Food Safety Process Validation

ASTA – Regulation/Legislation Workshop

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What Do We Mean by Validation?

Process Control Validation

- The process of establishing documented evidence that provides a high degree of assurance that a specific process or system will consistently produce a product meeting its predetermined specifications and quality attributes.

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A WHO Guide to GMP Requirements (Part 2 – Validation)

- Validation is defined as the establishing of documented evidence which provides a high degree of assurance that a planned process will consistently perform according to the intended specified outcomes.

National Advisory Committee on Microbial Criteria 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

“Validation” - Summary

- Able to deliver its intended specifications
- High degree of assurance
- Documentation

How Do We Define Specifications and Get High Assurance?

Outline

- Pre-validation
- Process validation
- Post-validation

Pre-Validation

Pre-Validation

- Selecting scientific expertise
- Validation plan
- Risk assessment of product/process

Expert Help

- There needs to be an individual/group identified that has the expert knowledge associated with the risks (product/process)
  - Prefer past experience
  - Education specific to your product/process
  - Knowledgeable in validation science

"FAA certified pilot"

Validation Plan

- System flow chart
- List of the critical requirements
- Responsibility/Authority matrix
- Traceability matrix
- Change control
- Reviews/Audits
- Validation flow chart

Risk Assesment[1]

- Hazard identification
  - Past outbreaks
  - Product similarities
- Exposure assessment
  - H_o-initial load
  - Consumer patterns
  - Complete product pathway

Risk Assesment[1] – Cont'd

- Hazard characterization
  - Dose response
- Risk characterization
  - Likelihood and severity of adverse effect
  - Uncertainties

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

Food Safety Objective

$$H_o - \sum R + \sum I \leq FSO$$

$$FSO \leq ALOP$$

Outcome of Pre-Validation

- Expert team
- Validation plan
- Level of hazard – H_o
- Acceptable level of protection (ALOP)

Process Validation

Process Validation

- Functional/Design specifications
- Validation protocol
- Identification of critical points
- Specification of critical limits
- Specification of performance standards
- Measurement of process to deliver necessary dose

Production/Laboratory 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

Establishing Performance Standards

- Identification of surrogate organism
- Setting level of treatment required
  - Surrogate vs. organism of concern
  - End target or log reduction
- Biological validation/Model estimation

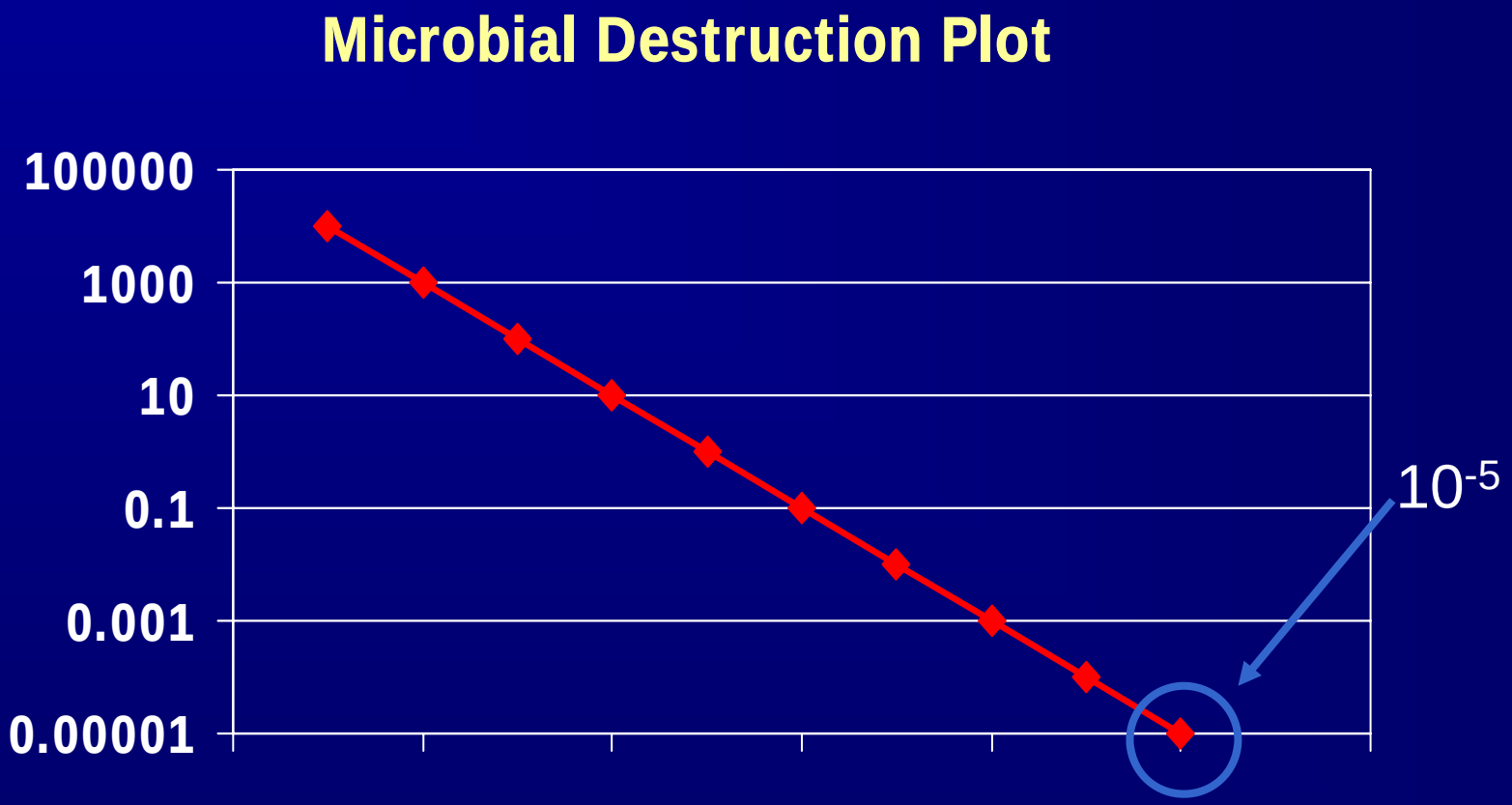
Desirable Surrogate Traits

- Nonpathogenic (BSL level 1)
- Stable kinetic characteristics
- Known enumeration/recovery procedures
- More resistant to process than pathogen of concern (optimum ~2x)
- Similar kinetics of pathogen of concern
  - Requires prior knowledge of pathogen of concern

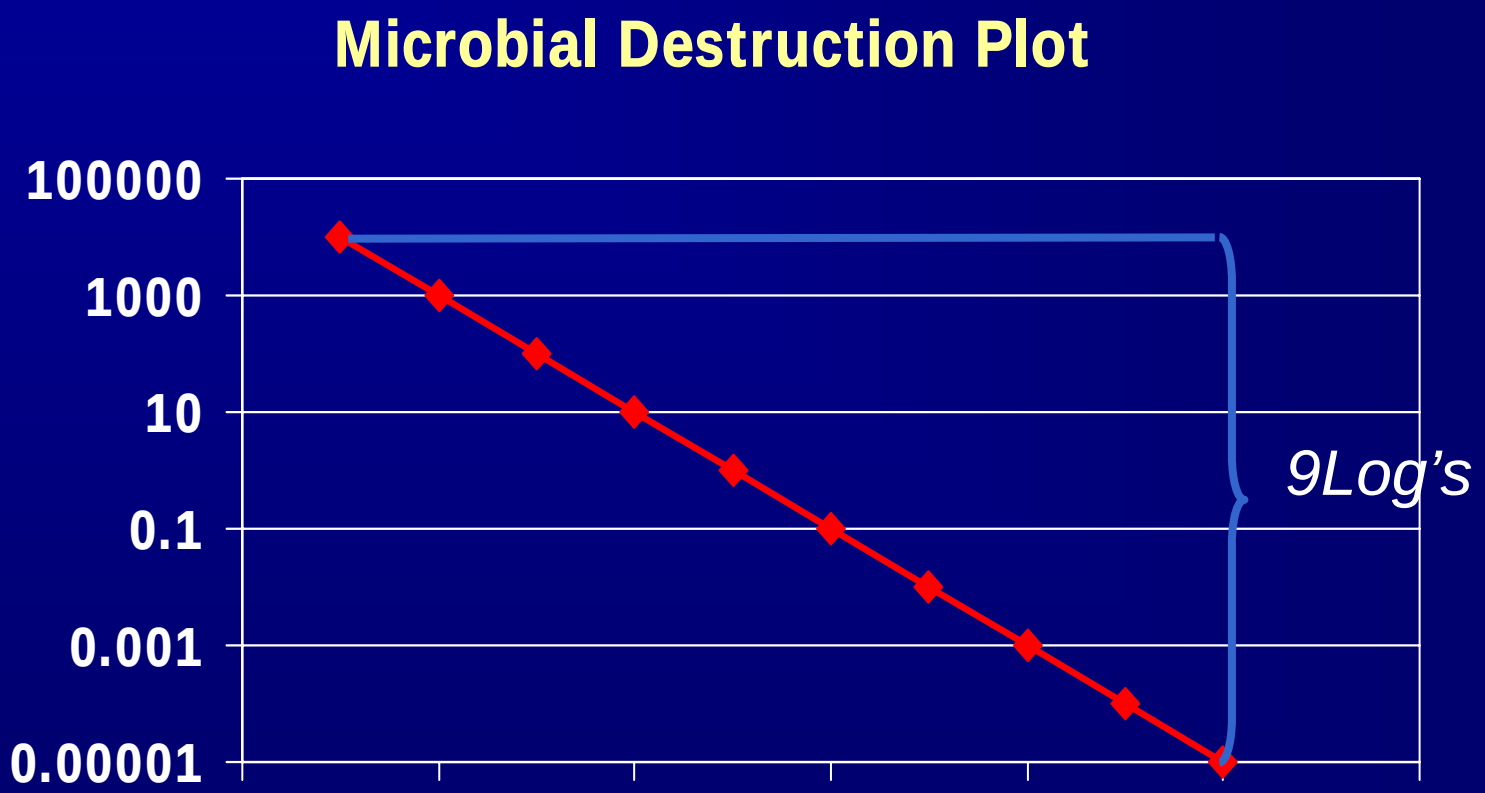
Kinetics of Surrogate

- Thermal effect/Growth history
- Osmotic effect
- Surface attachment
- Influence of pH, Aw, salt, etc.
- Processing history (i.e., stress adaptation)
- Chemical resistance
  - H_2O_2, O_3, sanitizers
  - Acidulants (citric, malic, acetic acid, etc.)

End Target Level of Safety



Performance Standard – Log's



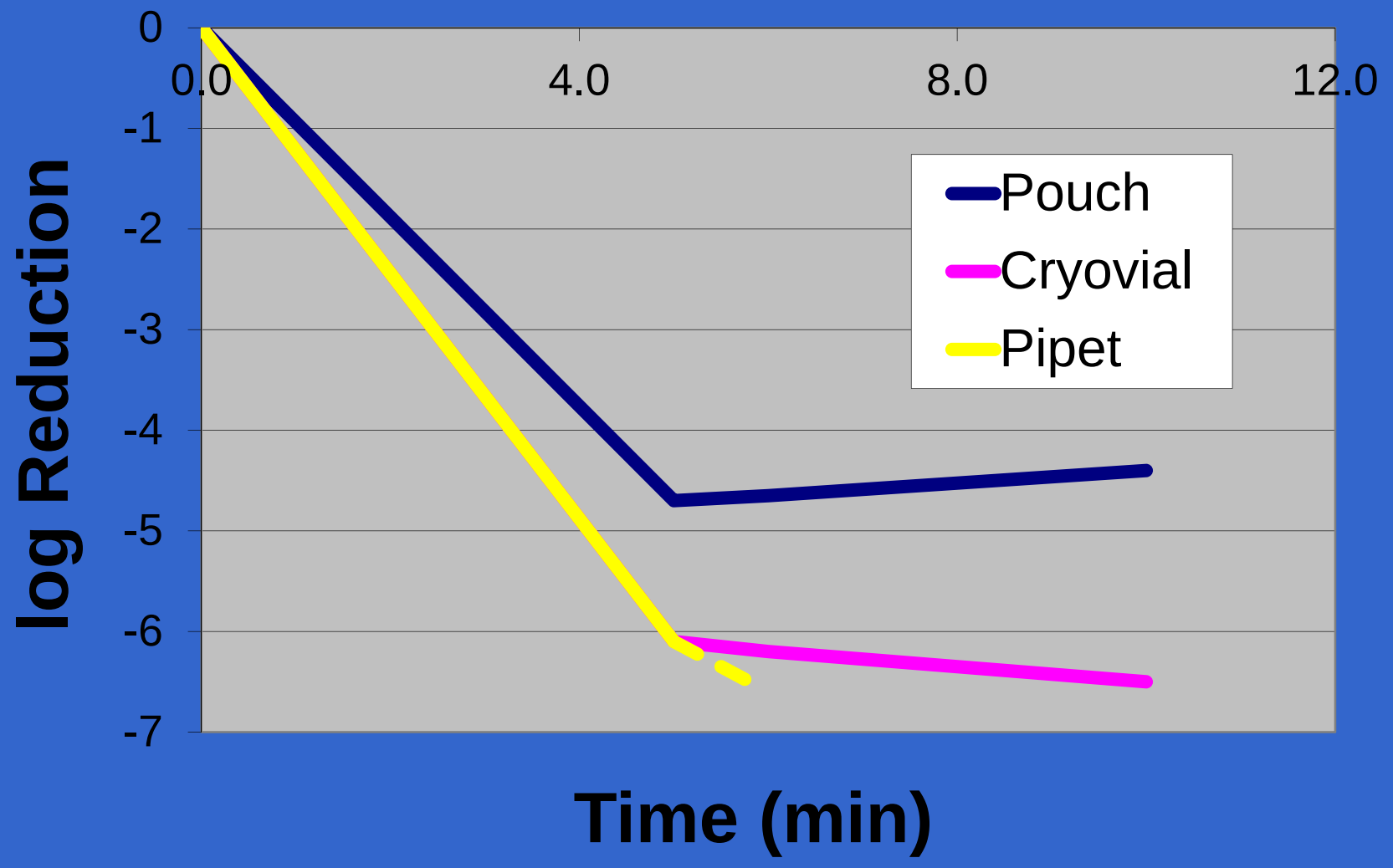
Examples – Log Reduction

- 5 log reduction for fruit and vegetable juices
- 5 log reduction for in-shell egg pasteurization

Biological Challenge Study

- Pathogen growth inhibition study
  - Most likely need to use organism of concern
  - Control of product composition/storage condition
- Pathogen inactivation study
  - Number of strains?
  - Inoculum levels and method of inoculation?
  - Enumeration procedures?
  - Duplication of processing conditions?
  - Interpretation of results

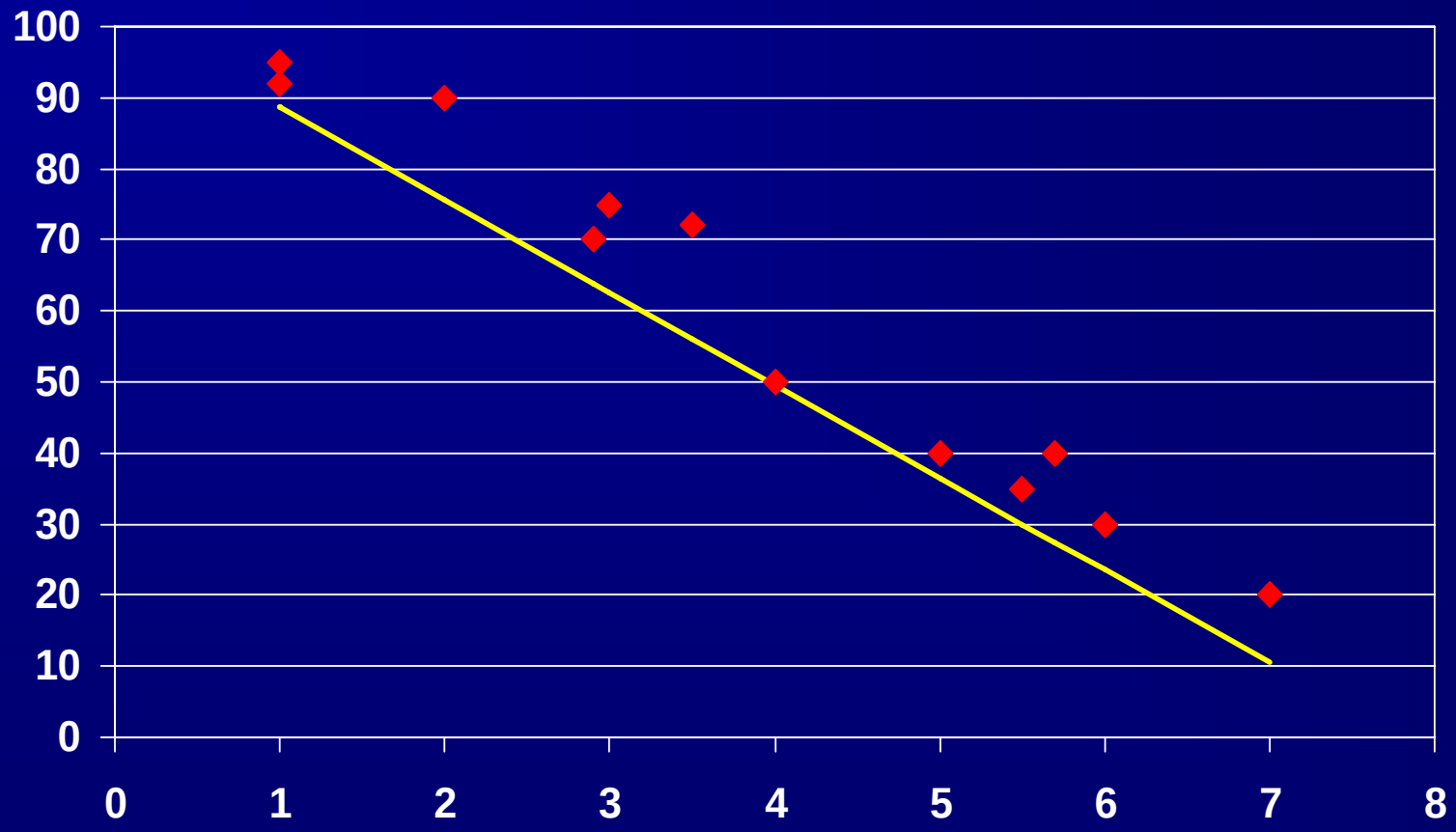
NACMCF – J. of Food Protection Vol. 73. No 1. 2010, 140-202


HPP of C. bot strain 69-A (118°C, 101.5 kPSI)
log Reduction
0
-1
-2
-3
-4
-5
-6
-7
0.0
4.0
8.0
12.0
Pouch
Cryovial
Pipet
Time (min)

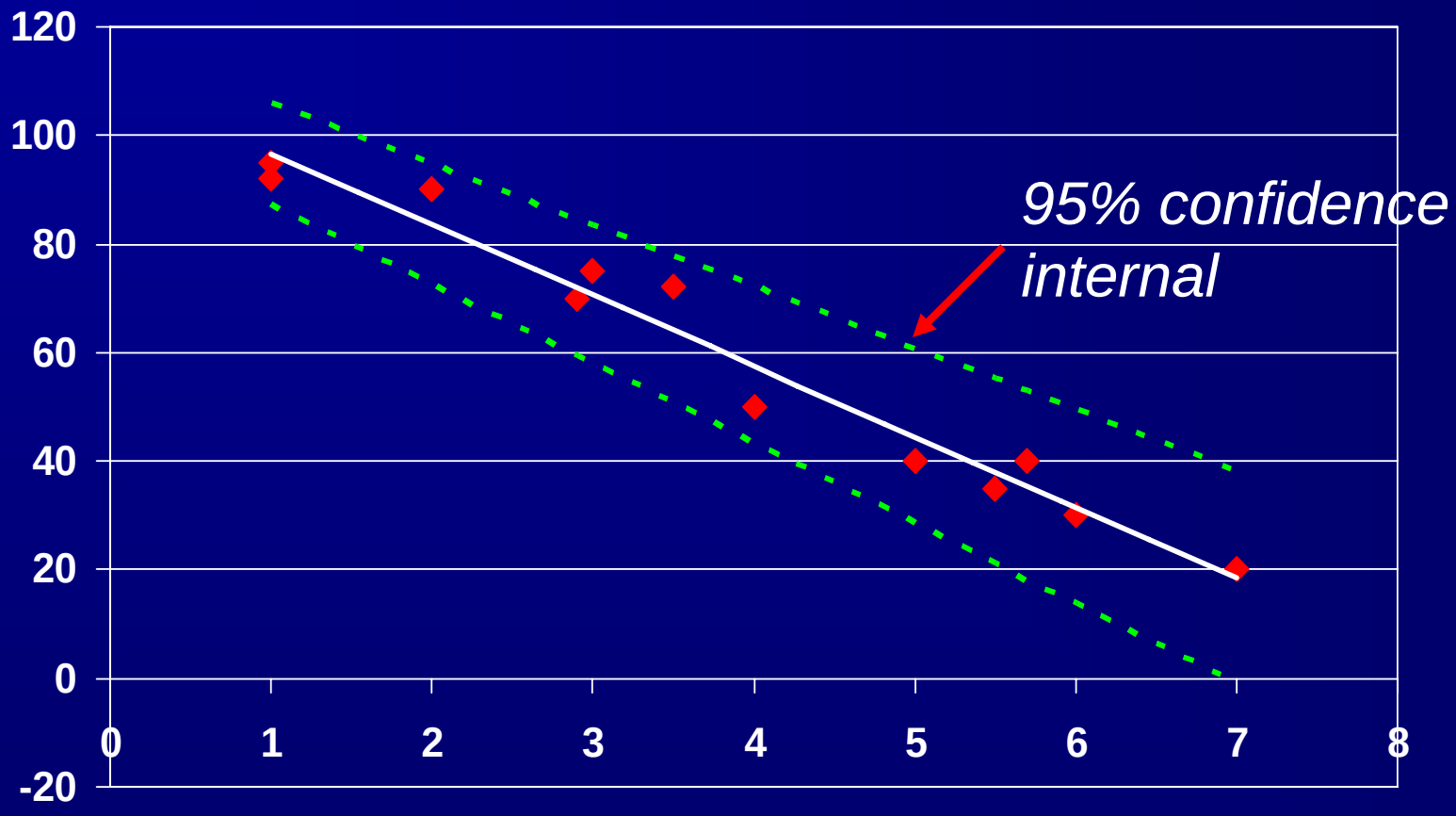
Worst Case vs. Confidence Interval

- Both assume sufficient data has been obtained to describe the destruction rate
- Worst case doesn’t allow for estimation of possible process condition failures (i.e., probability of a failure)
- Worst case attempts to make sure process results are on the safe side
- New statistical tools allow for better estimations of the likelihood of results

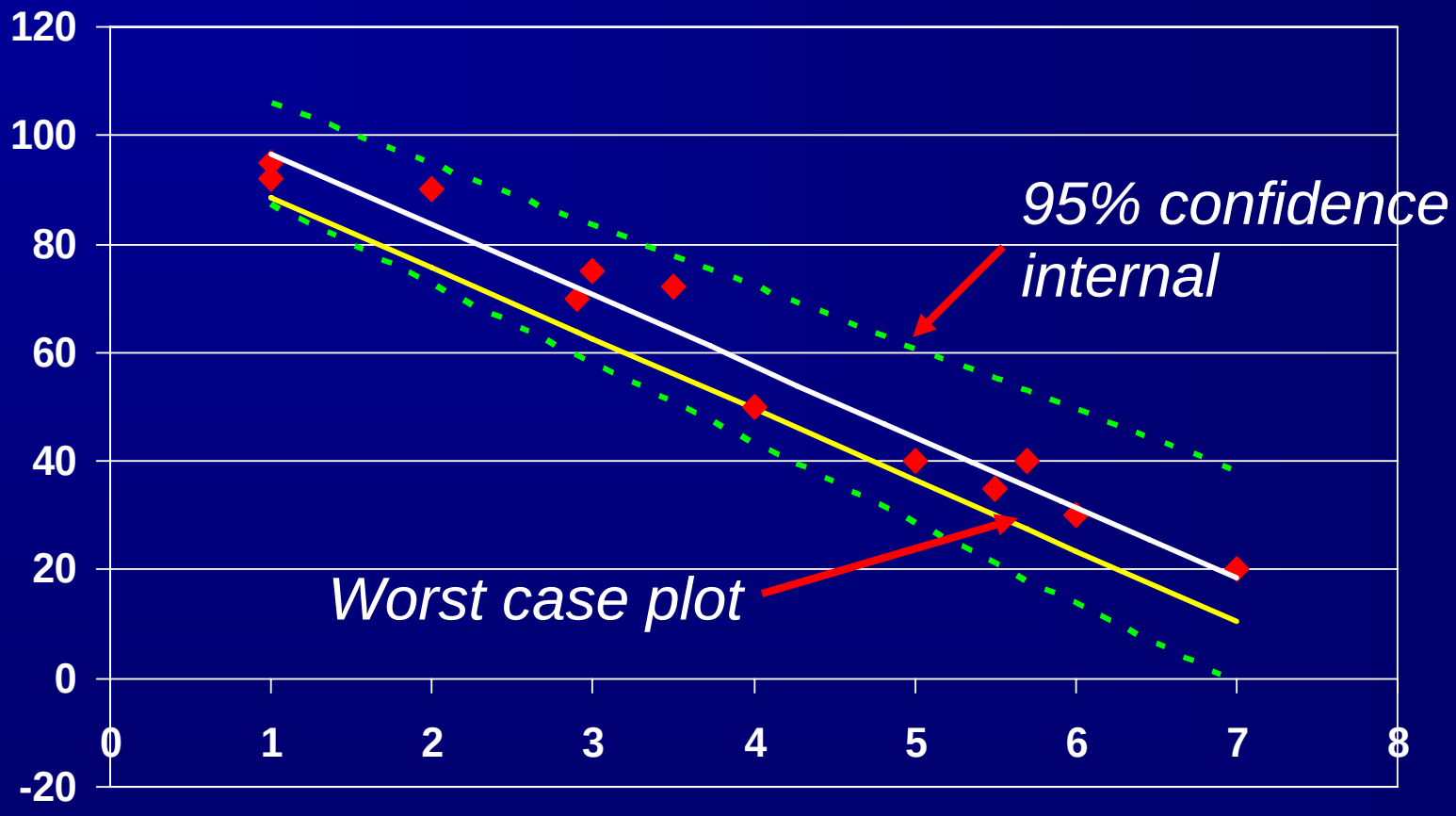
Worst Case of Process



95% Error of Process



95% Error of Process



Documentation

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

Outcome of Process Validation

- Quantification of reduction/inhibition

$$H_o - \sum R + \sum I \leq FSO$$

- Accounting of variability
- Documentation

Post-Validation

Verification

Process Control Verification

- Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, it is the process of examining results of activities to determine conformity with requirements. Ongoing activities include record review, direct observation, and calibration.

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Outcome of Verification

- History process is able to deliver intended specifications – record review
- Appropriate change control
- Effect of season/operator/supplier variations
- Periodic challenge testing/audits/reviews
- Maintenance and calibrations program

Formula for success: rise early, work hard, strike oil.

J. Paul Getty