

Hellenic Complex Systems Laboratory

Tool for Quality Control Design and Evaluation

Technical Report VIII

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Abstract

This Demonstration can be used to estimate various parameters of a measurement process and to design the quality control rule to be applied. You define the parameters of the control measurements that are the assigned mean, the observed mean, and the standard deviation, in arbitrary measurement units. In addition, you define the quality specifications of the measurement process, that is, the total allowable analytical error (as a percentage of the assigned mean), the maximum acceptable fraction of measurements nonconforming to the specifications, and the minimum acceptable probabilities for random and systematic error detection. Finally, you choose the number n of control measurements.

$S(1, n, d \sigma)$ is a quality control rule that rejects the analytical run if at least one of the c control measurements is less than $m_o - d \sigma$ or greater than $m_o + d \sigma$, where d is a positive real number and m_o and σ are the mean and the standard deviation of the control measurements. The quantities $m_o - d \sigma$ and $m_o + d \sigma$ are the lower and the upper quality control decision limits. Then the fraction nonconforming f , the critical random and systematic errors of the measurement process, as well as the quality control decision limits and the respective probabilities for critical random and systematic error detection and for false rejection are estimated. Finally, by choosing the type of output, you can see the estimated quality control (qc) parameters or plot the probability density function (pdf), the cumulative density function (cdf) of the control measurements, or the power function graphs for the random error (pfg re) and systematic error (pfg se).

The parameters are estimated and the functions are plotted if $10^{-100} \leq f \leq f_{max}$, where f is the fraction nonconforming and f_{max} is the maximum acceptable fraction nonconforming.

output

qc parameters

pdf

cdf

pfg re

pfg se

parameters of the control measurements (in measurement units)

assigned mean m_a

observed mean m_o

standard deviation σ

quality specifications

total allowable analytical error p (%)

maximum fraction nonconforming f_{max}

minimum probability for critical random error detection r_{min}

minimum probability for critical systematic error detection s_{min}

number of control measurements

control measurements

measurement process parameters

fraction nonconforming

critical random error

critical systematic error

quality control parameters

quality control rule

lower quality control decision limit

upper quality control decision limit

probability for critical random error detection

probability for critical systematic error detection

probability for false rejection

Figure 1: The measurement process parameters and the quality control parameters of a measurement process. Assigned mean of the control material: 100 units, observed mean: 99 units, standard deviation: 2 units. Total allowable analytical error: 10%, maximum fraction nonconforming: 0.1, minimum probability for critical random error detection: 0.5, minimum probability for critical systematic error detection: 0.9. Number of control measurements: 1.

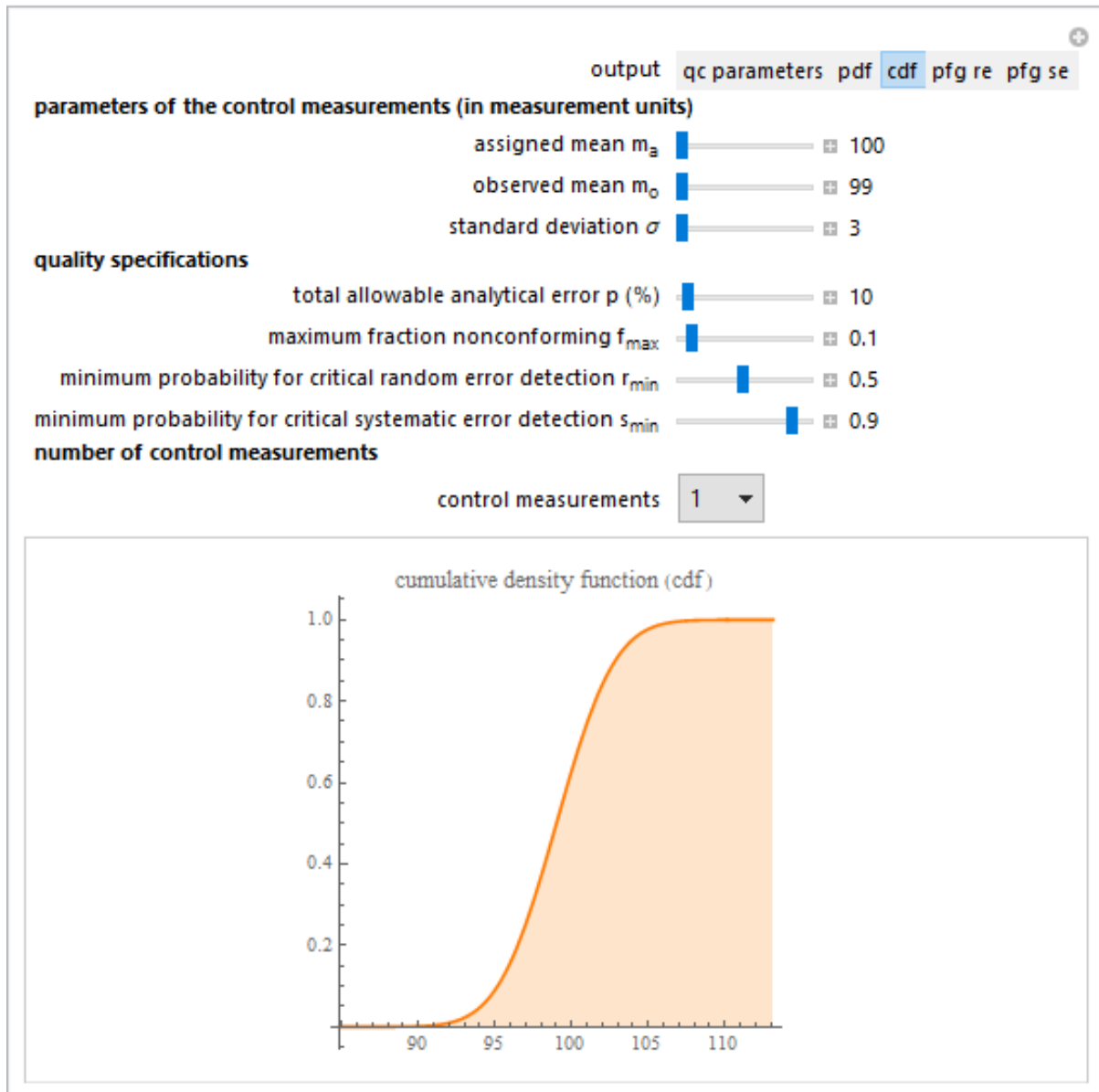


Figure 2: The cumulative density function of the measurement error of a measurement process. Assigned mean of the control material: 100 units, observed mean: 99 units, standard deviation: 3 units.

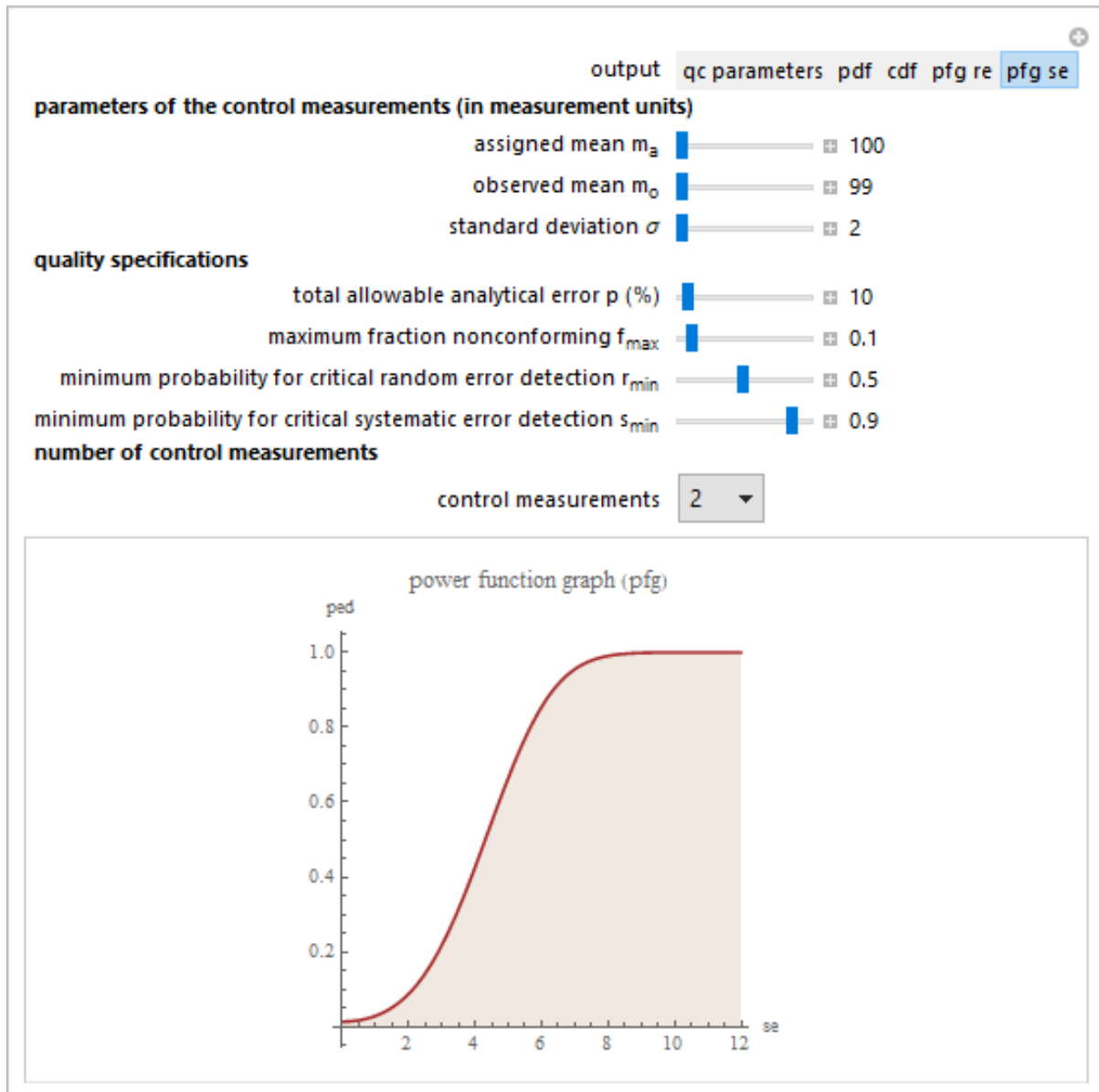


Figure 4: The power function graph for the systematic error of the quality control rule $S(1, 2, 2.74 \sigma)$ applied upon a measurement process. Assigned mean of the control material: 100 units, observed mean: 99 units, standard deviation: 2 units. Total allowable analytical error: 10%, maximum fraction nonconforming: 0.1, minimum probability for critical random error detection: 0.5, minimum probability for critical systematic error detection: 0.9. Number of control measurements: 2.

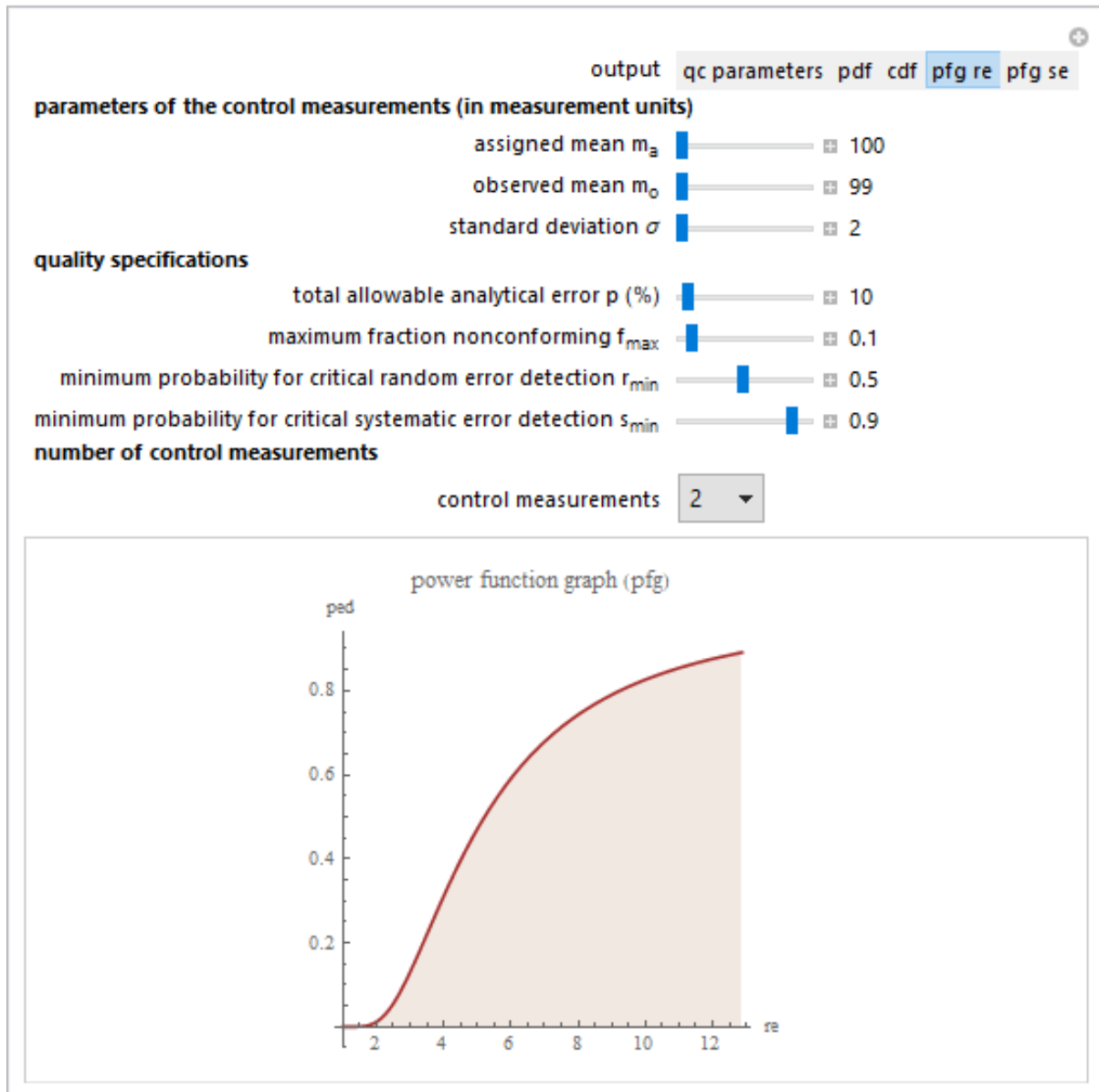


Figure 4: The power function graph for the random error of the quality control rule $S(1, 2, 2.74\sigma)$ applied upon a measurement process. Assigned mean of the control material: 100 units, observed mean: 99 units, standard deviation: 2 units. Total allowable analytical error: 10%, maximum fraction nonconforming: 0.1, minimum probability for critical random error detection: 0.5, minimum probability for critical systematic error detection: 0.9. Number of control measurements: 2.

Details

Let m_a , m_o , and σ be the assigned mean, the observed mean, and the standard deviation of the control measurements. Let $p/100$ be the total allowable analytical error (expressed as a fraction), f_{max} the maximum (acceptable) fraction nonconforming, and r_{min} and s_{min} the minimum (acceptable) probabilities for critical random and systematic error detection. Then the following equations are used to estimate the parameters [1, 2]:

$$(a) \text{ the fraction nonconforming: } f = 1 - \int_{m_a(1-\frac{p}{100})}^{m_a(1+\frac{p}{100})} \frac{e^{\frac{(-m_o+x)^2}{2\sigma^2}}}{\sigma\sqrt{2\pi}} dx$$

$$(b) \text{ the critical random error } r_c: 1 - \int_{m_o(1-\frac{p}{100})}^{m_o(1+\frac{p}{100})} \frac{e^{\frac{(-m_o+x)^2}{2r_c^2}}}{r_c\sqrt{2\pi}} dx = f_{max}$$

$$(c) \text{ the critical systematic error } s_c: \int_{m_o(1-\frac{p}{100})}^{m_o(1+\frac{p}{100})} \frac{e^{\frac{\epsilon s_c(-m_o+x)^2}{2s_c^2}}}{s_c\sqrt{2\pi}} dx = f_{max}, \text{ where } \epsilon=1 \text{ if } m_o < m_a \text{ and } \epsilon=-1$$

otherwise,

(d) the factor d of the decision limits $m_o \pm d\sigma$ of the quality control rule $S(1, n, d\sigma)$ is the minimum solution of both of the following two equations for the variable d :

$$(1) \left(\int_{m_o-d\sigma}^{m_o+d\sigma} \frac{e^{\frac{(-m_o+x)^2}{2r_c^2}}}{r_c\sqrt{2\pi}} dx \right)^n = r_{min}$$

$$(2) \left(\int_{m_o-d\sigma}^{m_o+d\sigma} \frac{e^{\frac{(\epsilon s_c-m_o+x)^2}{2s_c^2}}}{s_c\sqrt{2\pi}} dx \right)^n = s_{min}, \text{ with } \epsilon \text{ as before in (c),}$$

(e) the probability for false rejection p_f of the quality control rule $S(1, n, d\sigma)$:

$$p_f = 1 - \left(\int_{m_o-d\sigma}^{m_o+d\sigma} \frac{e^{\frac{(-m_o+x)^2}{2\sigma^2}}}{\sigma\sqrt{2\pi}} dx \right)^n$$

(f) the probability for error detection p_e of the random error r and the systematic error s of the quality

$$\text{control rule } S(1, n, d\sigma): p_e = 1 - \left(\int_{m_o-d\sigma}^{m_o+d\sigma} \frac{e^{\frac{(s-m_o+x)^2}{2r^2}}}{r\sqrt{2\pi}} dx \right)^n$$

The power function graphs ("pfg") are the plots of the probabilities for error detection versus the size of the error.

This Demonstration can be used as a tool for the design and evaluation of alternative quality control rules for a measurement process.

References

[1] A. T. Hatjimihail, "A Tool for the Design and Evaluation of Alternative Quality Control Procedures," Clinical Chemistry 38, 1992 pp. 204–210.

[2] A. T. Hatjimihail, "Estimation of the Optimal Statistical Quality Control Sampling Time Intervals Using a Residual Risk Measure," PLoS ONE 4(6), 2009 p. e5770.

Source Code

The updated Wolfram Mathematica® source code is available at:

<https://heracleitos.github.io/HCSL/Tools/ToolForQualityControlDesignAndEvaluation-author.nb>

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<http://demonstrations.wolfram.com/ToolForQualityControlDesignAndEvaluation/>

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