Statistical methods for shelf-life prediction

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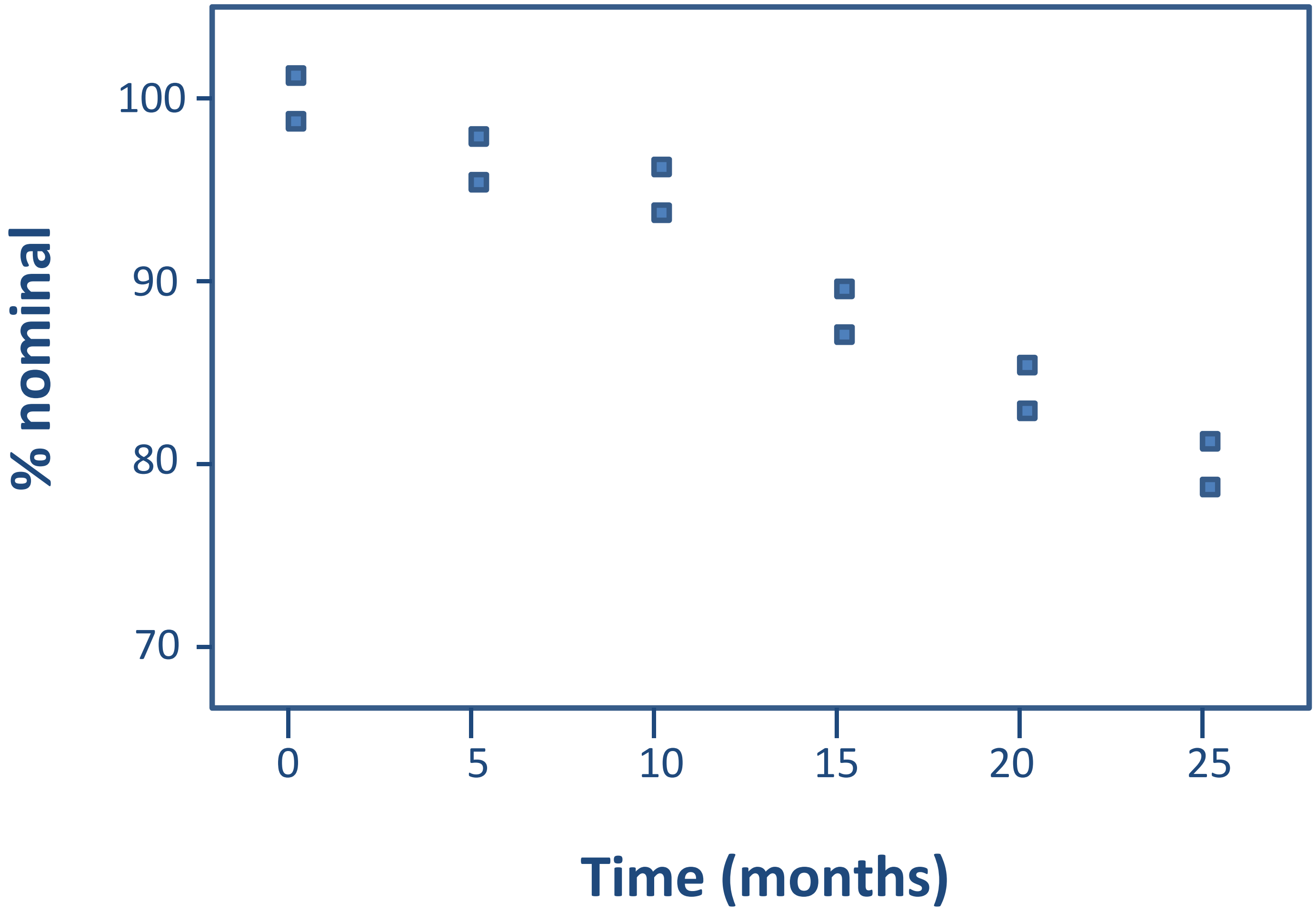
Learning Objectives

Calculate and interpret tolerance limit predictions in a range of use cases

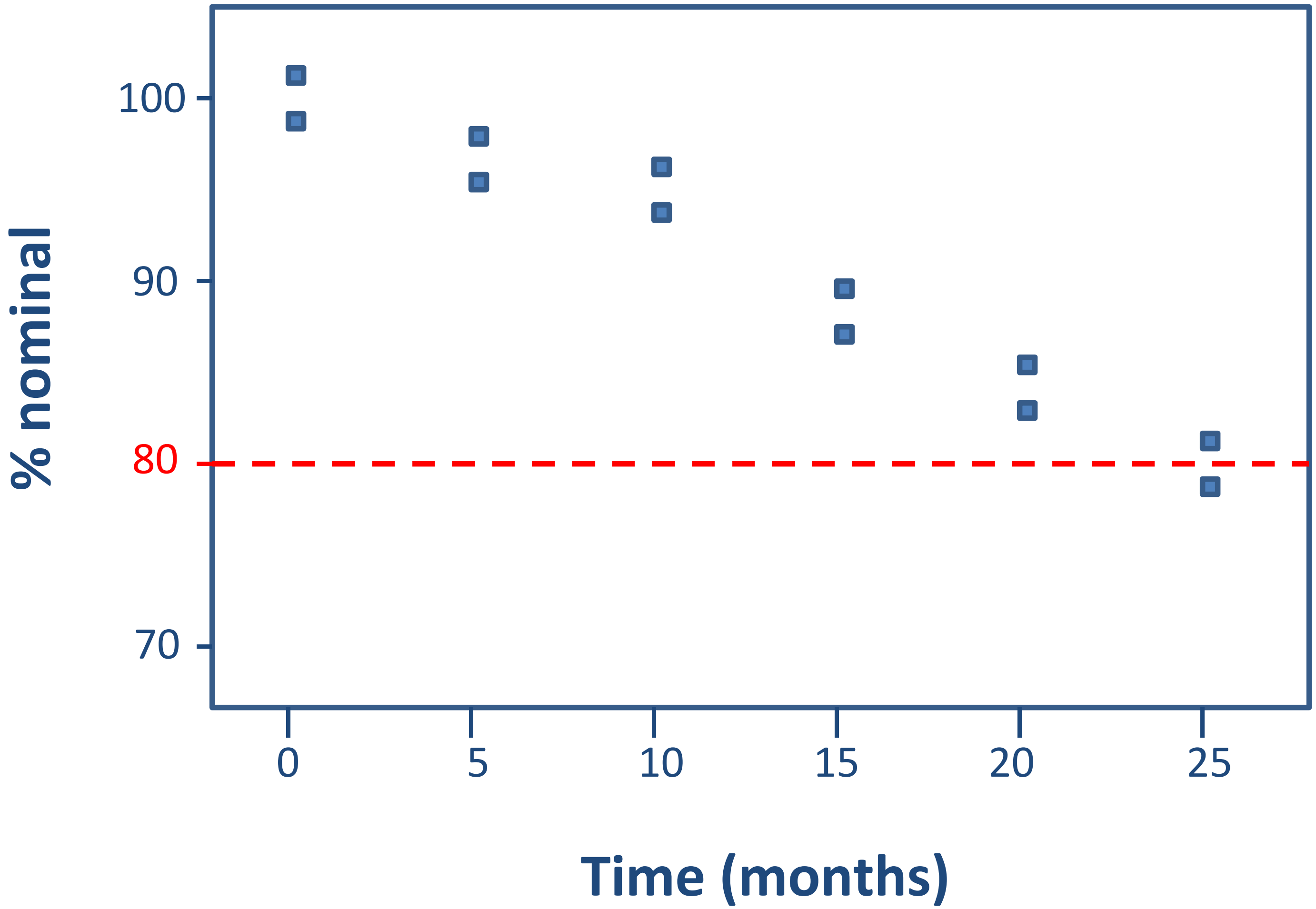
Statistical shelf-life prediction: Candidate

Product degradation seen in test data.



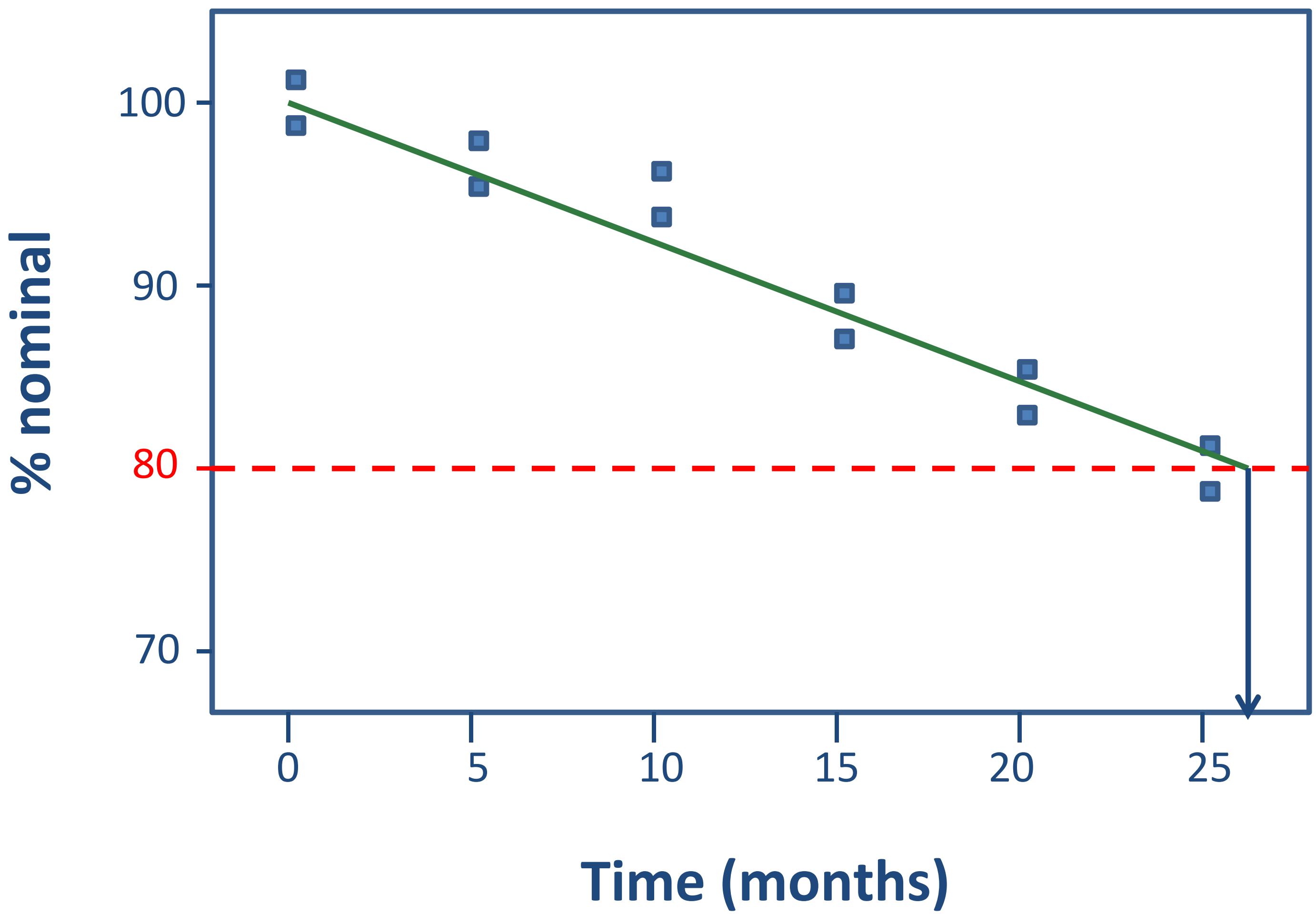
Statistical shelf-life prediction: Candidate

Expiration @ 80% of nominal



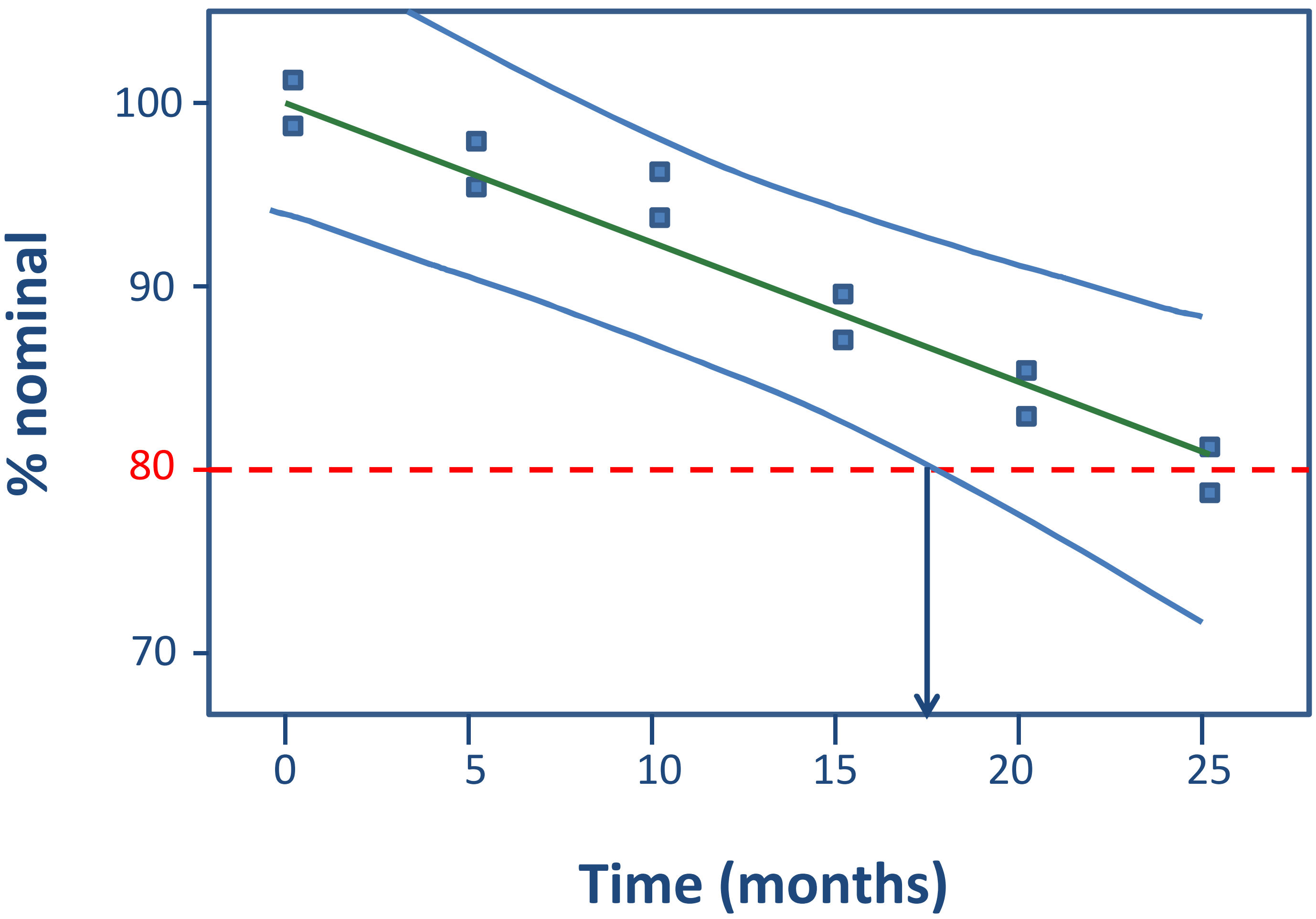
Statistical shelf-life prediction: Candidate

Expiration date from regression line: 25 months



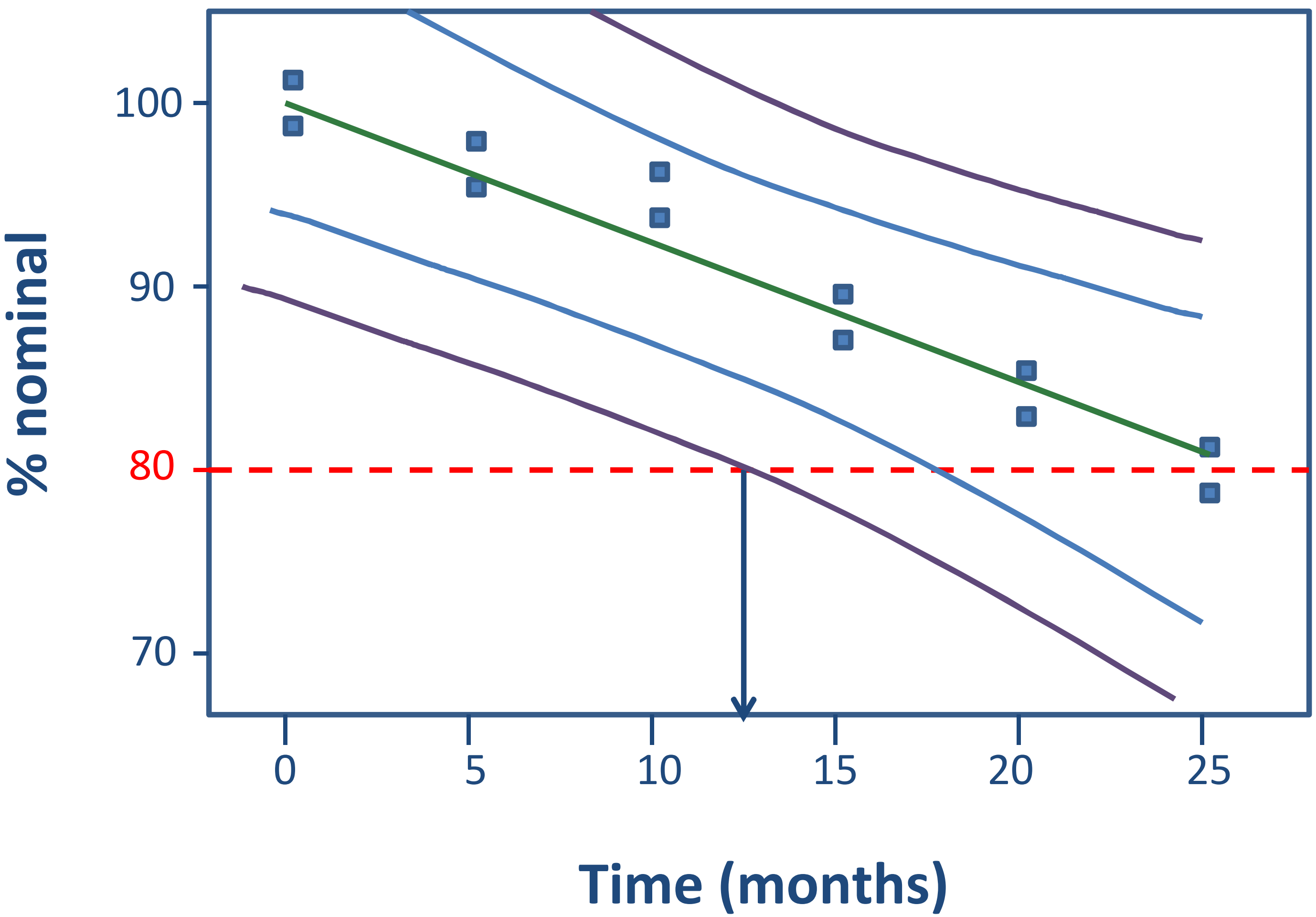
Statistical shelf-life prediction: Candidate

From 90% lower confidence limit: 17 months



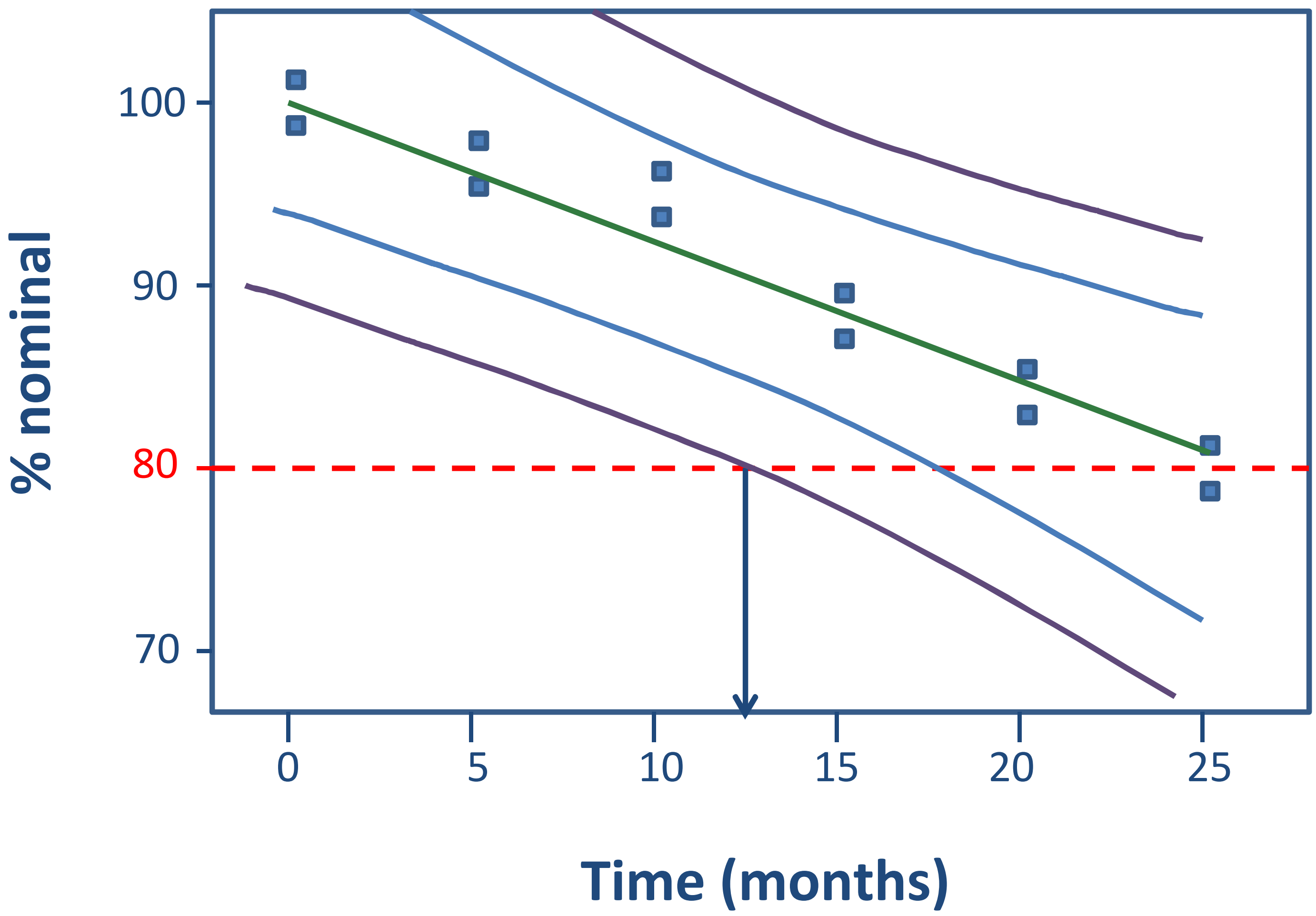
Statistical shelf-life prediction: Candidate

From 90:99 lower tolerance limit: 12 months



Statistical shelf-life prediction: Candidate

We have 90% confidence 99% in spec at 12 months



Statistical tolerance limits

- Quantify confidence
- In current & future reliability
- Under model assumptions
  - Linear (Quadratic, etc. trend)
  - Normal (etc.) error model

This talk discusses

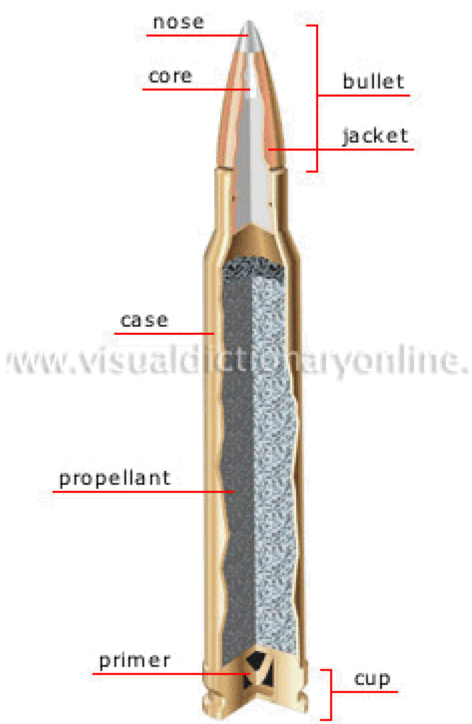
- Calculation of tolerance limits
- Application to shelf-life prediction
- Implications for sampling programs

Tolerance limits for WWII munitions procurement

“If every bullet was tested in advance, no bullets would be left to ship. If, on the other hand, none were tested, malfunctions might occur in the field of battle, with potentially disastrous results.”

NIST Statistical Handbook, Section 6.2.1. What is Acceptance Sampling
http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc21.htm

Go/no-go acceptance sampling



<u>500 bullets in batch:</u>

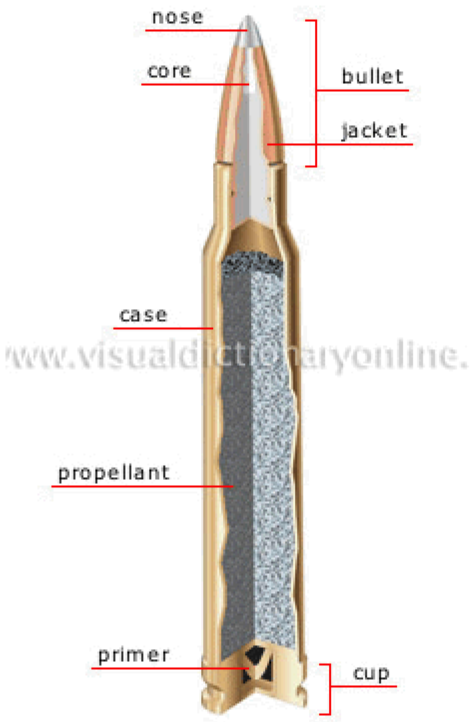
500 tested → 100% confidence 100% in spec

196 tested → 95% confidence 99% in spec

54 tested → 95% confidence 95% in spec

26 tested → 75% confidence 95% in spec

Binomial (large sample) approximation for confidence



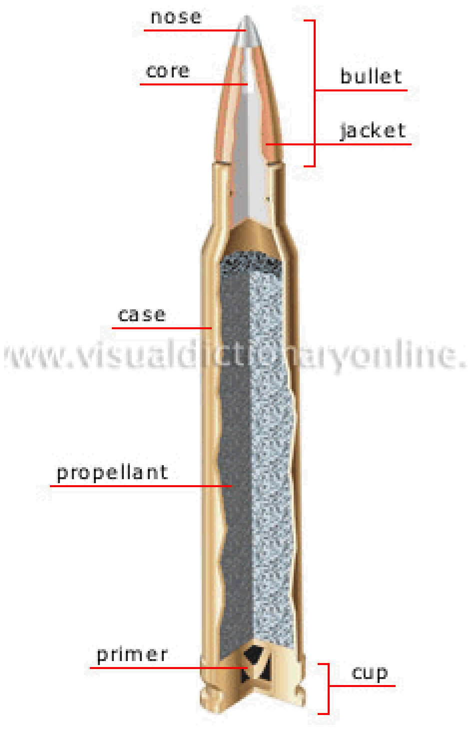
Confidence $\gamma = 1 - P^n$

where:

P is target reliability to be shown

n is sample size

Hypergeometric (exact) calculation for confidence



$$\gamma = \frac{\binom{NP}{n}\binom{N-NP}{0}}{\binom{N}{n}}$$

where:

P is target reliability to be shown

n is sample size

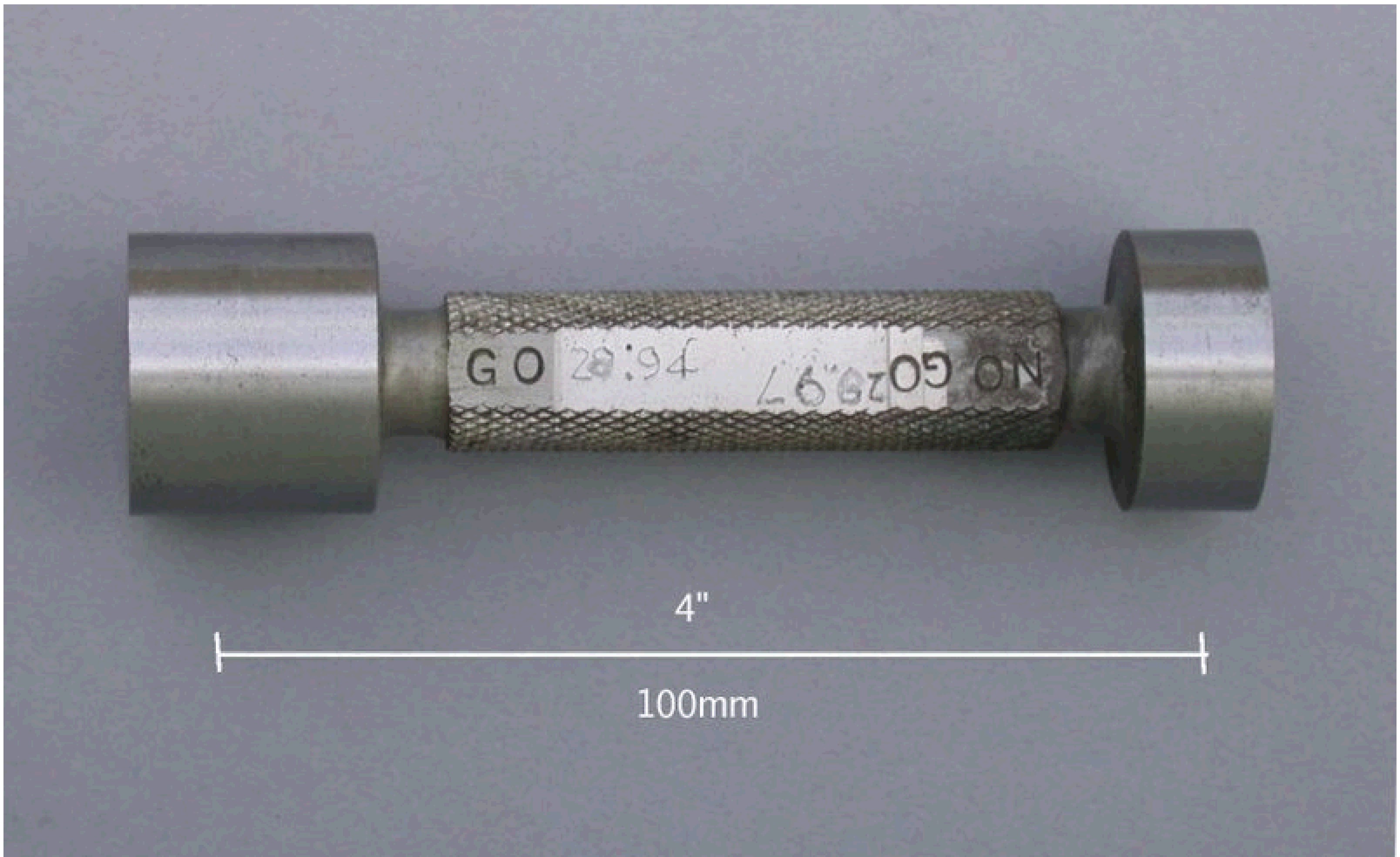
N is batch size

Variables acceptance when:

- Acceptance variable measurable
- Defect classification ⟺ variable level
- Performance ⟺ defect classification
- Production process in control ⟺ each unit informs about process

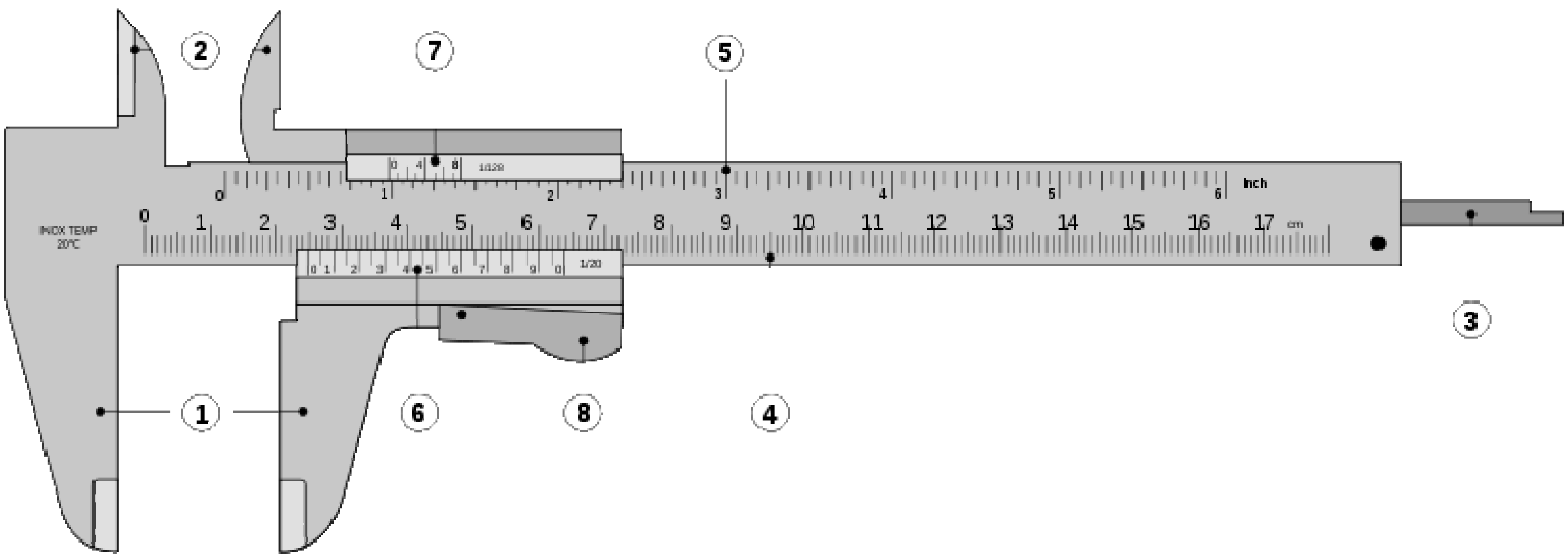
Acceptance by go/no-go

Inner diameter by go/no-go gauge

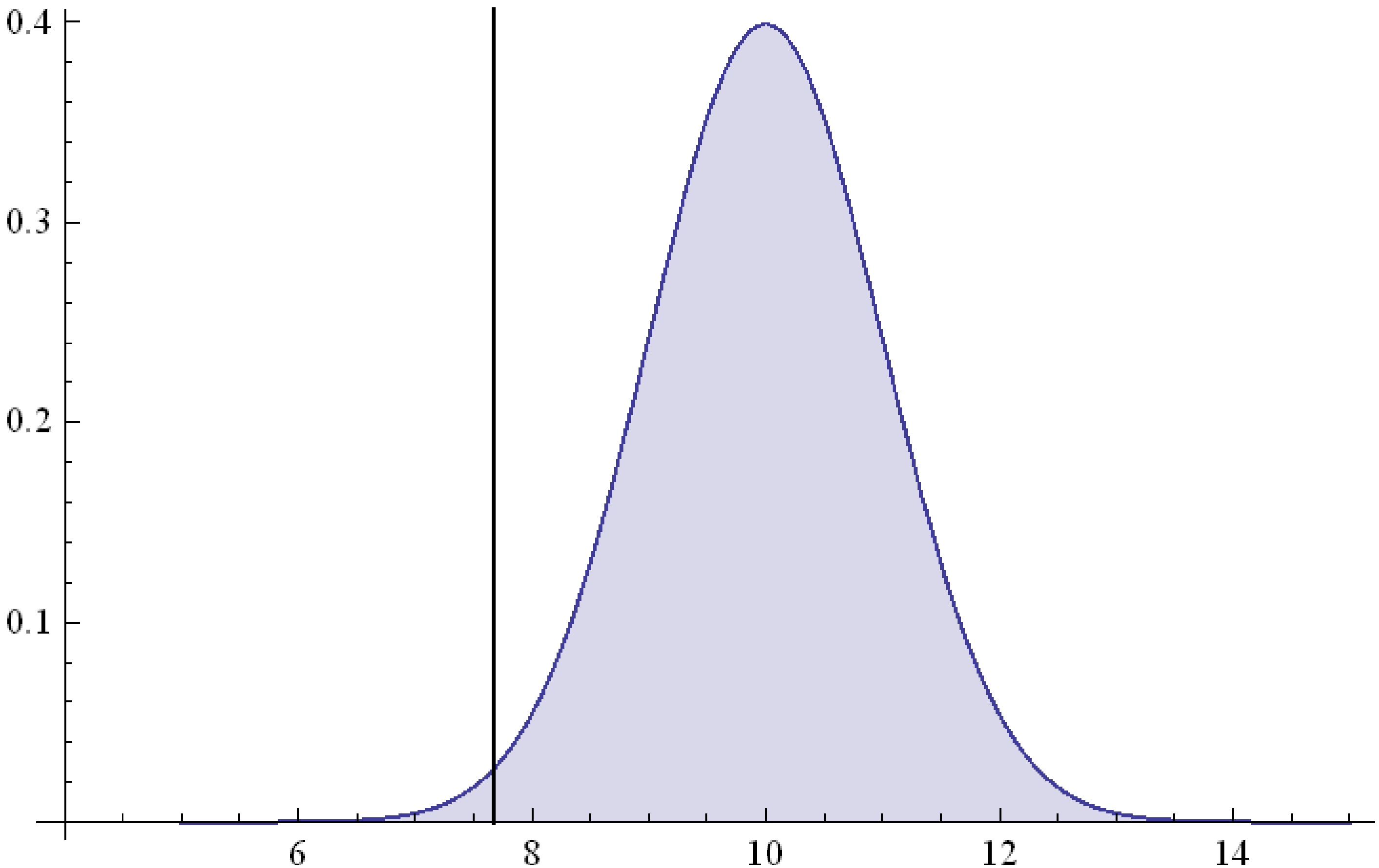


Could accept by variables

Inner diameter by vernier caliper

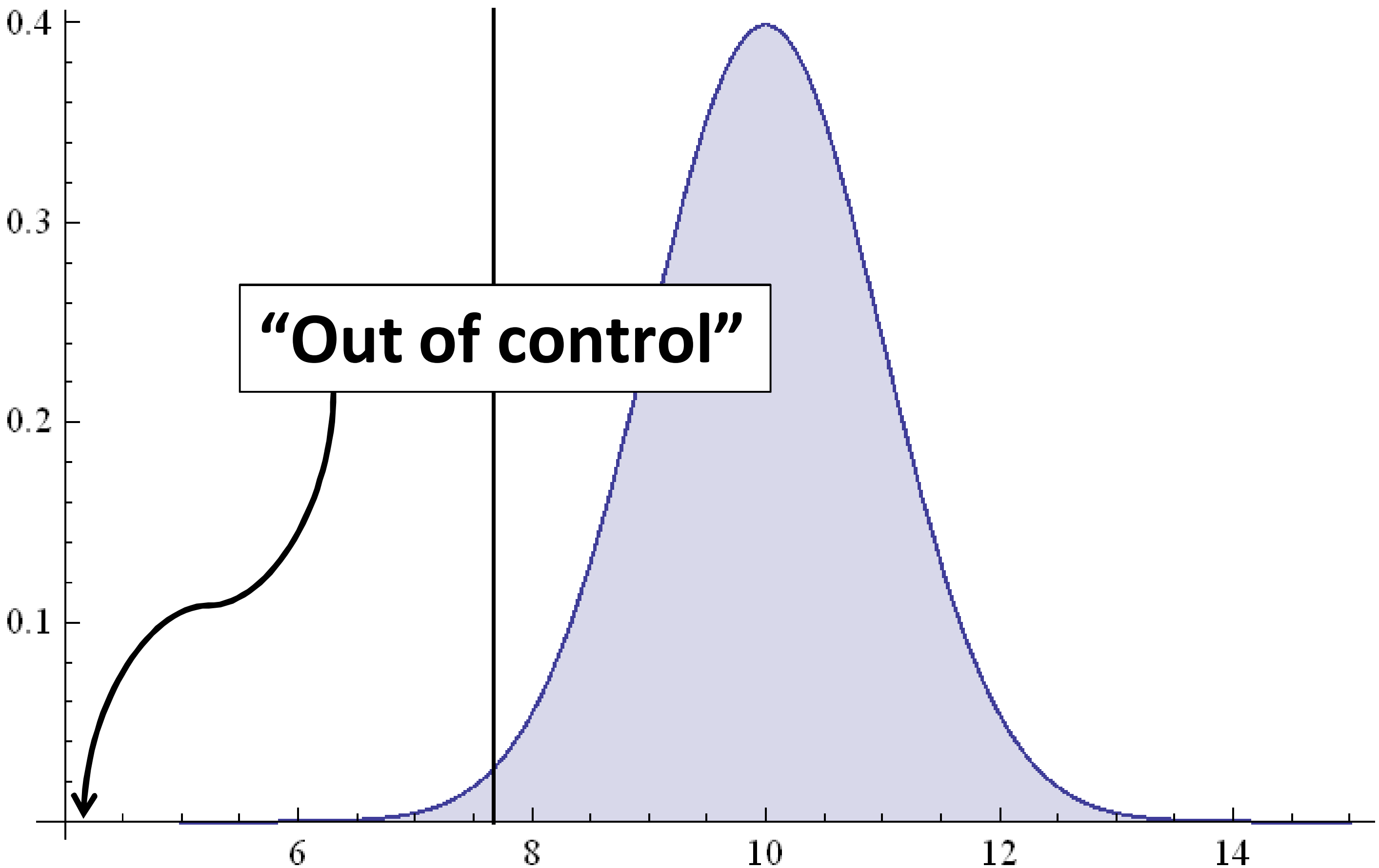


Defect = Inner diameter < Spec



Example 1% < Spec ⟺ P = 99%

"Out of control" anomalies / other defects not addressed.



Median samples for
γ = 90%, P = 90%

Go/no go sampling:

22 (if no defects found)

Variables sampling (normal, medians):

30 (if true in spec = 95%)

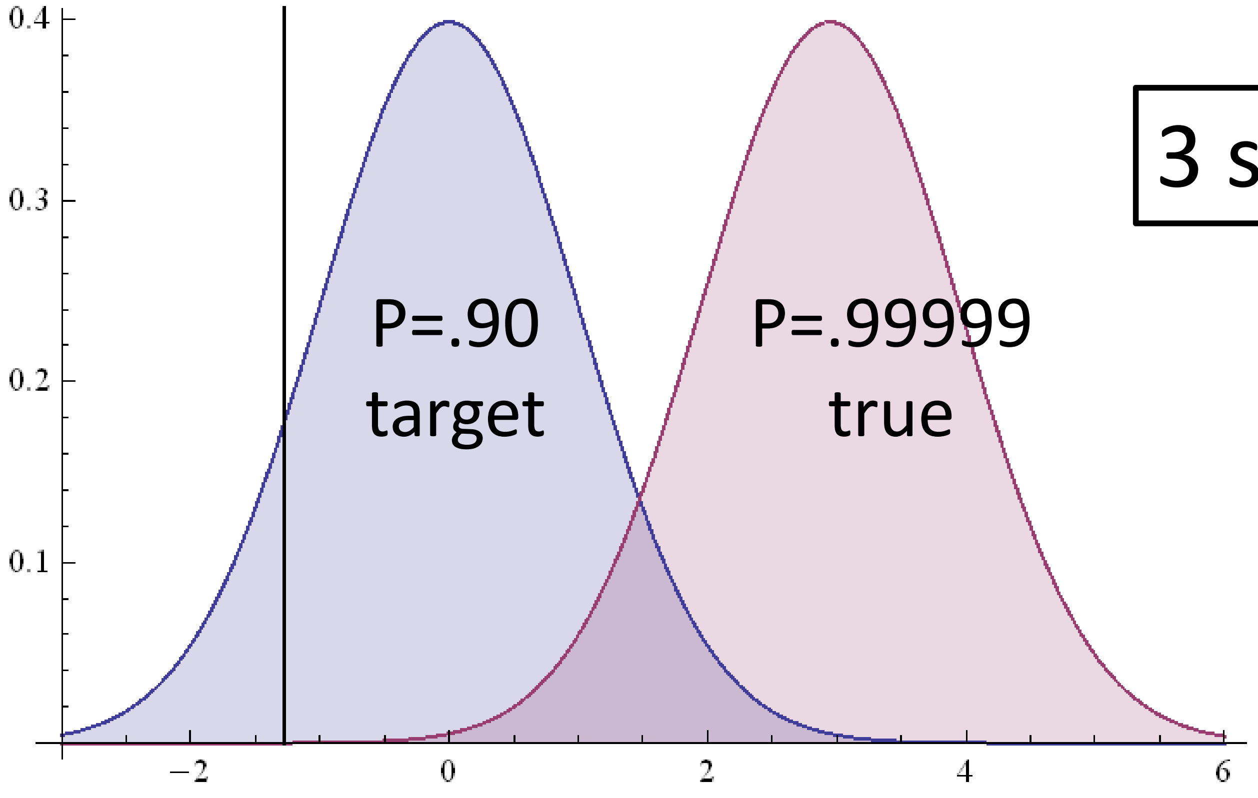
7 (if true in spec = 99%)

4 (if true in spec = 99.9%)

3 (if true in spec = 99.999%)

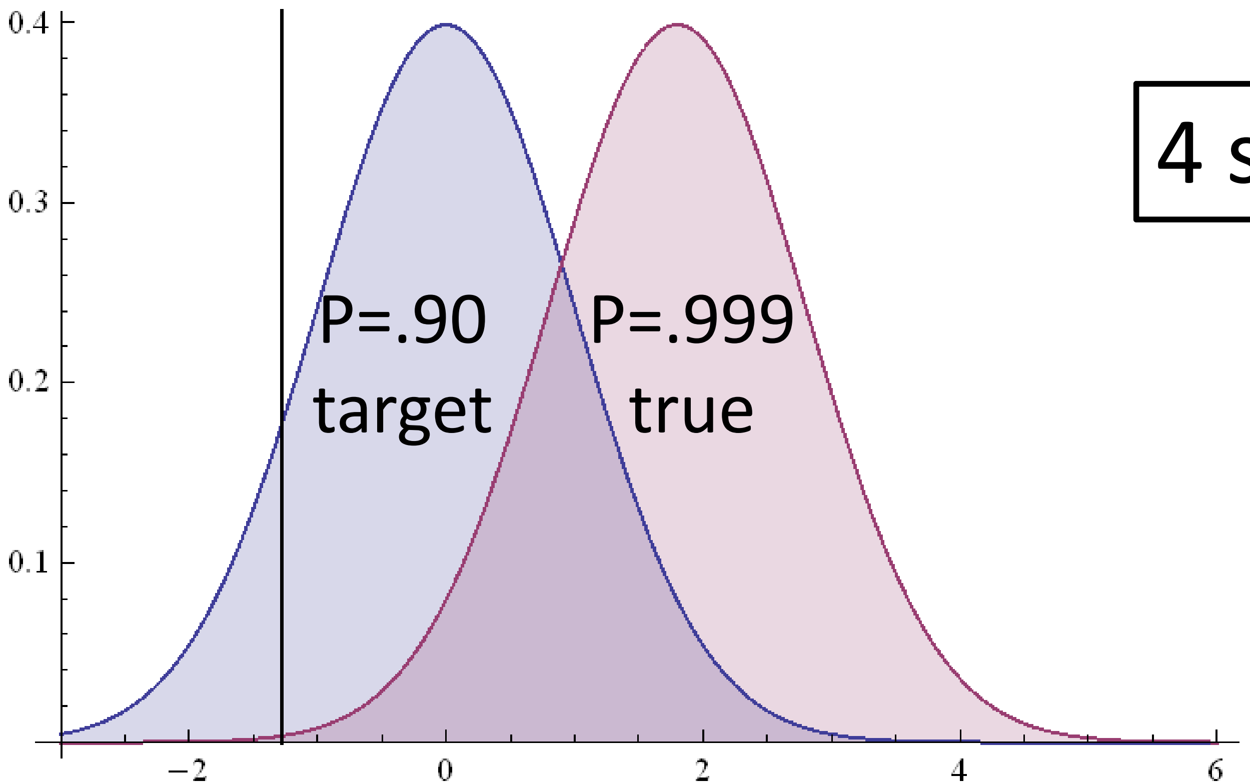
Savings greatest for P true >> P target

Median samples for γ = 90%, P = 90%



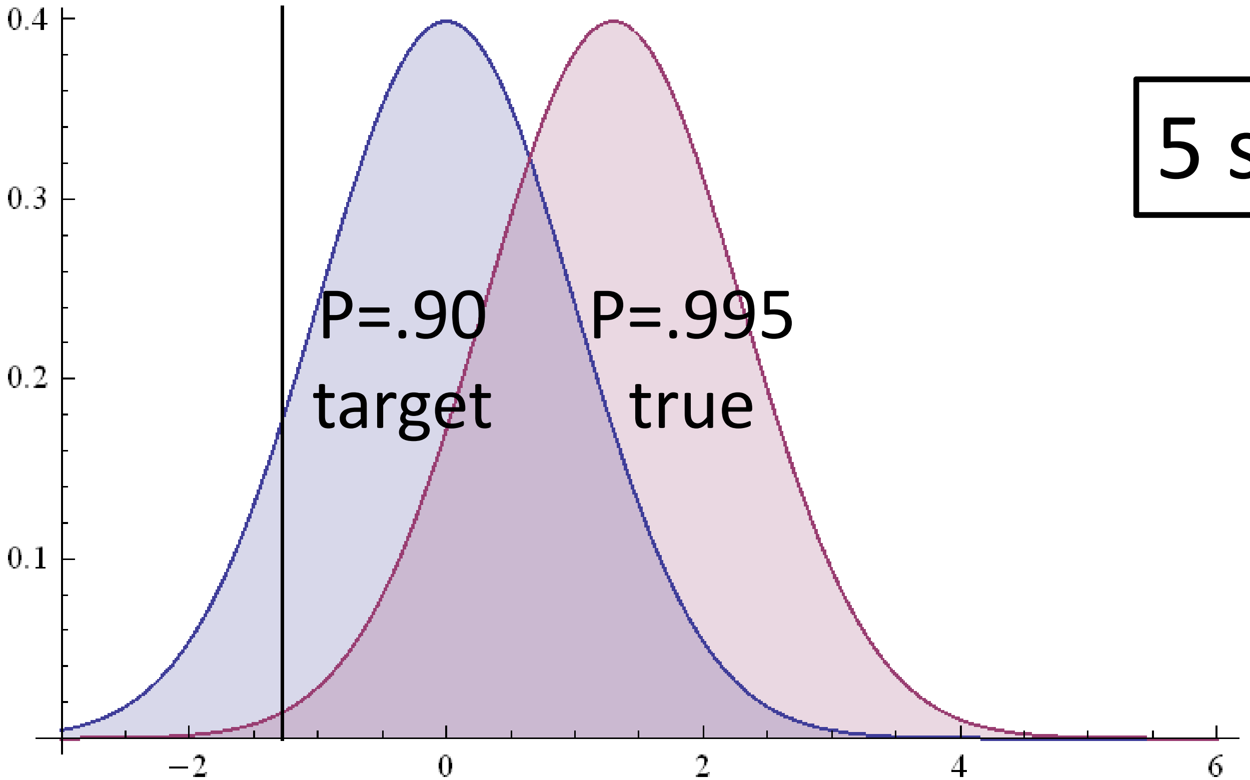
3 samples

Median samples for γ = 90%, P = 90%



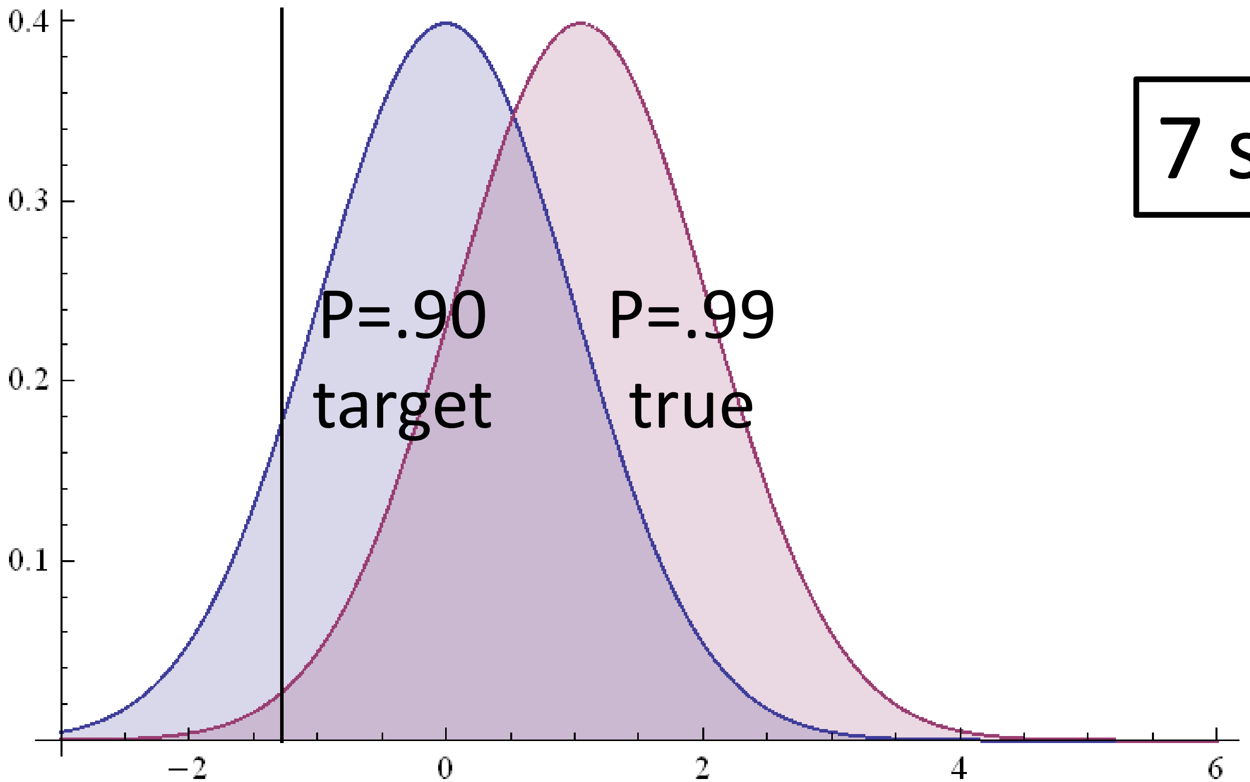
4 samples

Median samples for γ = 90%, P = 90%



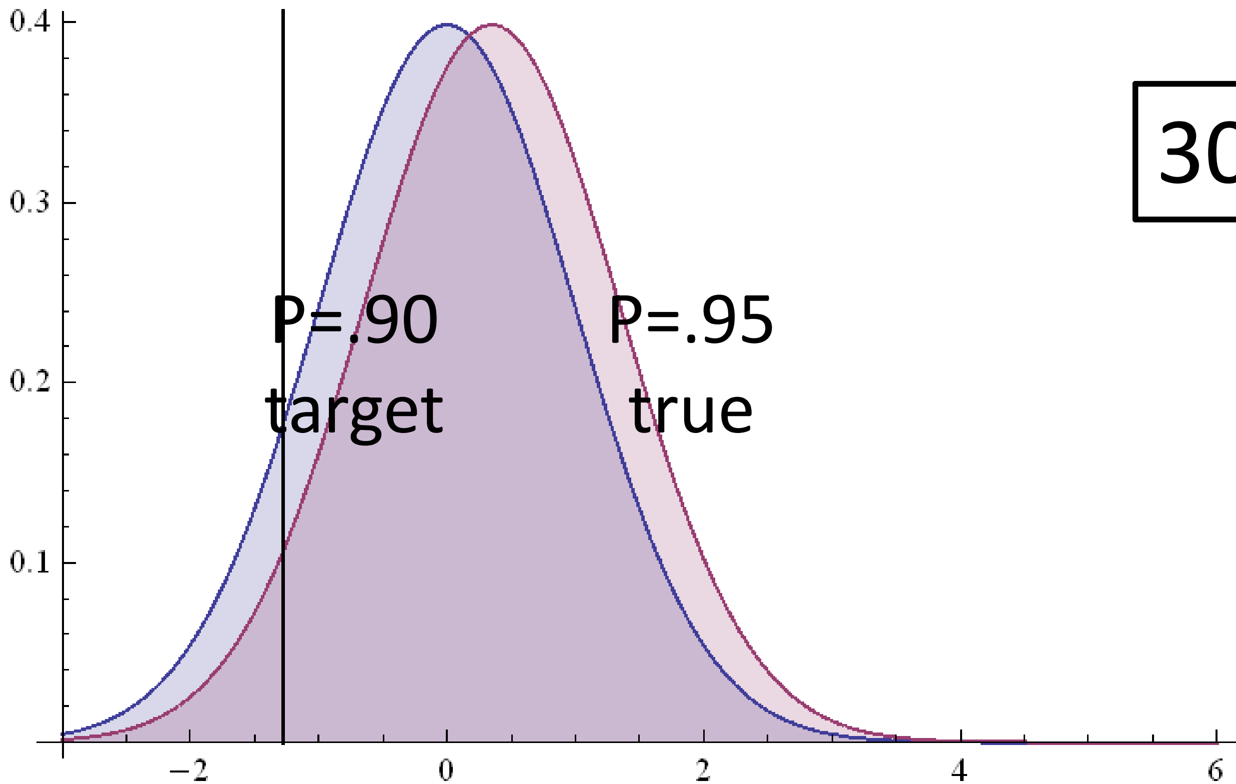
5 samples

Median samples for γ = 90%, P = 90%



7 samples

Median samples for γ = 90%, P = 90%



30 samples

Tolerance limit calculation

$$LTL = \overline{Y} - ks$$

$$UTL = \overline{Y} + ks$$

where:

LTL is lower tolerance limit

UTL is upper tolerance limit

Tolerance limit calculation

$$LTL = \overline{Y} - ks$$

$$UTL = \overline{Y} + ks$$

Tolerance factor, k

is the number of standard deviations from sample average to spec limit

Tolerance limit calculation

If mean and sigma were known, could read k from normal tables:

$$k = z_P$$

where:

z_P is the 100P% percentile of the standard normal distibution

P is the target fraction in spec

Tolerance limit calculation

Mean and sigma estimated from sample,
k = 100γ% percentile of noncentral-t
with n-1 degrees of freedom
and non-centrality

$$\delta = z_P \sqrt{n}$$

Tolerance limit calculation

Percentiles of noncentral t are available

Mathematica (for $n \leq 140$)

Matlab

R, etc.

Confidence calculation

Set tolerance limit equal to spec limit (L) to find confidence in target reliability:

$$\gamma = T_{\nu,\delta}\left(\frac{\bar{Y} - L}{s/\sqrt{n}}\right)$$

Confidence calculation

The noncentral-t is evaluated at

$$\frac{\overline{Y} - L}{s/\sqrt{n}}$$

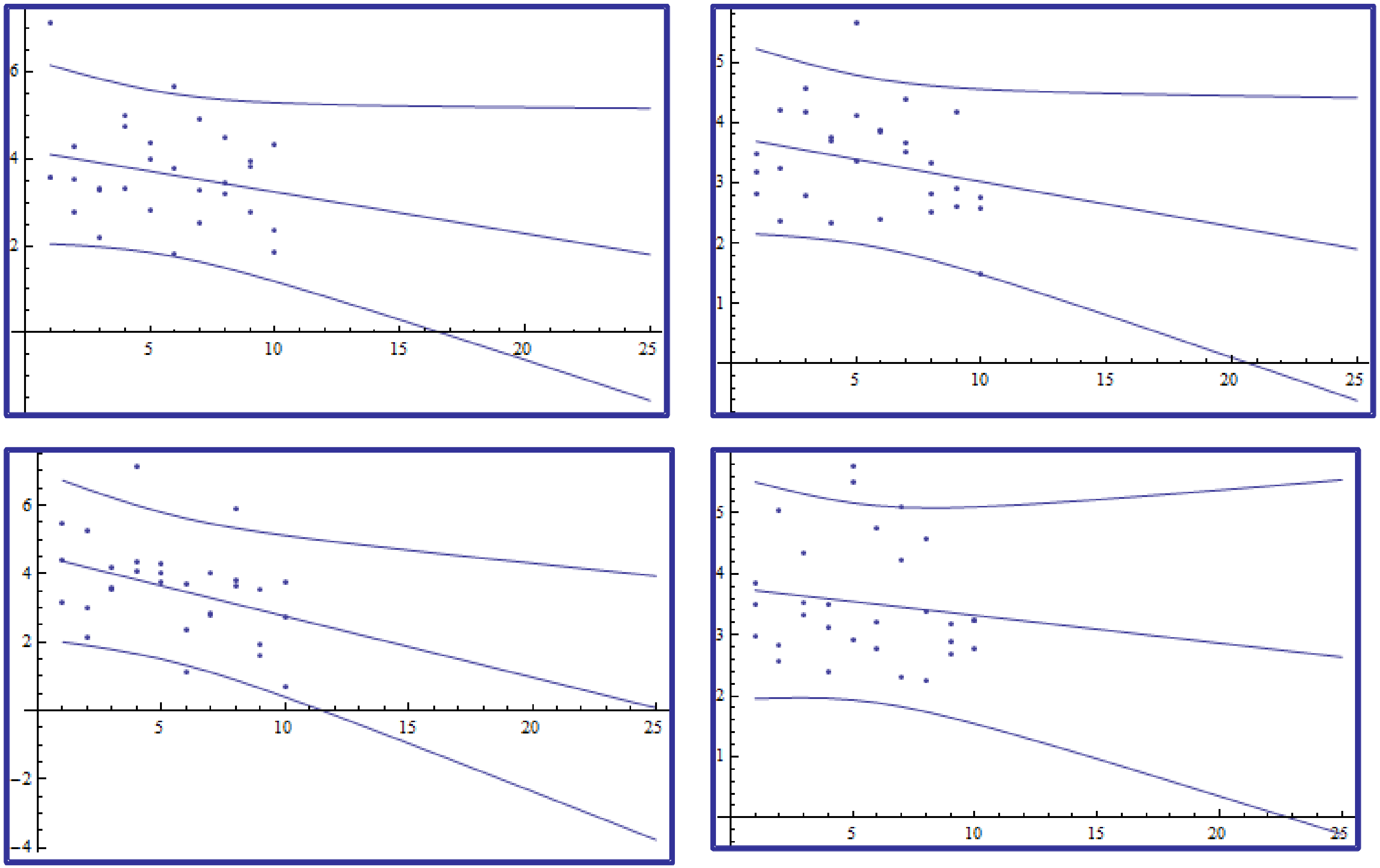
The “index of quality”

Sampling program evaluation

Use simulation

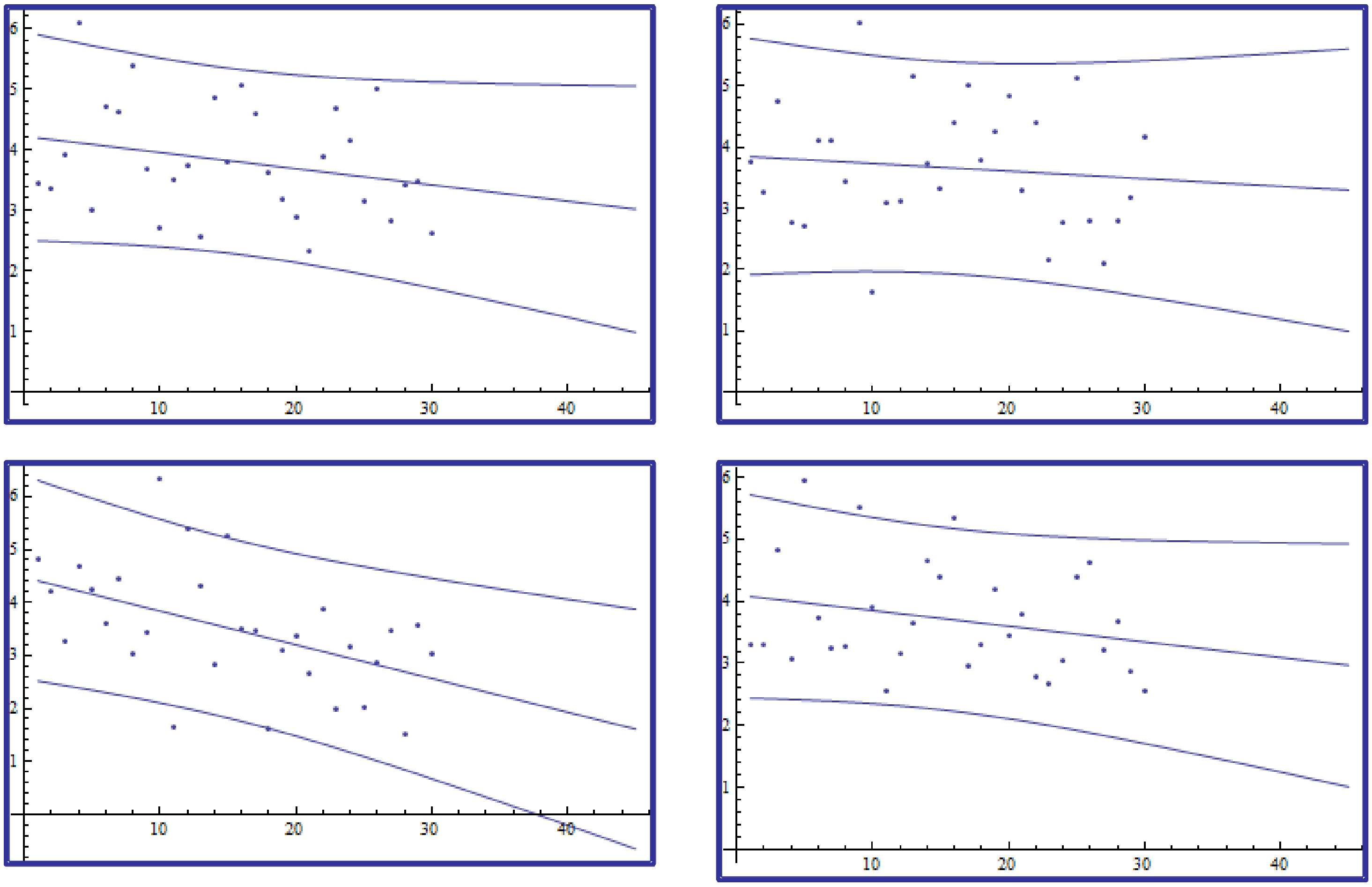
Sampling 3/yr for 10 years

90% confidence bounds (target = 0.9, true = 0.99)

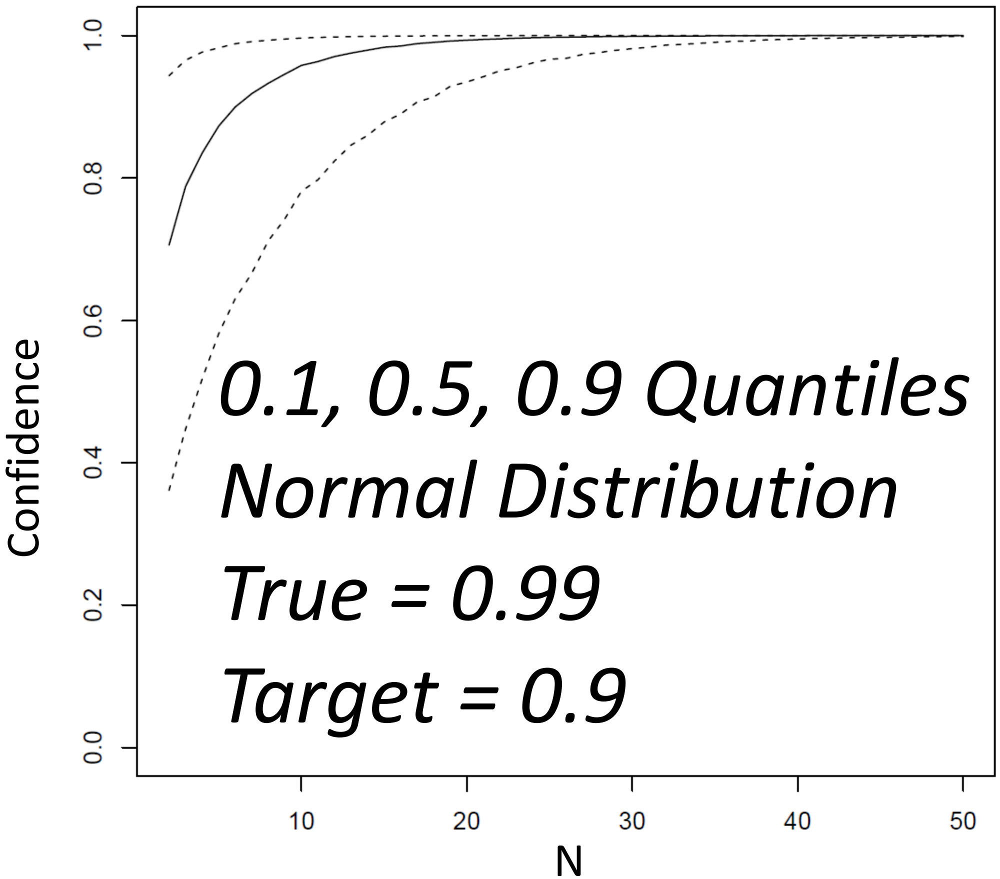


Sampling 1/yr for 30 years

90% confidence bounds (target = 0.9, true = 0.99)



Confidence is affected by actual margin and random sampling variation



Median number of samples to achieve metric level: target is 90% w/in spec

	Confidence			
True fraction in spec.	**0.6**	**0.7**	**0.8**	**0.9**
95%	3	6	14	30
99%	2	2	4	7
99.9%	2	2	3	4
99.999%	2	2	2	3

Tolerance in regression

$$Y_{L,t} = \widehat{Y}_t - k_t s$$

where,

$$k_t = T^{-1}_{\nu,\delta,\gamma}\sqrt{H}$$

$$\delta = \frac{\mathrm{z_P}}{\sqrt{\mathrm{H}}}$$

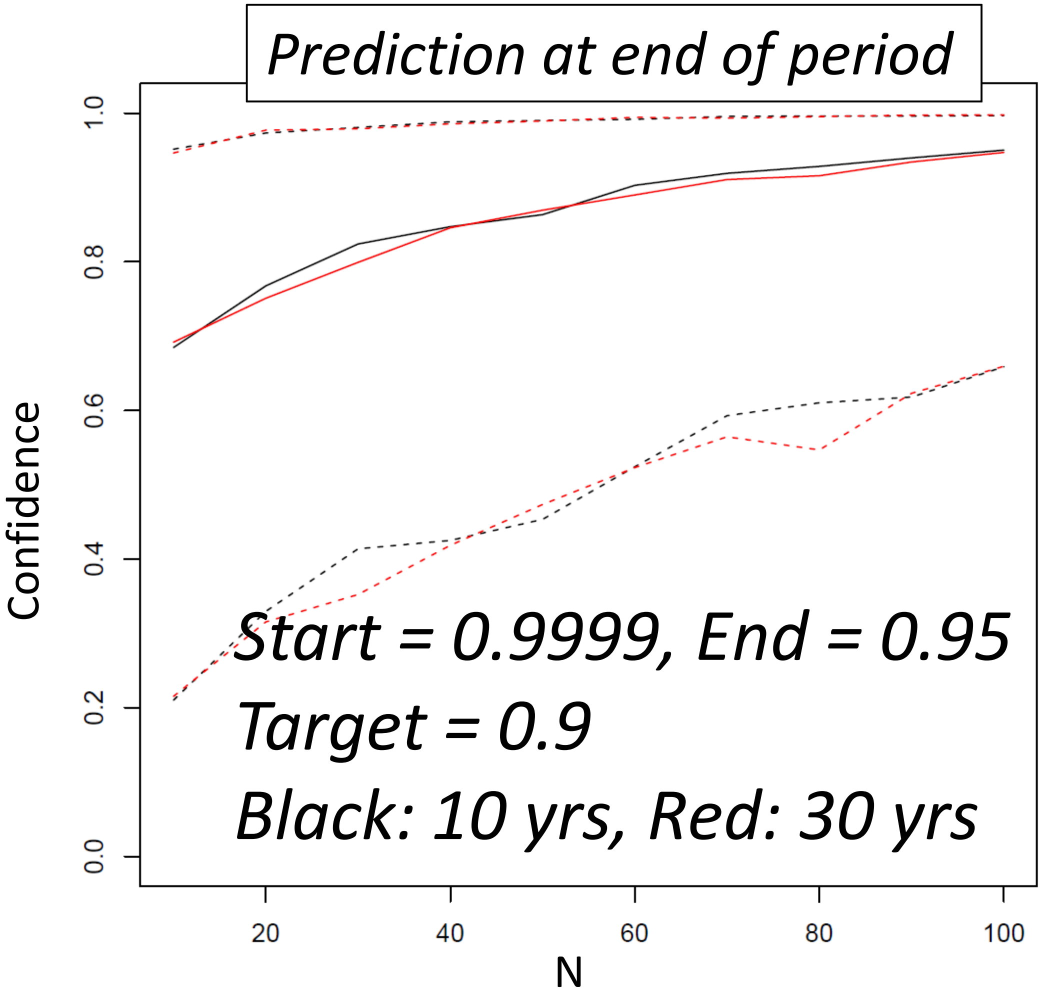
$$H = \sqrt{x_t{}'(X'X)^{-1}x_t}$$

s is the root mean square error.

Confidence in regression

$$\gamma = T_{\nu,\delta}\left(\frac{\widehat{Y}_t - L}{s\sqrt{H}}\right)$$

For regression case, confidence in remaining margin is affected by start/end margins and random sampling variation

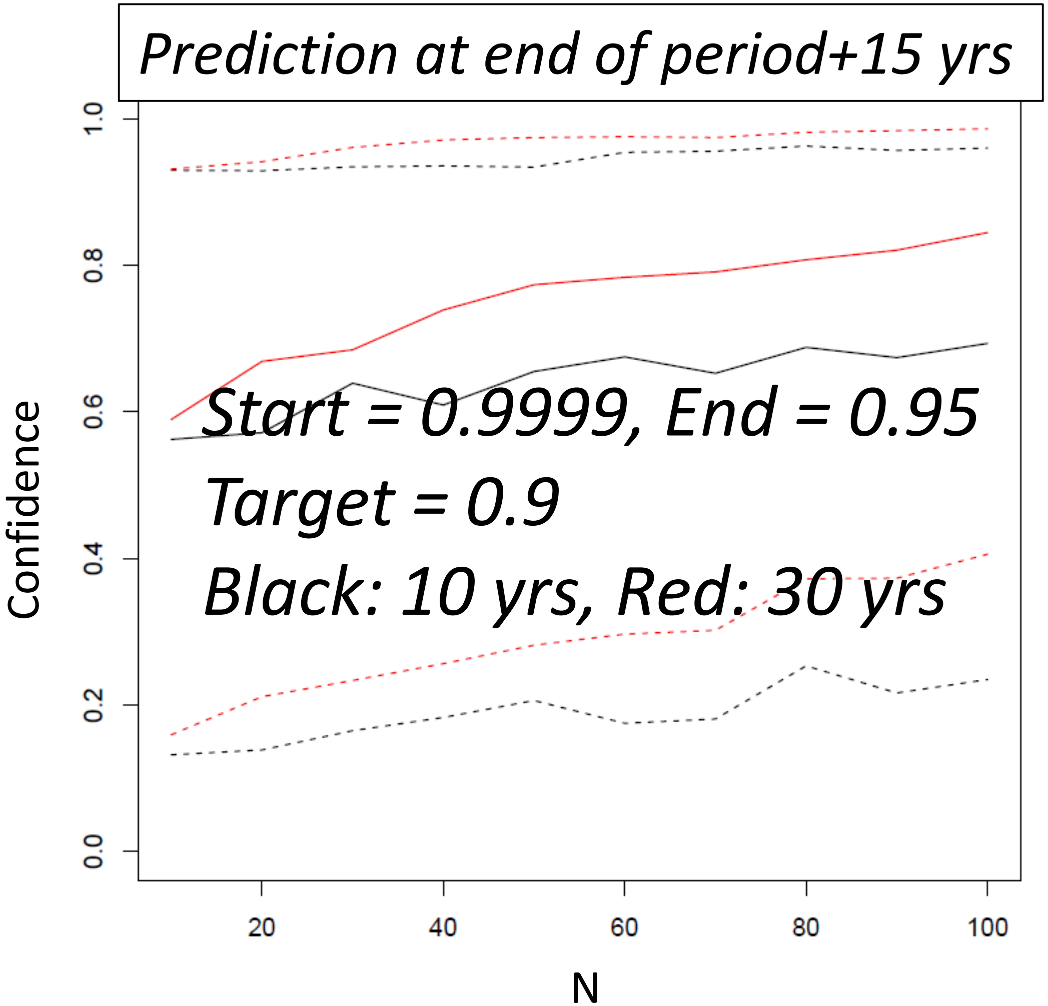


Median number of samples to achieve metric level: target is 90% w/in spec

	Confidence			
Sampling period	**0.6**	**0.7**	**0.8**	**0.9**
30 years	10	20	30	60
10 years	10	20	40	70

NB: In this example, slope takes 99.99% to 95% in spec.

Not surprisingly, predictions into the future result in reduced confidence compared to today's predictions



Confidence in 15 years is lower, and allocation of samples has more effect.

Caveats for application

- Normality test should be done, since non-normal distributions may yield misleading results if normality is assumed
  - Once recognized, Non-normal distributions can be handled via transformation or simulation
- Linearity?

Summary

- For some situations, tolerance limit calculations offer a powerful but simple tool for developing or evaluating sampling plans
- These calculations are readily extendable to shelf life programs, where concerns about product change become paramount