

Types of Measurement System Variation

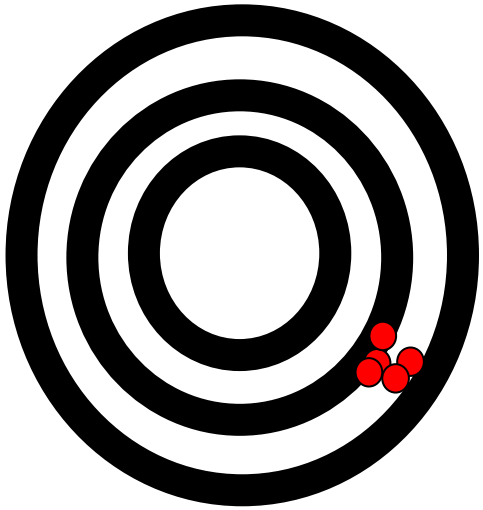
Accuracy (or bias*) describes the difference between the average measurement and the part's actual value.

Precision of a measurement system, related to reliability, is the degree to which repeated measurements under unchanged conditions show the same results.

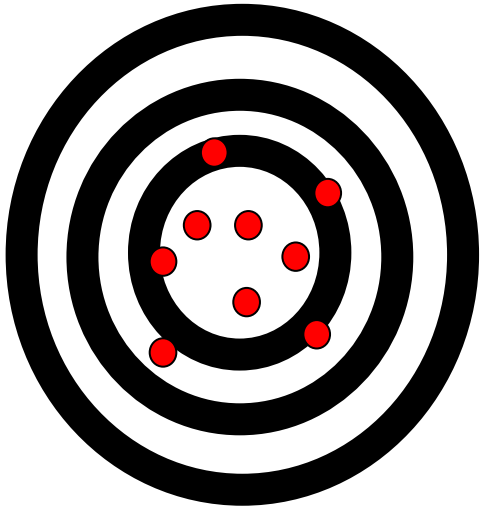
Statistical Considerations



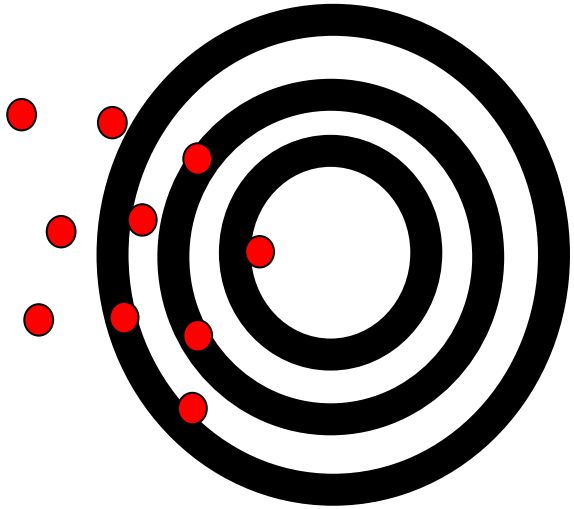
Unbiased and Precise



Precise but Biased



Unbiased but not Precise



Biased and not Precise

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Summary

Validation Study

Who do I need to sucessfully perform a validation?

Engineering / Operators / R&D / Quality management to consider

- Process and process design
- Products
- Monitoring
- Record Reviews

Technical Experts (e.g. Microbiologists) to consider

- hazard identification
- data collection
- sampling
- define relevant treatment conditions / parameters
- data interpretation
- result reporting

Statisticians to consider

- experimental Design
- data collection
- data interpretation

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Validation Study

What needs to be considered / agreed on as part of results?

Process

- Startup and end of run adequacy,
- Process reproducability
- Review Monitoring records

Monitoring Methods

- Which (target) parameters will be monitored,
- What are the critical values to be achieved to ensure control of hazard,
- When during the process they will be monitored,
- how these parameters will be monitored, and
- at what frequency

Corrective Actions

- Which paraneters are triggering an alarm,
- What are the design features of corrective actions (e.g. stop process, divert)

Validation Report

Shall include (or reference)

- Hazard Analysis
- Process description
- Product Description
- Experimental Design
- Study Results
- Conclusions (final outcome, summary, recommendations / design of future monitoring / alarms / corrective actions)
- Contributors (Experts involved)

The report shall be available at the site(s) as part of their Food Safety Management.

„Watch Outs“

- ☺ Get a project proposal up front
- ☺ Have a 3rd party technical expert review for technical merit and completeness of the validation
- ☺ Cover intrinsic parameter variability (e.g. temperatures moisture, pH)
- ☺ Include startup / end of run procedures in the consideration of the experimental design
- ☺ In case of Surrogate usage: ensure suitability of surrogate for each run / test

Use all Resources:

Get agreement and support from management – since budget and changes in work flows may be needed!

There are so many excellent resources for validation !

- Talk to Laboratory Services,
- Connect to other manufacturer,
- Connect to Research Associations,
- Connect to Trade Associations

Use learnings from former process deviations to improve the process!

Only outsource what you know – and not, what you do not know!

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