Hellenic Complex Systems Laboratory

Quality: A Software Tool for Statistical Quality Control Design

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Quality: A Software Tool for Statistical Quality Control Design

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Search Terms: quality control, quality control design, measurement, uncertainty, total allowable analytical error, fraction nonconforming, critical systematic error, critical random error, decision limits, probability for rejection, probability for false rejection

Introduction

Alternative quality control (QC) procedures can be applied to a process to test statistically the null hypothesis, that the process conforms to the quality specifications and consequently is in control, against the alternative, that the process is out of control. When a true null hypothesis is rejected, a statistical type I error is committed. We have then a false rejection of a run of the process. The probability of a type I error is called probability of false rejection. When a false null hypothesis is accepted, a statistical type II error is committed. We fail then to detect a significant change in the probability density function of a quality characteristic of the process. The probability of rejection of a false null hypothesis equals the probability of detection of the nonconformity of the process to the quality specifications.

The program *QCD* was developed for designing and exploring QC rules to meet defined quality specifications

The program modules

The program provides two modules:

1. *Design*

This module estimates various parameters of a measurement process and designs the quality control rule to be applied and plots the probability density function (pdf) and the cumulative density function (cdf) of the control measurements, and the probability for rejection for the random error and systematic error of the quality control rule.

2. *Compare*

This module explores and compares alternative statistical quality control rules $S(\boldsymbol{x}; m, s, l_i)$ (see Notation) applied on tuples $\boldsymbol{x}$ of n_i control measurements, k_i of them distributed as $\mathcal{N}(m, s^2)$, and n_i-k_i as $\mathcal{N}(0,1)$, plotting the probabilities for rejection $P(n_i, k_i, m, s; 0, 1, l_i)$ of the two statistical QC rules, their difference, relative difference and ratio.

The program interface

1. Design

1.1. *Input.*

1.1.1. Parameters of the control measurements (in arbitrary measurement units)

1.1.1.1. The assigned mean m_0 ($0.01 \leq m_0 \leq 1000.0$),

1.1.1.2. The observed mean m when the process is in control ($0.01 \leq m \leq 1000.0$), and

1.1.1.3. The standard deviation s when the process is in control ($0.01 \leq s \leq 1000.0$).

1.1.2. Quality specifications of the measurement process

1.1.2.1. The total allowable error t (as a percentage of the assigned mean) ($0.01 \leq t \leq 200.0$),

1.1.2.2. The maximum acceptable fraction f_{max} of measurements nonconforming to the specifications ($0.01 \leq f_{max} \leq 1.0$),

1.1.2.3. The minimum acceptable probability p_{s_c} for detection of the critical random error ($0.01 \leq p_{s_c} \leq 0.99$).

1.1.2.4. The minimum acceptable probability p_{m_c} for detection of the critical systematic error ($0.01 \leq p_{m_c} \leq 0.99$).

1.1.2.5. The number n of control measurements ($1 \leq n \leq 6$).

1.2. Output

1.2.1. Table of quality control parameters

1.2.1.1. The fraction nonconforming f,

1.2.1.2. The critical random error s_c,

1.2.1.3. The critical systematic error m_c,

1.2.1.4. The quality control decision limits $m \pm l s$,

1.2.1.5. The probability p_{s_c} for critical random error detection,

1.2.1.6. The probability p_{m_c} for critical systematic error detection

1.2.1.7. The probability p_{fr} for false rejection

1.2.2. Plots

1.2.2.1. The probability density function (pdf) plot of the control measurements,

1.2.2.2. The cumulative density function (cdf) plot of the control measurements,

1.2.2.3. the probability for rejection plot for the random error (p_r vs s), and

1.2.2.4. the probability for rejection plot for the systematic error (p_r vs m).

The parameters are estimated and the functions are plotted if $10^{-100} \leq f \leq f_{max}$

2. Compare

2.1. Input.

2.1.1. Plot options

2.1.1.1. Type of error:

2.1.1.1.1. Random error

2.1.1.1.2. Systematic error

2.1.1.2. Type of plot:

2.1.1.2.1. The probabilities for rejection of both quality control rules

2.1.1.2.2. The difference between the probabilities for rejection

2.1.1.2.3. The relative difference between the probabilities for rejection

2.1.1.2.4. The ratio of the probabilities for rejection

2.1.1.3. Plot range

2.1.1.3.1. The range r of the y-axis (1.0 – 10.0)

2.1.2. Quality control parameters

The following parameters are defined for two alternative quality control procedures:

2.1.2.1. The number n of the control measurements ($1 \leq n \leq 6$).

2.1.2.2. The number k of the control measurements distributed as $\mathcal{N}(m, s^2)$

2.1.2.3. Either:

2.1.2.3.1. The probability p_{fr} for false rejection ($0.000001 \leq p_{fr} \leq 0.1$) or

2.1.2.3.2. The quality control decision limit l ($1.0 \leq l \leq 4.0$)

2.2. Output

2.2.1. Table of quality control parameters

2.2.1.1. The quality control decision limit l s,

2.2.1.2. The probability p_0 for false rejection

2.2.2. Plots

2.2.2.1. The probabilities for rejection of both quality control rules

2.2.2.2. The difference between the probabilities for rejection

2.2.2.3. The relative difference between the probabilities for rejection

2.2.2.4. The ratio of the probabilities for rejection

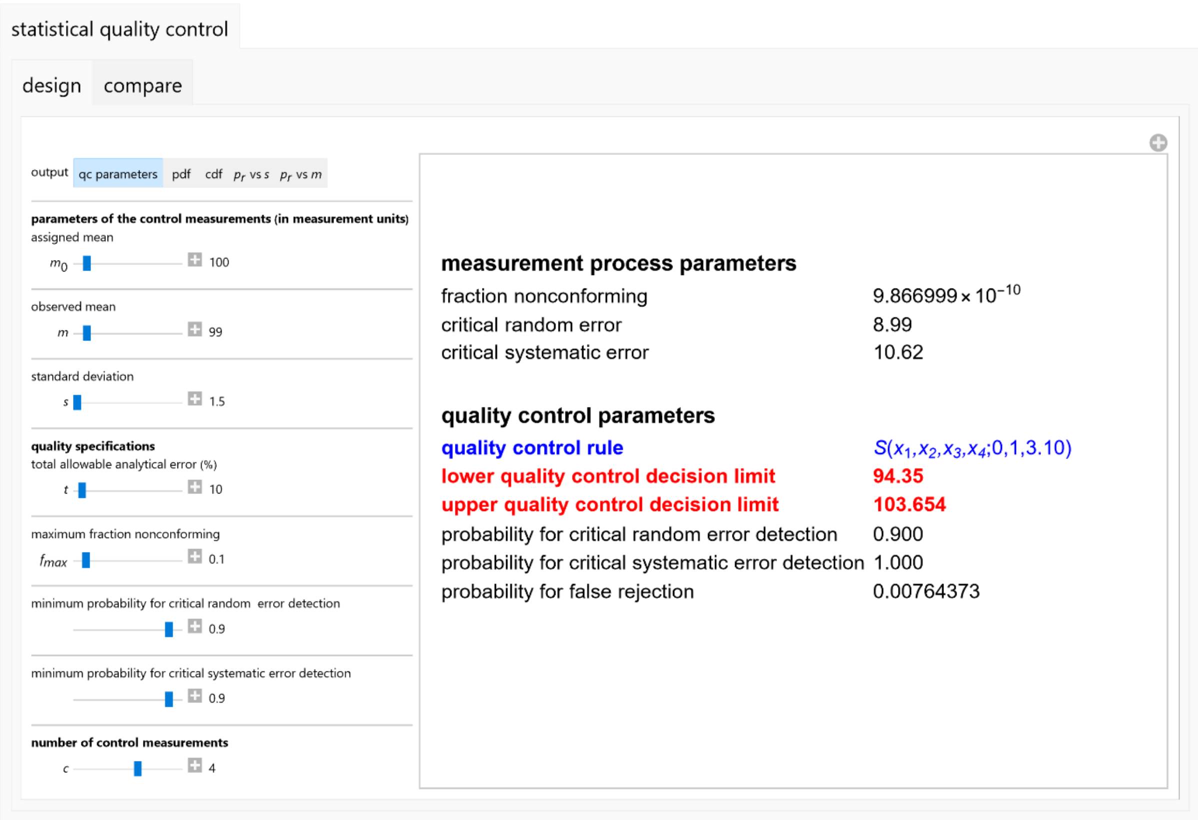

Figure 1: *The measurement process parameters and the quality control parameters of a measurement process, with the settings shown at the left.*

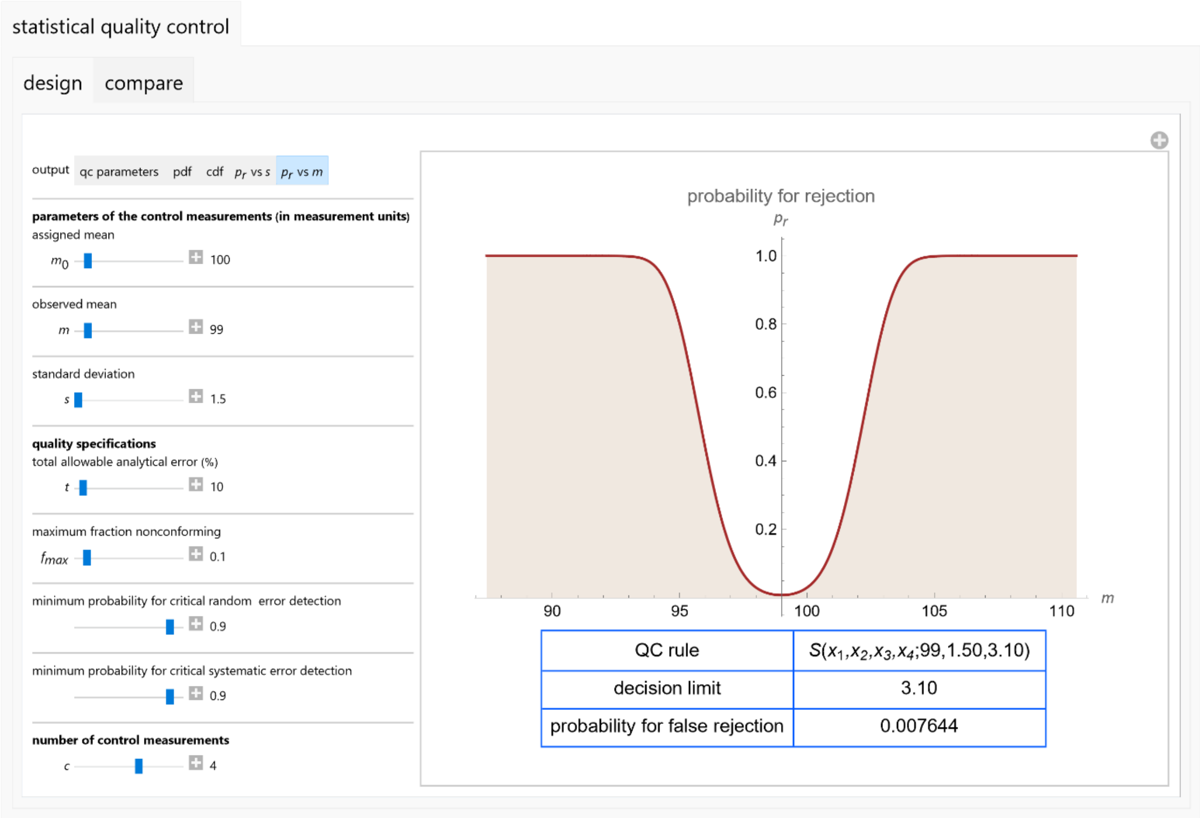

Figure 2: *The probability for rejection of a QC rule vs* the mean m *of the control measurements, with the settings shown at the left.*

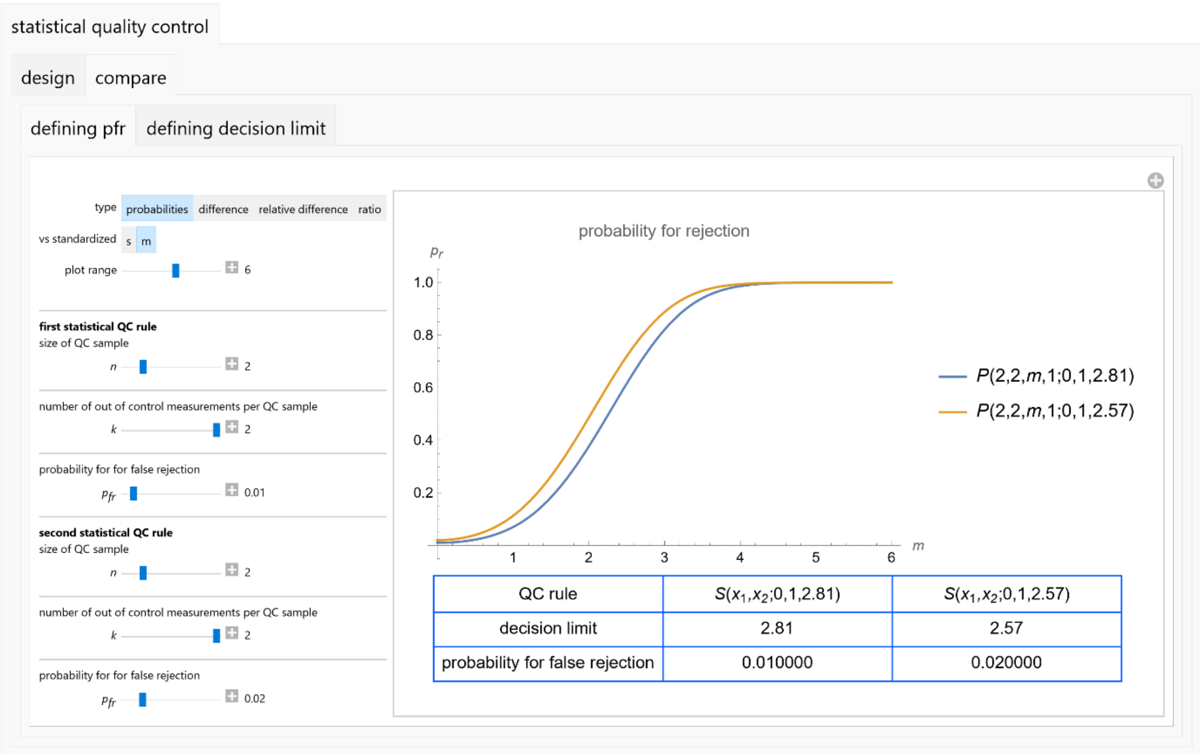

Figure 3: *The probabilities for rejection of two alternative QC rules vs* the standardized observed mean m *of the control measurements, with the settings shown at the left.*

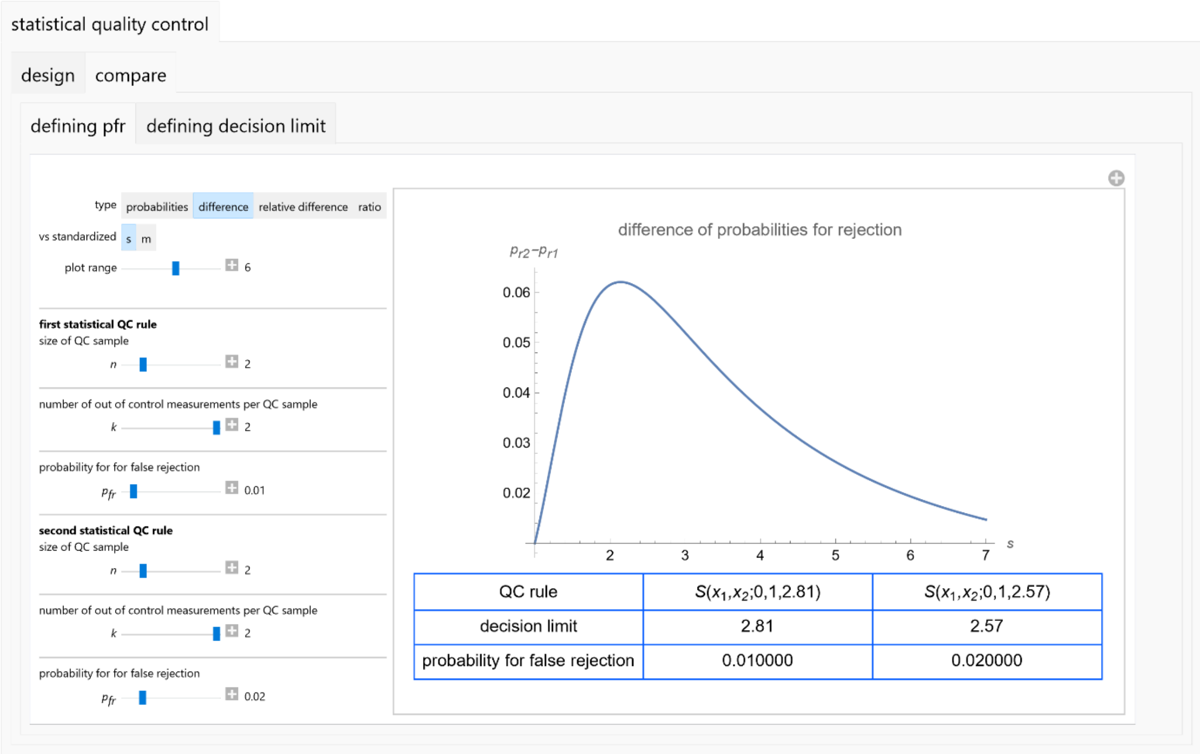

Figure 4: *The difference probabilities for rejection of two alternative QC rules vs* the standardized standard deviation s *of the control measurements, with the settings shown at the left.*

Details

Let m_0, m, and s be the assigned mean, the observed mean, and the standard deviation of the control measurements. Let t be the total allowable analytical error (expressed as percentage of the assigned mean). Then the following equations are used to estimate the respective parameters [1, 2, 3]:

(a) the fraction nonconforming f:

$$f = 1 - \int_{m_0\left(1-\frac{t}{100}\right)}^{m_0\left(1+\frac{t}{100}\right)} \left(\frac{e^{\frac{(-m+z)^2}{2s^2}}}{s\sqrt{2\pi}} \right) dz$$

(b) the critical random error s_c:

$$1 - \int_{m_0\left(1-\frac{t}{100}\right)}^{m_0\left(1+\frac{t}{100}\right)} \left(\frac{e^{\frac{(-m+z)^2}{2s_c^2}}}{s_c\sqrt{2\pi}} \right) dz = f_{max}$$

(c) the critical systematic error m_c:

$$\int_{m_0\left(1-\frac{t}{100}\right)}^{m_0\left(1+\frac{t}{100}\right)} \left(\frac{e^{\frac{(\epsilon\, m_c-m+z)^2}{2s^2}}}{s\sqrt{2\pi}} \right) dz = f_{max}$$

where ϵ=1 if $m_o < m_a$ and ϵ= -1 otherwise,

(d) the factor l of the decision limits $m \pm l\,s$ of the quality control rule $S(\boldsymbol{x}; m, s, l\,)$ is the minimum solution of both of the following two equations for the variable l:

$$\left(\int_{m-l\,s}^{m+l\,s}\left(\frac{e^{\frac{(-m+z)^2}{2s_c^2}}}{s_c\sqrt{2\pi}}\right)dz\right)^n = p_{s_c}$$

$$\left(\int_{m-l\,s}^{m+l\,s}\left(\frac{e^{\frac{(m_c-m+z)^2}{2s^2}}}{s\sqrt{2\pi}}\right)dz\right)^n = p_{m_c}$$

with ϵ as before in (c),

(e) the probability for false rejection of the quality control rule $S\,(\boldsymbol{x}; m, s, l\,)$:

$$P(n, n, m, s; m, s, l\,) = 1 - \left(\int_{m-l\,s}^{m+l\,s}\left(\frac{e^{\frac{(-m+z)^2}{2s^2}}}{s\sqrt{2\pi}}\right)dz\right)^n$$

(f) the probability for rejection for the random error s_e and the systematic error m_e of the quality control rule $S\,(\boldsymbol{x}; m, s, l\,)$:

$$P(n, n, m_e, s_e, m, s, l\,) = 1 - \left(\int_{m-l\,s}^{m+l\,s}\left(\frac{e^{\frac{(m_e-m+z)^2}{2s_e{}^2}}}{s_e\sqrt{2\pi}}\right)dz\right)^n$$

$$P(n, k, m_e, s_e; m, s, l) = P(k, k, m_e, s_e; m, s, l\,) + P(n-k, n-k, m, s; m, s, l\,) -$$

$$P(k, k, m_e, s_e; m, s, l\,)P(n-k, n-k, m, s; m, s, l\,)$$

Conclusion

The program *Quality* can be used as an educational or laboratory 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. Tool for Quality Control Design and Evaluation, Wolfram Demonstrations Project, Champaign: Wolfram Research, Inc., 2010.

[3] 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.

Notation

$\boldsymbol{x}$: n-tuple $(x_1, x_2, \dots, x_n)$ of control measurements
m_0: the assigned mean of the control measurements
m : the observed mean of the control measurements

s : the observed standard deviation of the control measurements

m_e : the observed mean of the control measurements when the measurement process is out of control

s_e : the observed standard deviation of the control measurements when the measurement process is out of control

s_c : the critical random error

m_c : the critical systematic error

p_r : probability for rejection

p_{fr} : probability for false rejection

p_{s_c} : the probability for critical random error detection

p_{m_c} : the probability for critical systematic error detection

$S(\boldsymbol{x}; m, s, l)$: statistical QC rule with decision limits $m \pm l\, s$, applied on $\boldsymbol{x}$. The rule rejects an analytical run if: $\exists\, x_i \in \boldsymbol{x}: x_i < m - ls \lor x_i > m + l$

$\mathcal{N}(m, s^2)$: normal distribution with mean m and standard deviation s.

$P_S(n, k, m_e, s_e; m, s, l)$: probability for rejection of the QC rule $S(\boldsymbol{x}; m, s, l)$ applied on a n-tuple $\boldsymbol{x}$ of control measurements, k of them distributed as $\mathcal{N}(m_e, s_e^2)$ and n-k as $\mathcal{N}(m, s^2)$

Source Code

Programming language: Wolfram Language

Availability: The updated source code is available at: https://www.hcsl.com/Tools/Quality/Quality.nb

Software Requirements

Operating systems: Microsoft Windows, Linux, Apple iOS

Other software requirements: Wolfram Player®, freely available at: https://www.wolfram.com/player/ or Wolfram Mathematica®.

System Requirements

Processor: Intel Core i7® or equivalent CPU

System memory (RAM): 8 GB+ recommended.

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