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, 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) rules and 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 *Quality* was developed for designing and exploring statistical single-value QC rules $S(\boldsymbol{x}; m, s, l_i)$ (see Notation) 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 statistical single-value QC rule $S(\boldsymbol{x}; m, s, l_i)$ 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 $S(\boldsymbol{x}; m, s, l_i)$.

2. *Compare*

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

The program interface

1. Design

1.1. Input.

1.1.1. Parameters of the QC 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 ($0.01 \le m \le 1000.0$), and

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

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) ($0.01 \le t \le 200.0$) ,

1.1.2.2. The maximum acceptable fraction f_{max} of measurements nonconforming to the specifications ($0.01 \le f_{max} \le 1.00$),

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

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

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

1.2. Output

1.2.1. Table of QC 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 designed statistical single-value QC rule

1.2.1.5. The decision limits $m \pm l\,s$ of the rule

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

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

1.2.1.8. The probability p_{fr} for false rejection

1.2.2. Plots

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

1.2.2.2. The cumulative density function (cdf) plot of the QC 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 $10^{-100} \le f \le f_{max}$

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 QC 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. QC parameters

The following parameters are defined for two alternative QC 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 ($0.000001 \leq p_{fr} \leq 0.100000$) or

2.1.2.3.2. The QC decision limit l ($1.00 \leq l \leq 4.00$)

2.2. Output

2.2.1. Table of QC parameters

2.2.1.1. The 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 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

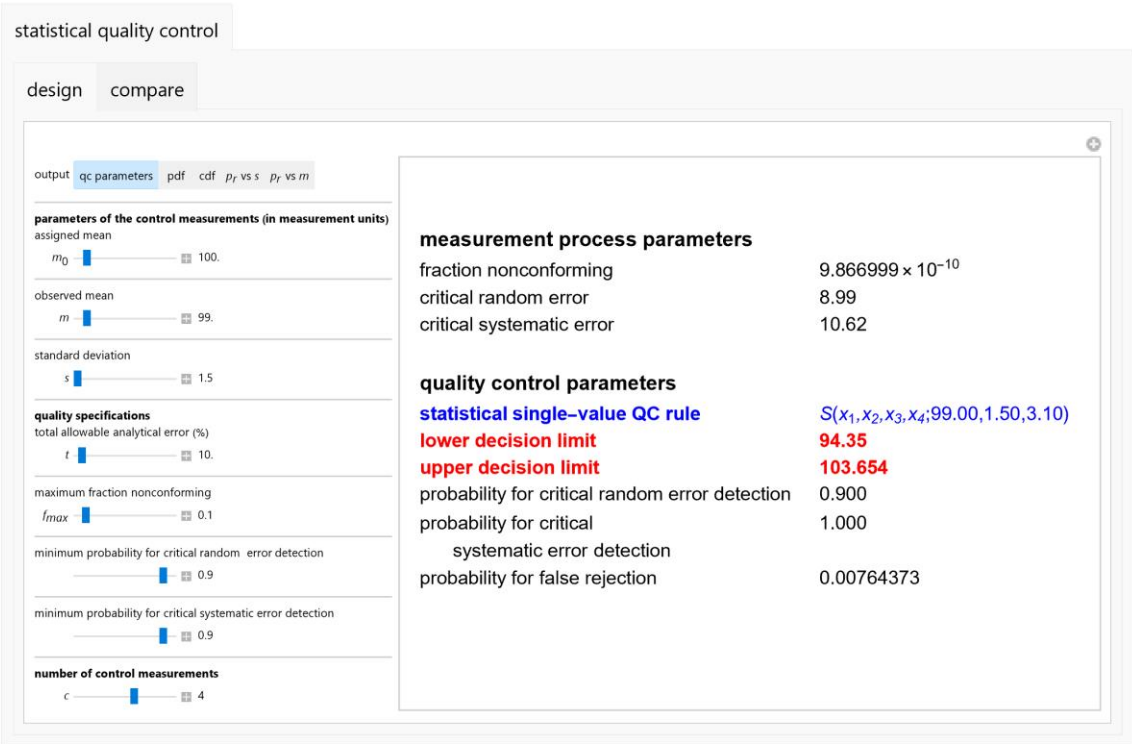

Figure 1: *The measurement process parameters and the QC parameters of a measurement process, with the settings shown at the left.*

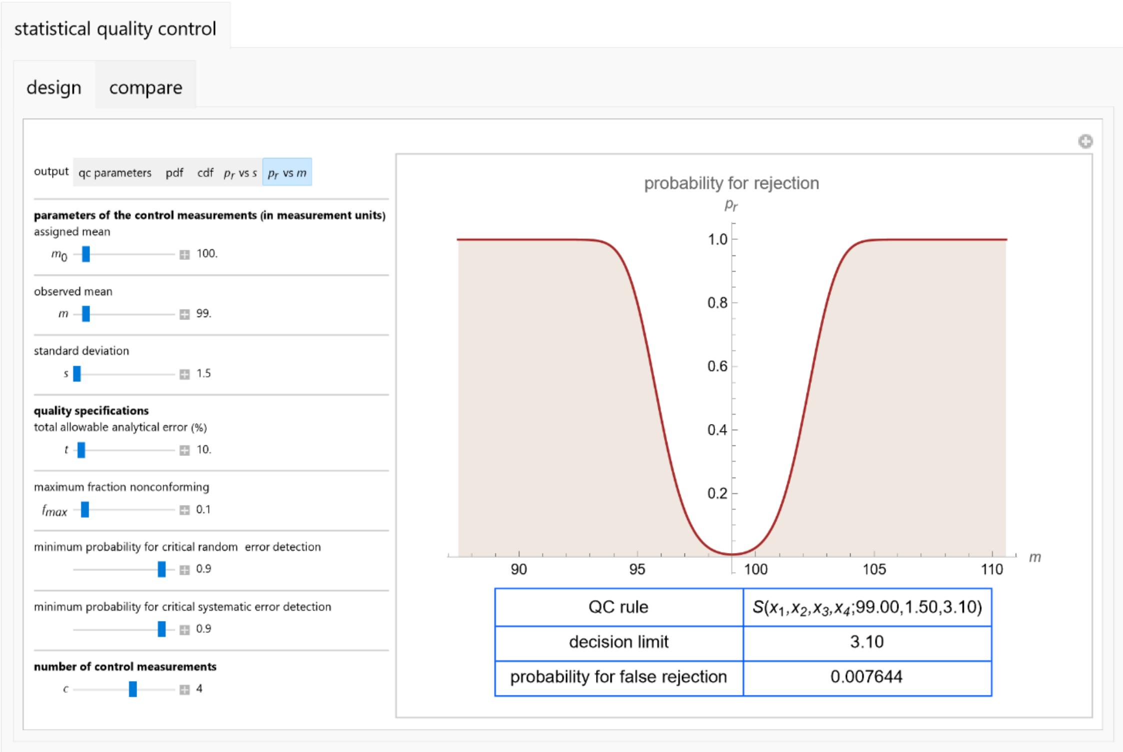

Figure 2: *The probability for rejection of a statistical single-value QC rule vs the mean m of the control measurements, with the settings shown at the left.*

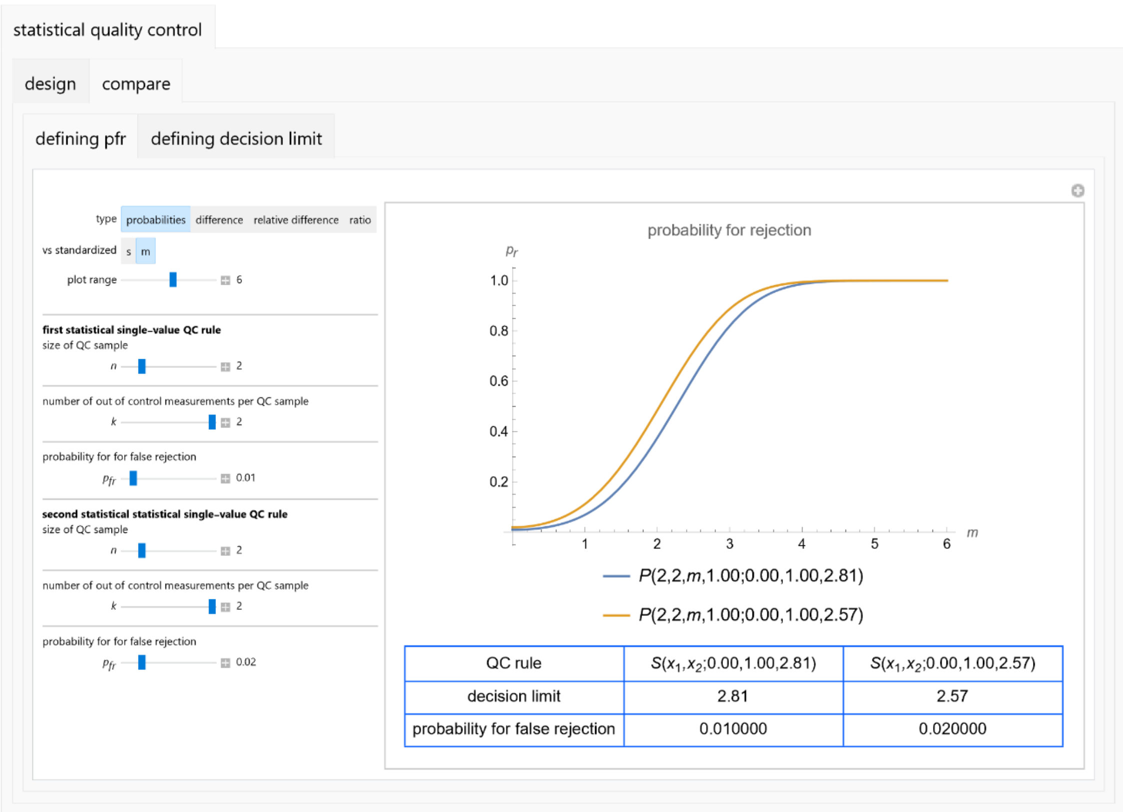

Figure 3: *The probabilities for rejection of two alternative statistical single-value QC rules vs the standardized observed mean m of the control measurements, with the settings shown at the left.*

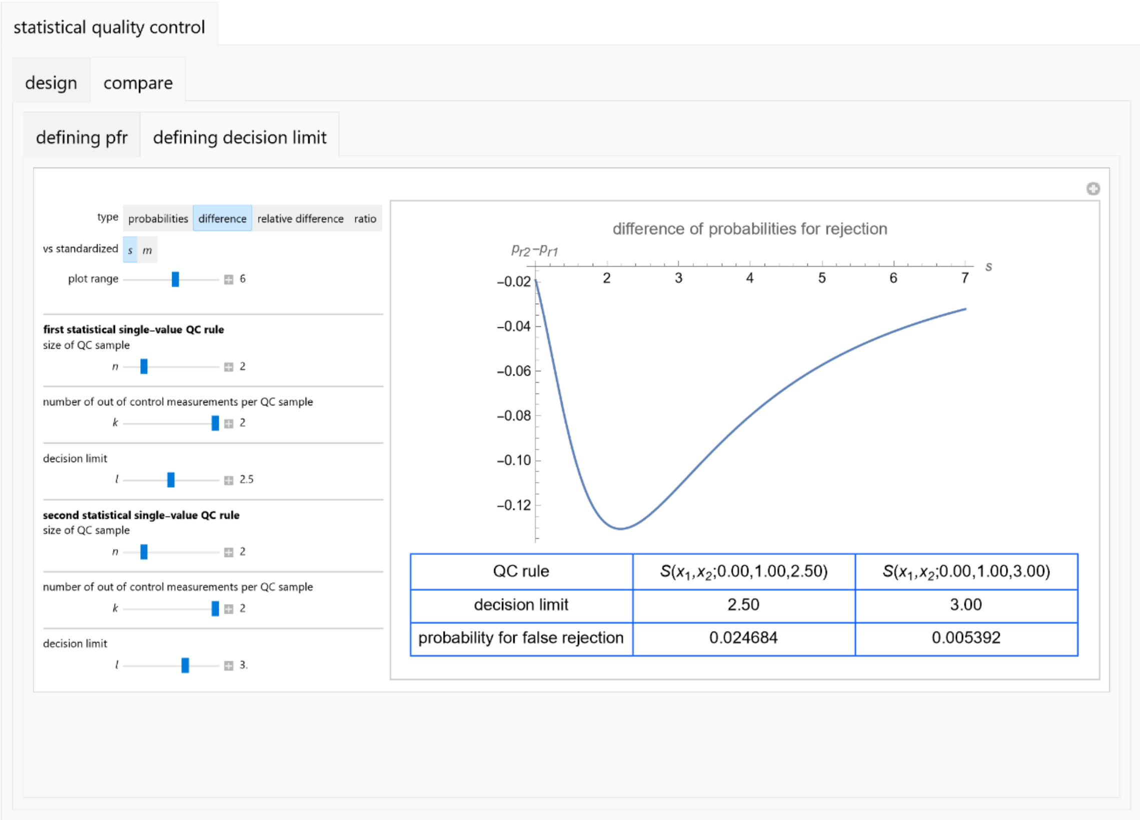

Figure 4: *The difference probabilities for rejection of two alternative statistical single-value QC rules vs the standardized standard deviation s of the control measurements, with the settings shown at the left.*

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 $\epsilon = 1$ if $m_o < m_a$ and $\epsilon = -1$ otherwise,

(d) the factor l of the decision limits $m \pm l\, s$ of the statistical single-value QC 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 $S\,(\boldsymbol{x}; m, s, l\,)$:

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

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

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

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

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

Conclusion

The program *Quality* can be used as an educational or laboratory tool for the design and evaluation of alternative statistical single-value QC 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 single-value QC rule with decision limits $m \pm l\, s$, applied on $\boldsymbol{x}$. The rule rejects an analytical run if: $\exists\, x_i \in \boldsymbol{x}: x_i < m - ls \vee x_i > m + l$

$\mathcal{N}(m, s^2)$: 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 statistical single-value 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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