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Acceptance sampling theory applied to EQA sample homogeneity testing

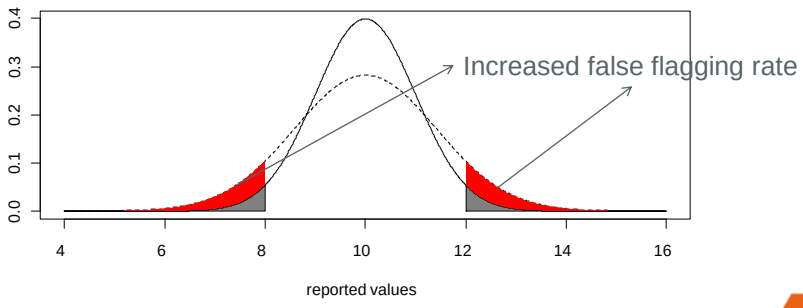
Wim Coucke, Bernard China, Marianne Demarteau, Vanessa Ghislain, Yolande Lenga, Mohamed Rida Soumali, Marjan Van Blerk, Nathalie Vandevelde, Hannelien Verbeke, Christel Van Campenhout

wim.coucke@wiv-isp.be

Rue Juliette Wytsmanstraat 14 | 1050 Brussels | Belgium
T +32 2 642 51 11 | F +32 2 642 50 01 | email: info@wiv-isp.be | www.wiv-isp.be

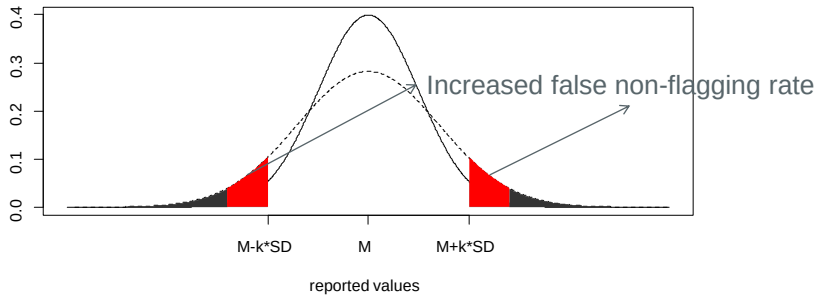
Effect on laboratory evaluation: fixed limits

Target value: 10 g/L, limits: 20%



The larger the sample heterogeneity, the larger the false flagging rate

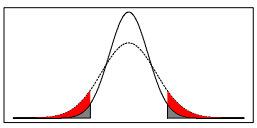
Effect on laboratory evaluation: standard deviation-dependent limits



The larger the sample heterogeneity, the larger the false non-flagging rate

Deriving sample heterogeneity limits

Fixed limits:

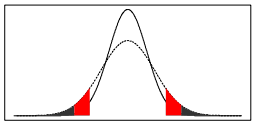


- Risk of false flagging should not increase by x %-points
- Effective limit: distance from center that gives same chance of false flagging as under homogeneity

The larger the EQA standard deviation, the stricter the limit

Deriving sample heterogeneity limits

SD-dependent limits:



- risk of false not-flagging should not increase by x %-points
- Effective Z-score: distance from center that gives same chance of false flagging as under homogeneity

The smaller the EQA standard deviation, the stricter the limit

Acceptance sampling theory

Designed for evaluating a batch of products

Number of nonconforming units too high: reject batch

Number of nonconforming units low enough: accept batch

Variable sampling plans:

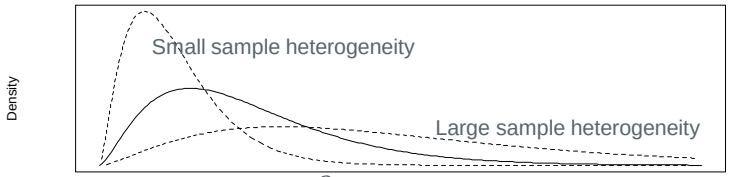
Test a number of samples and stop testing when there is enough information to reject or accept the batch

Schilling EG, Neubauer DV. *Acceptance sampling in quality control*. CRC Press, 1982.

Acceptance sample theory for variability

$$\frac{s_s^2(n-1)}{\sigma_m^2+\sigma_a^2} \sim \chi^2_{(n-1)}$$

s_s: Standard deviation of n measured samples
σ_m: Maximum allowed sample heterogeneity
σ_a: Analytical variability



$$\frac{s_s^2(n-1)}{\sigma_m^2+\sigma_a^2}$$

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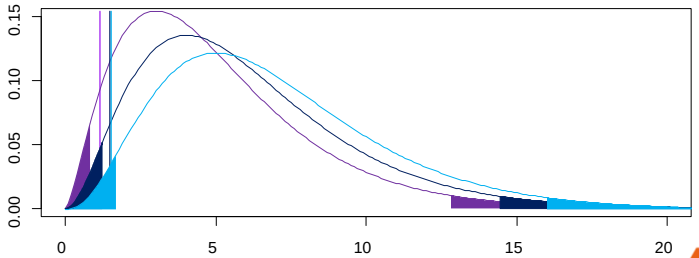
Variable acceptance sample plan for sample homogeneity: example

Ethanol sample, 3 g/L
Allowed sample heterogeneity: 0.057 g/L
Analytical variability: 0.0521 g/L

2.99
2.99
3.05
2.97
3.05
3.05
2.97
3.03



$$\frac{s_s^2(n-1)}{\sigma_m^2+\sigma_a^2} = \frac{s_s^2(n-1)}{0.057^2+0.0521^2}$$

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Sampling plans for qualitative data

Sample good or bad ?

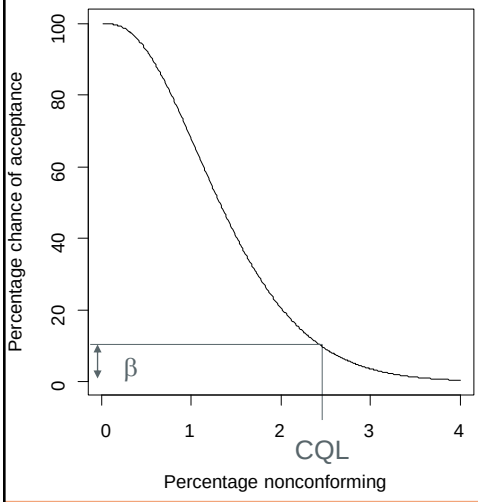
Blood group, absence/presence of pathogen, absence/presence of malignant cells, wrong or right interpretation

Principle:

From a batch, take a number of samples n

Only a small fraction of nonconforming are allowed

Sampling plans for attributes

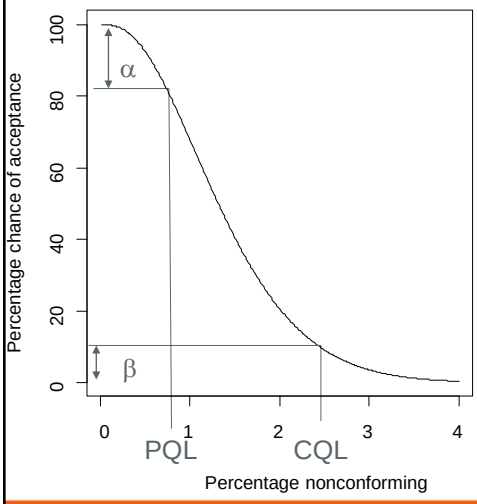


As an EQA organizer,
we only want to accept batches if the proportion of nonconforming is low enough

We want to avoid to accept batches that have a high level of nonconforming

CQL: consumer's quality level
β: consumer's risk

Sampling plans for attributes



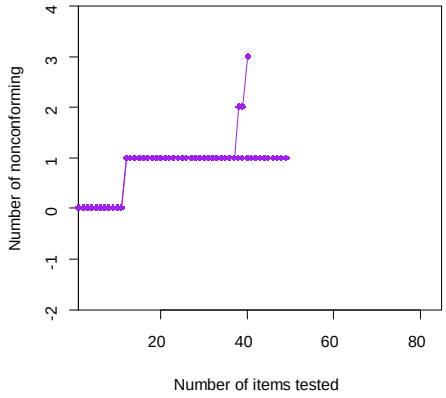
As a sample manufacturer, we only want to reject batches if the proportion of nonconforming is too high

We want to avoid to reject batches that have a low level of nonconformint

PQL: producer's quality level
α: producer's risk

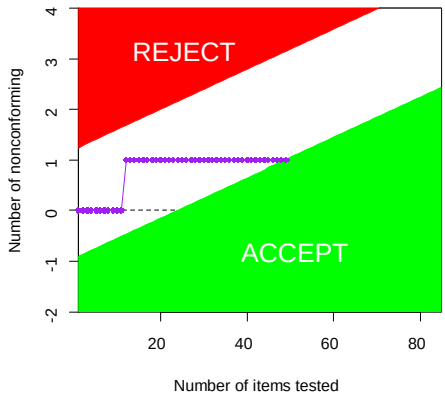
Variable sampling plans

Plot the cumulative number of nonconforming versus number of items tested



Variable sampling plans

Determine PQL, CQL, α, β based on cost of batch loss and false laboratory evaluation tolerance



PQL: 1%

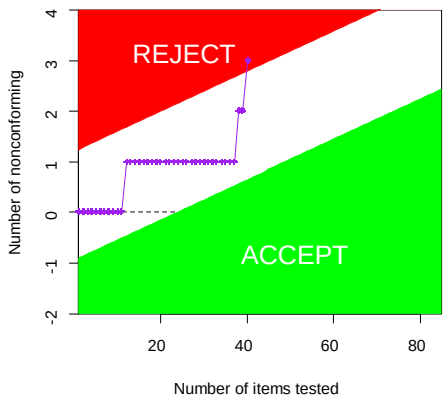
CQL: 10%

α: 1%

β: 10%

Variable sampling plans

Determine PQL, CQL, α, β based on cost of batch loss and false laboratory evaluation tolerance



PQL: 1%

CQL: 10%

α: 1%

β: 10%

Discussion

- Alternative and scientifically sound
- Direct match with laboratory evaluation
- Possibility of less samples than stipulated by ISO 13528 for quantitative parameters
- Large number of samples needed for qualitative parameters
- Applies only on batches with unknown sample production sequence