

Hellenic Complex Systems Laboratory

Quality Control: A Software Tool for Statistical Quality Control Design and Evaluation

Technical Report XXIII

Rallou A. Chatzimichail and Aristides T. Hatjimihail

2022

Quality Control: A Software Tool for Statistical Quality Control Design and Evaluation

Rallou A. Chatzimichail, PhD ^a, Aristides T. Hatjimihail, MD, PhD ^a

^a Hellenic Complex Systems Laboratory

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 statistically test the null hypothesis, that the process conforms to the quality specifications and consequently is in control, and against the alternative, that the process is out of control. A statistical type I error is committed when a true null hypothesis is rejected. We then have a false rejection of the run of the process. The probability of a type I error is called the probability of false rejection (pfr). A statistical type II error is committed when a false null hypothesis is accepted. 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 Control was developed for designing and exploring QC rules $R_S(\mathbf{x}; m_0, s_0, n, k, l)$, where $1 \leq k \leq n$ and $R_M(\mathbf{x}; m_0, s_0, n, l)$ (see Notation) to meet defined quality specifications.

The program

The program provides two modules:

Design

This module estimates various parameters of a measurement process and designs the optimal QC rule $R_S(\mathbf{x}; m_0, s_0, n, k, l)$, where $1 \leq k \leq n$, or $R_M(\mathbf{x}; m_0, s_0, n, l)$, to be applied to detect the critical random and systematic errors with stated probabilities and minimum pfr. It plots the probability density

function (pdf) and the cumulative distribution function (cdf) of the control measurements, as well as the probability for rejection for the random and systematic error of the designed QC rule (see Figures 1 and 2).

Compare

This module explores and compares alternative statistical QC rules $R_S(\mathbf{x}; m_0, s_0, n, k, l)$, for $1 \leq k \leq n$, and $R_M(\mathbf{x}; m_0, s_0, n, l)$ (see Notation), applied on tuples \mathbf{x} of n control measurements, distributed as $\mathcal{N}(m, s^2)$. It plots the respective probabilities for rejection. $P_S(m, s; m_0, s_0, n, k, l)$ and $P_M(m, s; m_0, s_0, n, l)$ of the statistical QC rules and calculates their probabilities for false rejection and random and systematic critical error detection (see Figures 3 and 4).

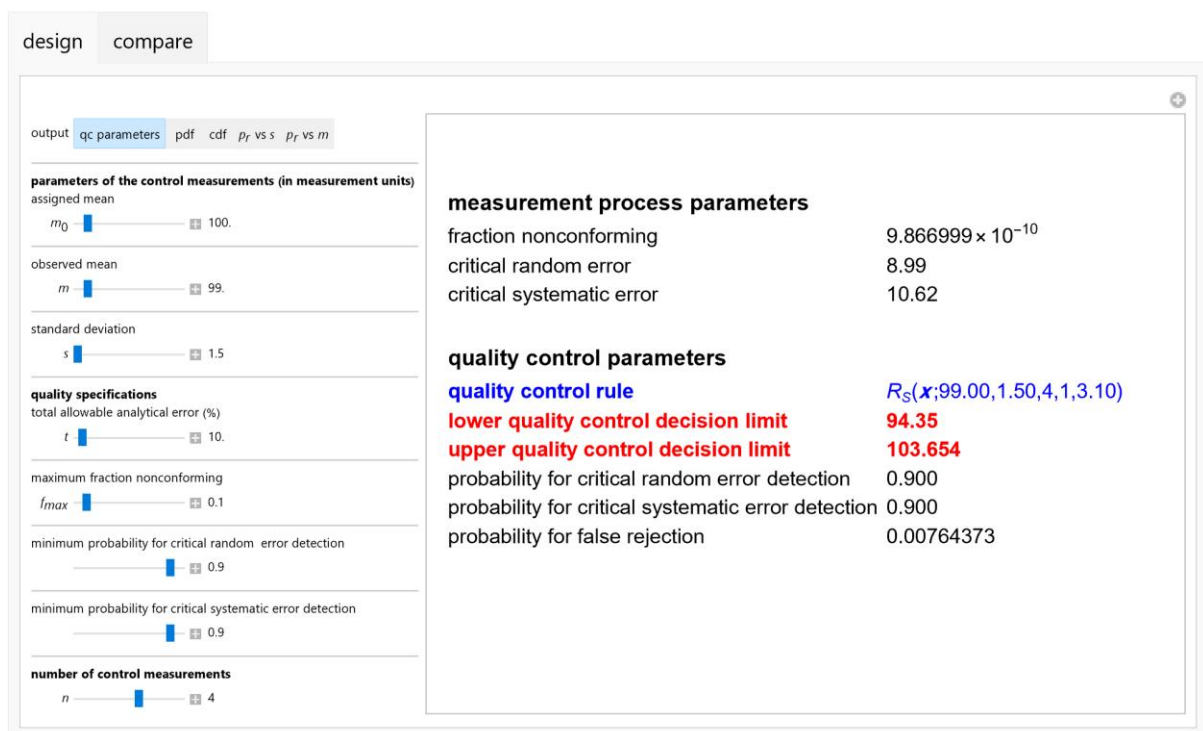


Figure 1: The measurement process parameters and the QC parameters of a measurement process, with the settings shown at the left.

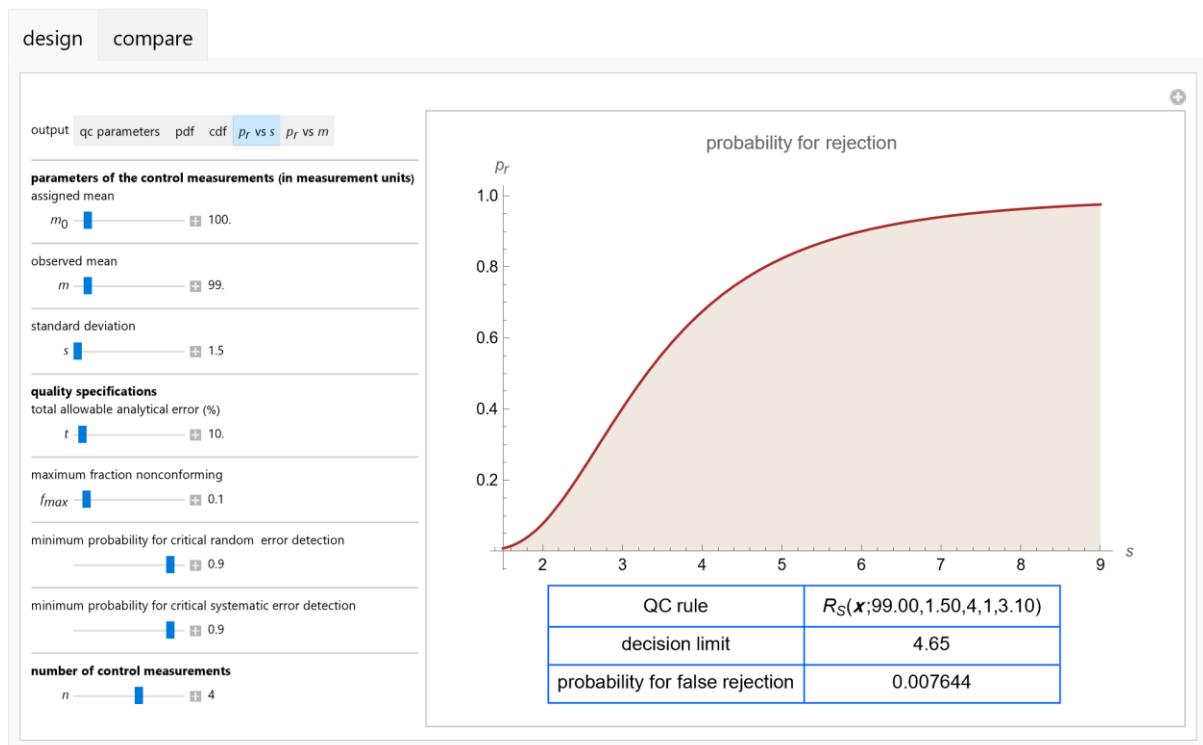


Figure 2: The probability for rejection of a QC rule vs the standard deviation s of the control measurements, with the settings shown at the left.

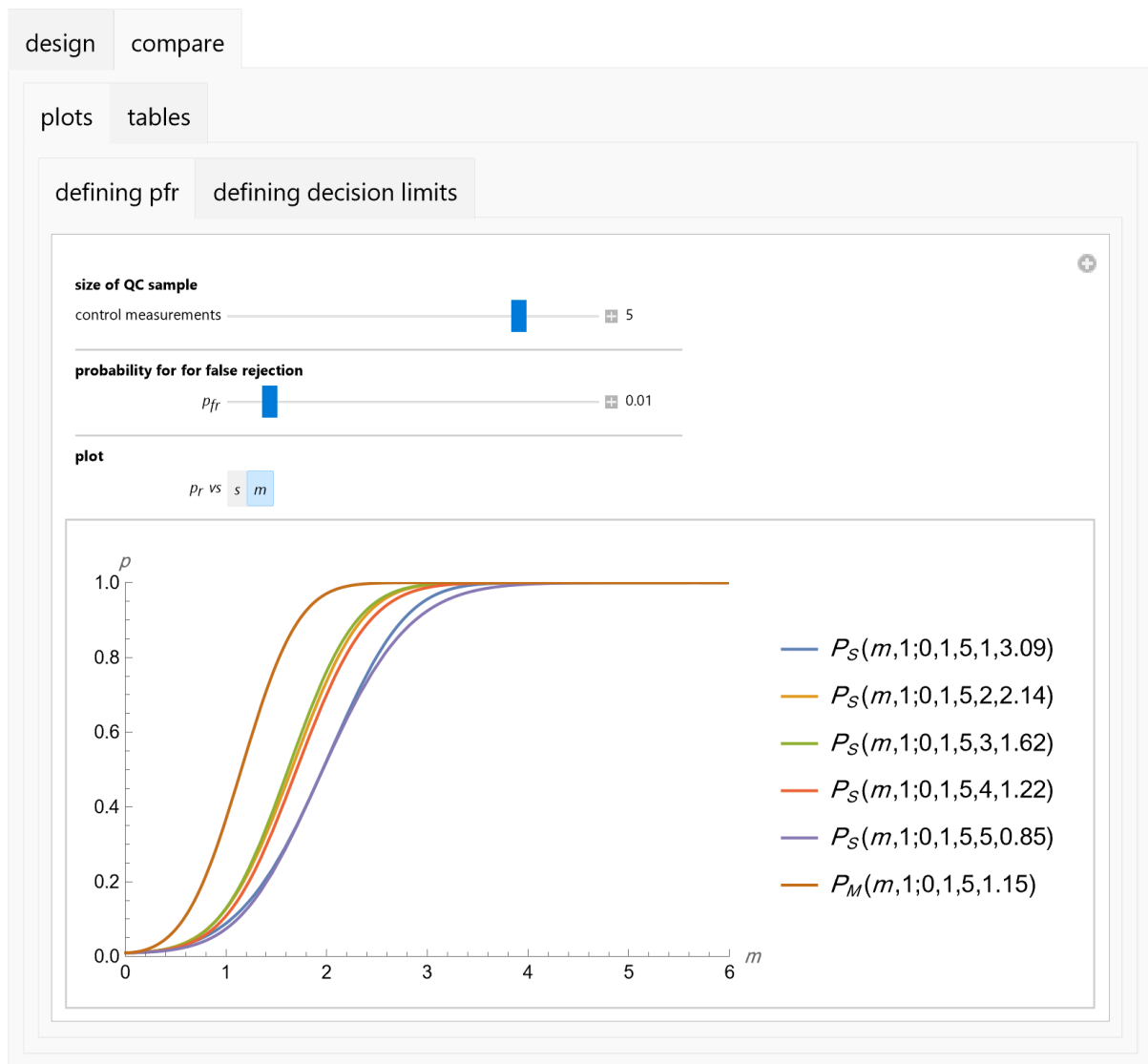


Figure 3: The probabilities for rejection of the alternative QC rules shown at the right vs the standardized observed mean of the control measurements, with the settings at the top.

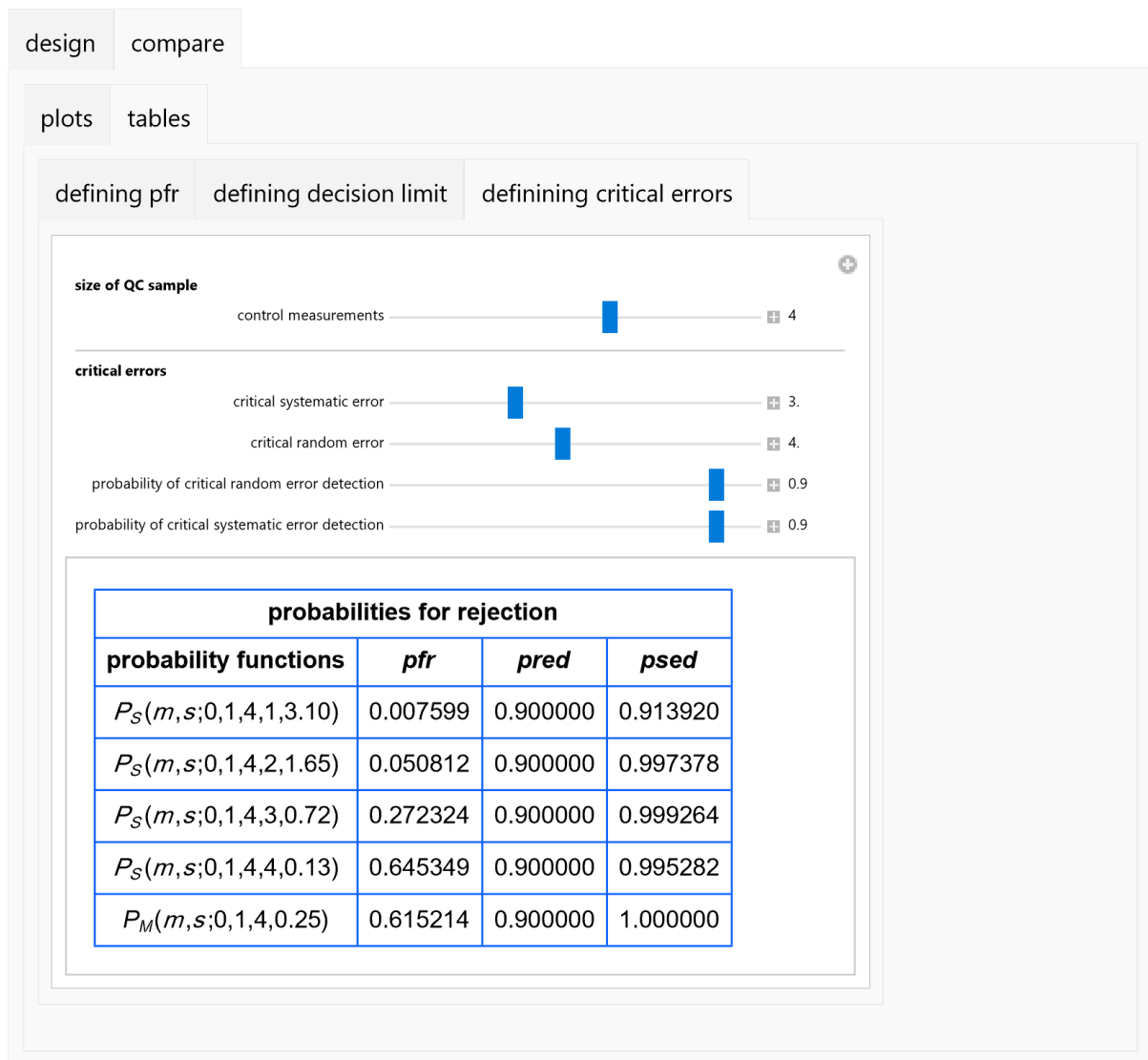


Figure 4: The probabilities for false rejection and critical error detection of the QC rules are shown at the left of the table, with the settings at the top.

Details

Let m_a , m_0 , and s_0 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 a percentage of the assigned mean). Then, the following equations are used to estimate the respective parameters [1, 2, 3, 4]:

(a) The fraction nonconforming f :

$$f = \frac{\operatorname{erfc}\left(\frac{m_a - m_0\left(1 - \frac{t}{100}\right)}{s_0\sqrt{2}}\right) + \operatorname{erfc}\left(-\frac{m_a + m_0\left(1 + \frac{t}{100}\right)}{s_0\sqrt{2}}\right)}{2}$$

(b) the critical random error s_c :

$$\frac{\operatorname{erfc}\left(\frac{m_a - m_0\left(1 - \frac{t}{100}\right)}{s_c\sqrt{2}}\right) + \operatorname{erfc}\left(-\frac{m_a + m_0\left(1 + \frac{t}{100}\right)}{s_c\sqrt{2}}\right)}{2} = f_{max}$$

(c) the critical systematic error m_c :

$$\frac{\operatorname{erfc}\left(\frac{m_a - (\epsilon m_c - m_0)\left(1 - \frac{t}{100}\right)}{s_0\sqrt{2}}\right) + \operatorname{erfc}\left(-\frac{m_a + (\epsilon m_c - m_0)\left(1 + \frac{t}{100}\right)}{s_0\sqrt{2}}\right)}{2} = f_{max}$$

where f_{max} the maximum acceptable fraction nonconforming, and $\epsilon = 1$ if $m_a < m_0$ and $\epsilon = -1$ otherwise,

(d) the factor l of the decision limits $m_0 \pm l s_0$ of the QC rule $R_S(x; m_0, s_0, n, k, l)$ is the minimum solution of both of the following two equations for the variable l , where p_{s_c} and p_{m_c} the minimum probabilities for critical random and systematic error detection:

$$\begin{aligned} & \frac{1}{k!(n-k)!} 2^{-n} \left(-1 + \operatorname{erf}\left(\frac{ls_0}{s_c\sqrt{2}}\right) + \operatorname{erfc}\left(\frac{-ls_0}{s_c\sqrt{2}}\right) \right)^{n-k} \left(1 + \operatorname{erf}\left(\frac{-ls_0}{s_c\sqrt{2}}\right) + \operatorname{erfc}\left(\frac{ls_0}{s_c\sqrt{2}}\right) \right)^k \Gamma(1 \\ & + n) {}_2F_1 \left(1, k-n; 1+k; 1 + \frac{2}{\operatorname{erf}\left(\frac{-ls_0}{s_c\sqrt{2}}\right) - \operatorname{erf}\left(\frac{ls_0}{s_c\sqrt{2}}\right)} \right) = p_{s_c} \end{aligned}$$

$$\begin{aligned} & \frac{1}{k!(n-k)!} 2^{-n} \left(-1 + \operatorname{erf} \left(\frac{m_c - m_0 + ls_0}{s_0 \sqrt{2}} \right) + \operatorname{erfc} \left(\frac{m_c - m_0 - ls_0}{s_0 \sqrt{2}} \right) \right)^{n-k} \left(-1 + \operatorname{erf} \left(\frac{m_c - m_0 - ls_0}{s_0 \sqrt{2}} \right) \right. \\ & \quad \left. + \operatorname{erfc} \left(\frac{m_c - m_0 + ls_0}{s_0 \sqrt{2}} \right) \right)^k \Gamma(1+n) {}_2F_1 \left(1, k-n; 1+k; 1 \right. \\ & \quad \left. + \frac{2}{\operatorname{erf} \left(\frac{m_c - m_0 - ls_0}{s_0 \sqrt{2}} \right) - \operatorname{erf} \left(\frac{m_c - m_0 + ls_0}{s_0 \sqrt{2}} \right)} \right) = p_{m_c} \end{aligned}$$

(e) the factor l of the decision limits $m_0 \pm l s_0$ of the QC rule $R_M(\mathbf{x}; m_0, s, n, l)$ is the minimum solution of both of the following equations for the variable l :

$$\begin{aligned} & \frac{\left(1 + \operatorname{erf} \left(\frac{(-ls_0)\sqrt{n}}{s_c \sqrt{2}} \right) + \operatorname{erfc} \left(\frac{(ls_0)\sqrt{n}}{s_c \sqrt{2}} \right) \right)}{2} = p_{s_c} \\ & \frac{\left(1 + \operatorname{erf} \left(\frac{(m_c - m_0 - ls_0)\sqrt{n}}{s_0 \sqrt{2}} \right) + \operatorname{erfc} \left(\frac{(m_c - m_0 + ls_0)\sqrt{n}}{s_0 \sqrt{2}} \right) \right)}{2} = p_{m_c} \end{aligned}$$

(f) the probability for rejection for the random error s and the systematic error m of the QC rule $R_S(\mathbf{x}; m_0, s_0; n, k, l)$:

$$\begin{aligned} & P_S(m, s; m_0, s_0, n, k, l) \\ & = \frac{1}{k!(n-k)!} 2^{-n} \left(-1 + \operatorname{erf} \left(\frac{m - m_0 + ls_0}{s \sqrt{2}} \right) + \operatorname{erfc} \left(\frac{m - m_0 - ls_0}{s \sqrt{2}} \right) \right)^{n-k} \left(-1 \right. \\ & \quad \left. + \operatorname{erf} \left(\frac{m - m_0 - ls_0}{s \sqrt{2}} \right) + \operatorname{erfc} \left(\frac{m - m_0 + ls_0}{s \sqrt{2}} \right) \right)^k \Gamma(1+n) {}_2F_1 \left(1, k-n; 1+k; 1 \right. \\ & \quad \left. + \frac{2}{\operatorname{erf} \left(\frac{m - m_0 - ls_0}{s \sqrt{2}} \right) - \operatorname{erf} \left(\frac{m - m_0 + ls_0}{s \sqrt{2}} \right)} \right) \end{aligned}$$

(g) the probability for rejection for the random error s and the systematic error m of the QC rule $P_M(m, s; m_0, s_0, n, l)$:

$$P_M(m, s; m_0, s_0, n, l) = \frac{\left(1 + \operatorname{erf} \left(\frac{(m - m_0 - ls_0)\sqrt{n}}{s \sqrt{2}} \right) + \operatorname{erfc} \left(\frac{(m - m_0 + ls_0)\sqrt{n}}{s \sqrt{2}} \right) \right)}{2}$$

Among the QC rules satisfying the equations (c) or (d), the optimal one has the minimum pfr.

Conclusion

The program Quality Control can be used as an educational or laboratory tool to design and evaluate alternative 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.
- [4] R.A. Chatzimichail, A.T Hatjimihail. Quality: A Software Tool for Statistical Quality Control Design. Drama: Hellenic Complex Systems Laboratory, 2022.

Abbreviations

QC: quality control

pfr: probability for false rejection

pdf: probability density function

cdf: cumulative distribution function

Notation

\mathbf{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

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

$R_S(\mathbf{x}; m, s, n, k, l)$: statistical QC rule with decision limits $m \pm l s$, applied on \mathbf{x} . The rule rejects an analytical run if fork of the n $x_i \in \mathbf{x}$: $x_i < m - l s \vee x_i > m + l$.

$R_M(\mathbf{x}; m, s; n, l)$: statistical QC rule with decision limits $m \pm l s$, applied on \mathbf{x} . The rule rejects an analytical run if for the mean of \mathbf{x} : $\bar{x} < m - l s \vee \bar{x} > m + l s$.

$P_S(m, s; m_0, s_0, n, k, l)$: probability for rejection of the QC rule $R_S(\mathbf{x}; m_0, s_0, n, k, l)$ applied on a n -tuple of control measurements, distributed as $\mathcal{N}(m, s^2)$

$P_M(m, s; m_0, s_0, n, l)$: probability for rejection of the QC rule $R_M(\mathbf{x}; m_0, s_0, n, l)$ applied on a n -tuple of control measurements, distributed as $\mathcal{N}(m, s^2)$

$\text{erf}(z)$: error function

$\text{erfc}(z)$: complementary error function

$\Gamma(z)$: gamma function

${}_2F_1(a, b; c; z)$: hypergeometric function

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 QC parameters

- 1.2.1.1. The fraction nonconforming f ,
- 1.2.1.2. The standardized critical random error s_c ,
- 1.2.1.3. The standardized critical systematic error m_c ,
- 1.2.1.4. The optimal QC rule $R_S(x; m, s, n, k, l)$, where $1 \leq k \leq n$, or $R_M(x; m, s, n, l)$,
- 1.2.1.5. The QC decision limits $m \pm l s$,
- 1.2.1.6. The probability p_{sc} for critical random error detection,
- 1.2.1.7. The probability p_{mc} 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 control measurements,
- 1.2.2.2. The cumulative probability function (cdf) plot of the control measurements,
- 1.2.2.3. the probability for rejection plot for the standardized random error (p_r vs s), and
- 1.2.2.4. the probability for rejection plot for the standardized 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. Plots

2.1.1. Defining pfr

2.1.1.1. Input.

2.1.1.1.1. QC parameters

- 2.1.1.1.1.1. The number n of the control measurements ($1 \leq n \leq 6$), and
- 2.1.1.1.1.2. The probability p_{fr} for false rejection of the QC rules ($0.0001 \leq p_{fr} \leq 0.1$)

2.1.1.2. Output

- 2.1.1.2.1. The probability for rejection plot for the random error (p_r vs s) and
- 2.1.1.2.2. The probability for rejection plot for the systematic error (p_r vs m), of the QC rules $R_S(x; m, s, n, k, l)$, for $1 \leq k \leq n$, and $R_M(x; m, s, n, l)$.

2.1.2. Defining decision limit

2.1.2.1. Input.

2.1.2.1.1. QC parameters

- 2.1.2.1.1.1. The number n of the control measurements ($1 \leq n \leq 6$)
- 2.1.2.1.1.2. The decision limit ($1.0 \leq l \leq 5.0$)

2.1.2.1.2. Plot options

2.1.2.1.2.1. Type of error:

2.1.2.1.2.1.1. Random error

2.1.2.1.2.1.2. Systematic error

2.1.2.2. Output

2.1.2.2.1. The probability for rejection plot for the standardized random error (p_r vs s), and

2.1.2.2.2. The probability for rejection plot for the standardized systematic error (p_r vs. m),

of the QC rules $R_S(x; m, s, n, k, l)$, for $1 \leq k \leq n$, and $R_M(x; m, s, n, l)$.

2.2. Tables

2.2.1. Defining pfr

2.2.1.1. Input.

2.2.1.1.1. QC parameters

2.2.1.1.1.1. The number n of the control measurements ($1 \leq n \leq 6$), and

2.2.1.1.1.2. The probability p_{fr} for false rejection of the QC rules ($0.0001 \leq p_{fr} \leq 0.1$)

2.2.1.1.2. Critical errors

2.2.1.1.2.1. The critical random error s_c ,

2.2.1.1.2.2. The critical systematic error m_c ,

2.2.1.2. Output

2.2.1.2.1. Table of probabilities for rejection

2.2.1.2.1.1. The probabilities for false rejection,

2.2.1.2.1.2. The probabilities for critical random error detection, and

2.2.1.2.1.3. The probabilities for critical systematic error detection

of the QC rules $R_S(x; m, s, n, k, l)$, for $1 \leq k \leq n$, and $R_M(x; m, s, n, l)$.

2.2.2. Defining decision limit

2.2.2.1. Input.

2.2.2.1.1. QC parameters

2.2.2.1.1.1. The number n of the control measurements ($1 \leq n \leq 6$), and

2.2.2.1.1.2. The decision limit ($1.0 \leq l \leq 5.0$)

2.2.2.1.2. Critical errors

2.2.2.1.2.1. The critical random error s_c ,

2.2.2.1.2.2.The critical systematic error m_c ,

2.2.2.2. Output

2.2.2.2.1. Table of probabilities for rejection

2.2.2.2.1.1.The probabilities for false rejection,

2.2.2.2.1.2.The probabilities for random critical error detection, and

2.2.2.2.1.3.The probabilities for systematic critical error detection

of the QC rules $R_S(x; m, s, n, k, l)$, for $1 \leq k \leq n$, and $R_M(x; m, s, n, l)$.

2.2.3. Defining critical errors

2.2.3.1. Input.

2.2.3.1.1. QC parameters

2.2.3.1.1.1.The number n of the control measurements ($1 \leq n \leq 6$), and

2.2.3.1.2. Critical errors

2.2.3.1.2.1.The standardized critical random error s_c ,

2.2.3.1.2.2.The standardized critical systematic error m_c ,

2.2.3.1.2.3.The minimum acceptable probability for critical random error
detection

2.2.3.1.2.4.The minimum acceptable probability for critical systematic error
detection

2.2.3.2. Output

2.2.3.2.1. Table of probabilities for rejection

2.2.3.2.1.1.The probabilities for false rejection,

2.2.3.2.1.2.The probabilities for critical random error detection, and

2.2.3.2.1.3.The probabilities for critical systematic error detection

of the QC rules $R_S(x; m, s, n, k, l)$, for $1 \leq k \leq n$, and $R_M(x; m, s, n, l)$.

Source Code

Programming language: Wolfram Language

Availability: The updated source code is available at:

<https://www.hcsl.com/Tools/QualityControl/QualityControl.nb>

Software Requirements

Operating systems: Microsoft Windows, Linux, Apple macOS and iOS

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

System Requirements

Processor: Intel Core i9® or equivalent CPU

System memory (RAM): 16 GB+ recommended.

Permanent Citation:

Chatzimichail RA, Hatjimihail AT. Quality Control: A Software Tool for Statistical Quality Control Design. Technical Report XXIII. Hellenic Complex Systems Laboratory; 2022. Available at: <https://www.hcsl.com/TR/hcsltr23/hcsltr23.pdf>

License

[Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License.](https://creativecommons.org/licenses/by-nc-sa/4.0/)

First Published: September 14, 2022

Revised: November 9, 2024