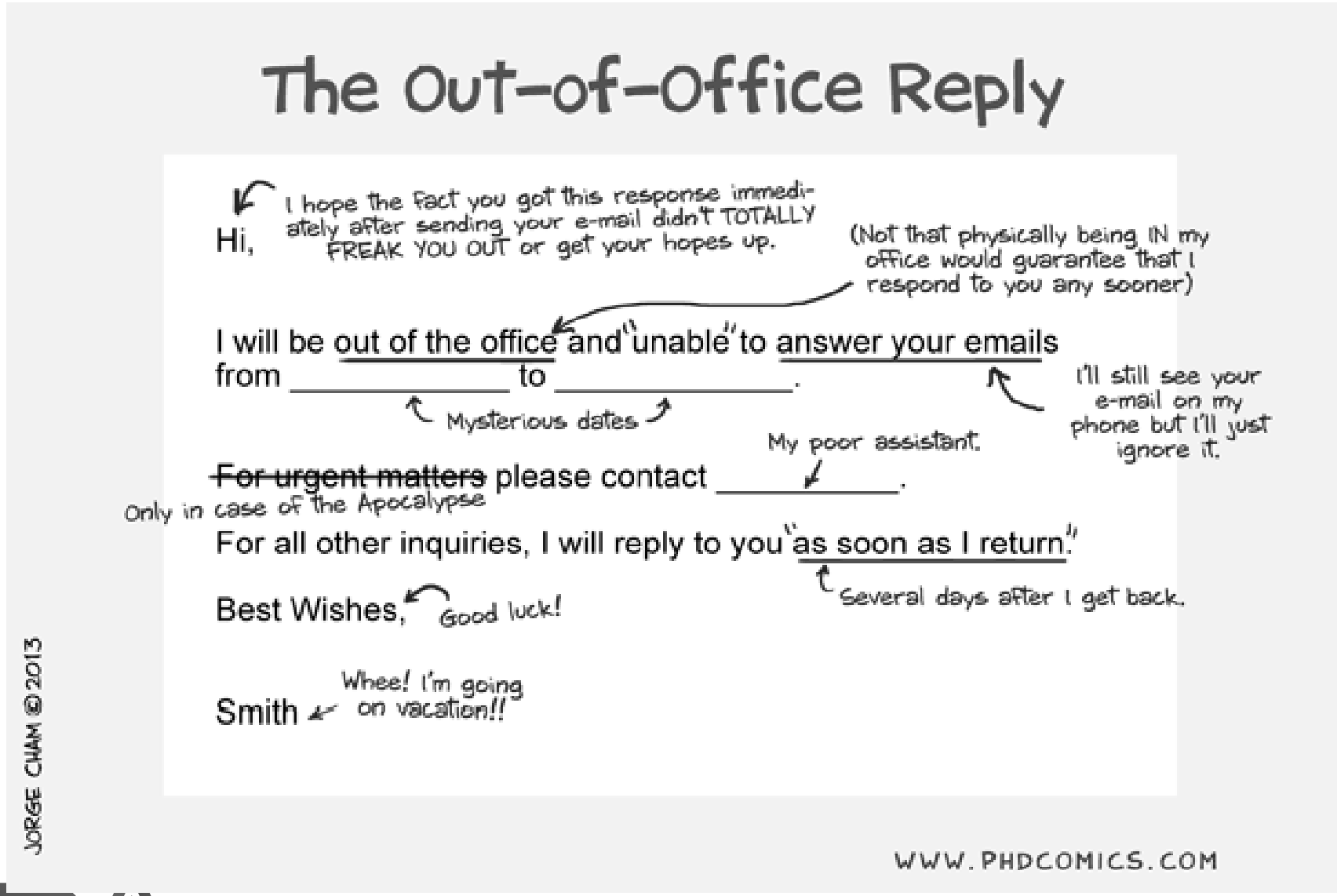
FDA Perspective on Validation

IFTPS 2013 Annual Meeting
March 5, 2013



(PhD Comics, 2/27/13)

Definitions

NACMC for Foods - Pasteurization

Validation is the collection and evaluation of scientific and technical information to determine if the treatment when properly applied, will effectively control the hazard.

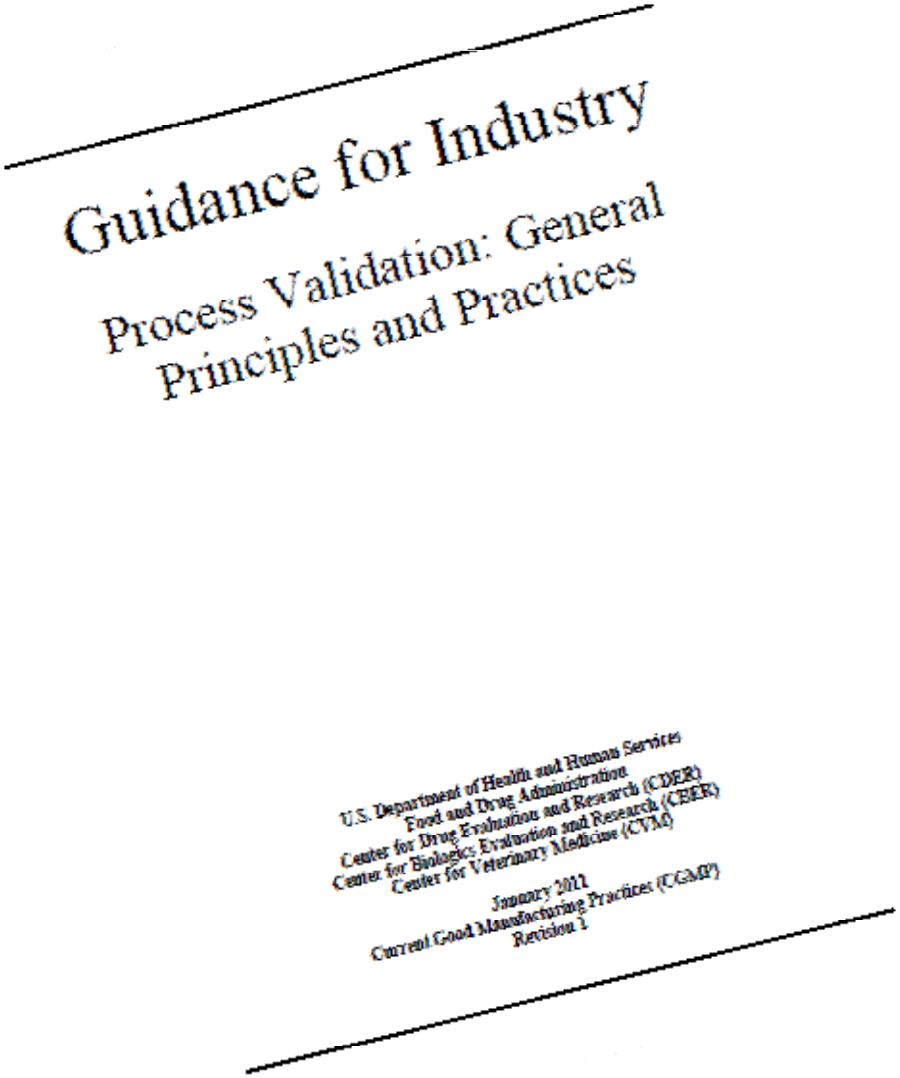
J. of Food Protection, Vol 69, No. 5, 2006, 1190-1216

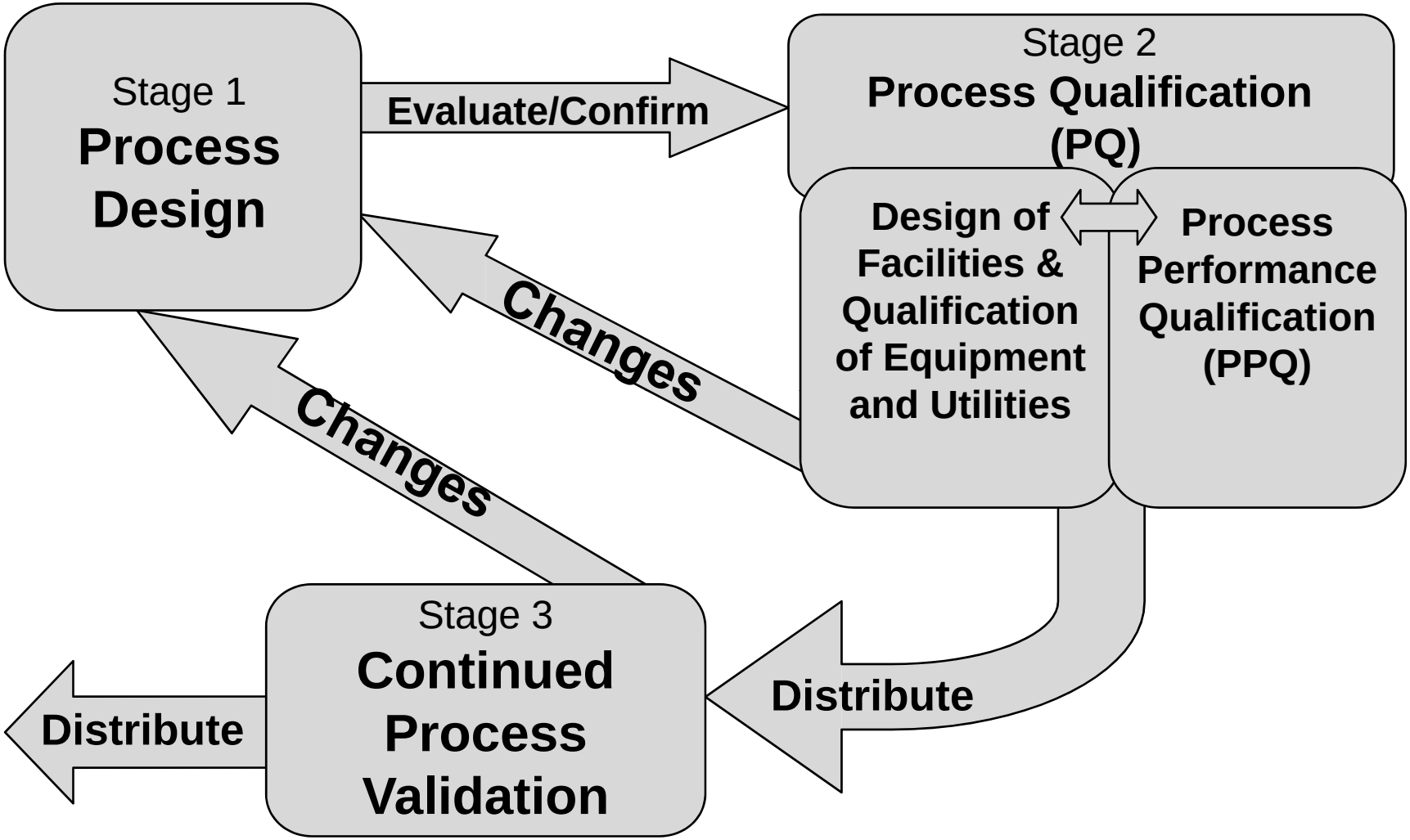
CODEX

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

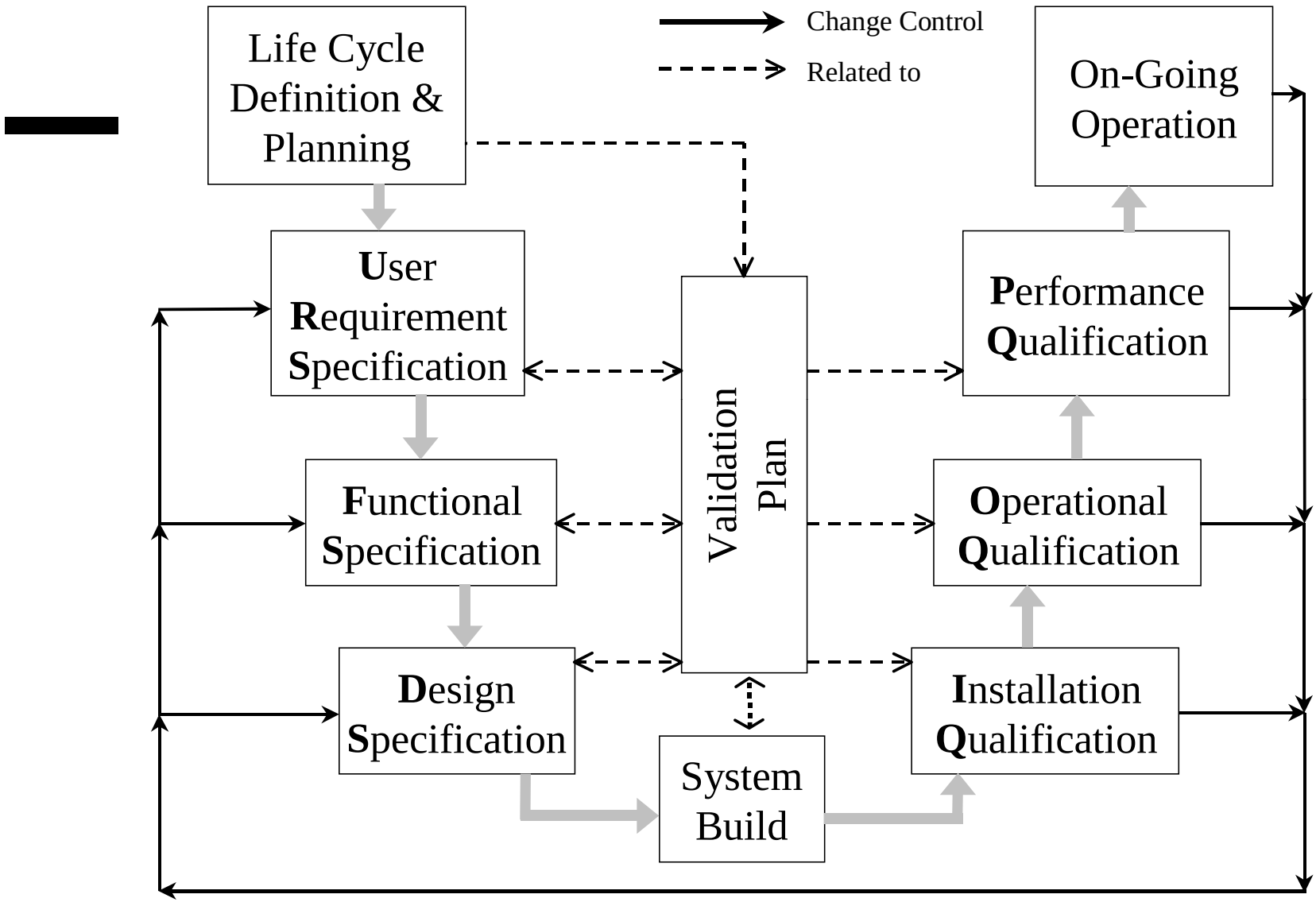
Guidelines For The Validation of Food Safety Control Measures, CAC/GL 69 - 2008

Process Validation:
The collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality products





G. E. McNally, FDA, May 6, 2011



NFPA Bulletin 43-L

FSMA Preventive Controls Proposed Rule

"FDA is proposing to define the term 'validation' to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards."

Federal Register, Wednesday, January 16, 2013, Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

What regulations require validation?

What Systems Need Validation

- Juice products 21 CFR 120.3(p) – HACCP plan
- There is no direct regulatory requirement for the validation of a system (considering the restriction placed on part 11)
- Validation as a requirement is implied for many regulations (infant formula, seafood, low-acid canned foods, acidified foods, and now preventive controls)
- Proposed preventive controls rule (21 CFR 117.3, 117.150(a), 117.155(a)(2))

“Validation” - Summary

1. Process operates as it was intended and is able to control the hazard
2. Scientific and technical documentation of sufficient evidence (high degree of assurance)

Validation Characteristic 1

1. Process operates as it was intended and is able to control the hazard

Validation Characteristic 1

- Selecting scientific expertise

The Expanding Role of the Validation Group

Author: Paul L. Pluta

"US and international documents issued over the past 10 years have signaled a changing approach to pharmaceutical manufacturing directly impacting validation. These signals culminated in the November 2008 US Food and Drug Administration process validation draft guidance. The guidance integrated the ideas of quality by design (QbD), ICH, and FDA, and introduced the lifecycle approach to process validation. This approach includes product and process development supportive to validation (Stage 1). It further includes post-validation monitoring and maintenance of the validated state (Stage 3). **Validation is no longer a single event in the product timeline. Validation is the focal point in a comprehensive and coordinated effort that extends over the entire product lifecycle and requires involvement of multiple groups in the organization.**

http://www.gxpandjvt.com/ivtnews/templates/IVTNews.aspx

Validation Characteristic 1

- There needs to be a group identified that has the expert knowledge associated with procedure/practice/process risks
  - Prefer past experience
  - Education specific to your procedures/practices/processes
  - Knowledgeable in validation science

Validation Characteristic 1

- Selecting scientific expertise
- Risk assessment of procedures, practices, and processes

Risk Assessment/Evaluation[1]

- Hazard identification
- Exposure assessment
- Hazard characterization
- Risk characterization

[1]Principles and guidelines for the conduct of microbiological risk assessment CAC/GL-30 (1999)

Validation Characteristic 1

- Selecting scientific expertise
- Risk assessment of procedures, practices, and processes
- Validation plan

Making Bad Validation Plan Assumptions

- The process behaves the way that I believe (or think) it behaves
- The validation plan used before will work here
- My collected samples all represent the same expected treatment
- My system is well behaved and will never change
- The process will follow the mathematical procedure I will use to analyze my data

Validation Characteristic 2

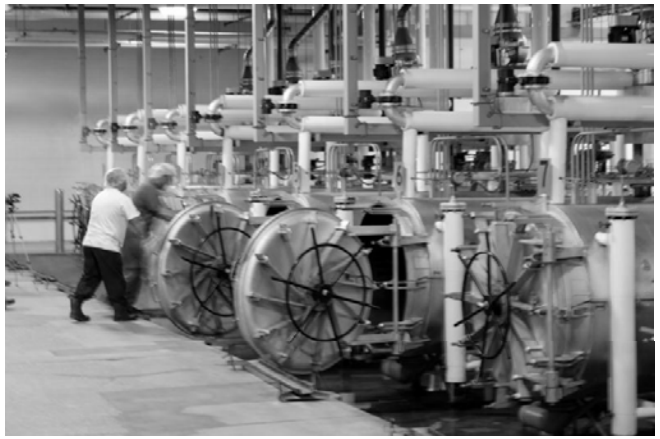
- Scientific and technical documentation of sufficient evidence (high degree of assurance)

Validation Characteristic 2

Overall Validation Documentation

- Operational procedures – Standards, SOP's, best practices
- System flow chart/process description
- Target hazard identification
- Level of control necessary (FSO, PO)
- Demonstration of process effectiveness
- Verification – continue process control

Demonstration of Process Effectiveness



Operational Verification Results

- Verify proper processing equipment operation/installation
- Verify proper sensor operation
- Ability to replicate results
- Ability to record necessary process conditions
- Take into account potential process time durations
- Take into account possible cleaning malfunctions

Challenge Studies

- When conducting challenge tests, conditions for critical elements should reflect the “worst case” expected operating conditions
- It is useful to “test to failure”
  - Understand the boundaries between inactivation and survival
  - Provide information for deviation evaluation

Documentation

- Data collected needs to be clear and supportive of the process establishment conclusions
- Data collected must support the analysis procedures used

Continued Process Validation

"Verification"