Hellenic Complex Systems Laboratory

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

Technical Report XXIII

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2022

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

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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 Control* was developed for designing and exploring QC rules 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 quality control rule $R_S(\boldsymbol{x}; m, s, n, k, l_i)$, where $1 \leq k \leq n$ or $R_S(\boldsymbol{x}; m, s, n, n, l_i)$ (see Notation), to be applied, to detect the critical random and systematic errors with stated probabilities. It plots the probability density function (pdf) and the cumulative density function (cdf) of the control measurements, and the probability for rejection for the random and systematic error of the designed quality control rule (see Figures 1 and 2).

Compare

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

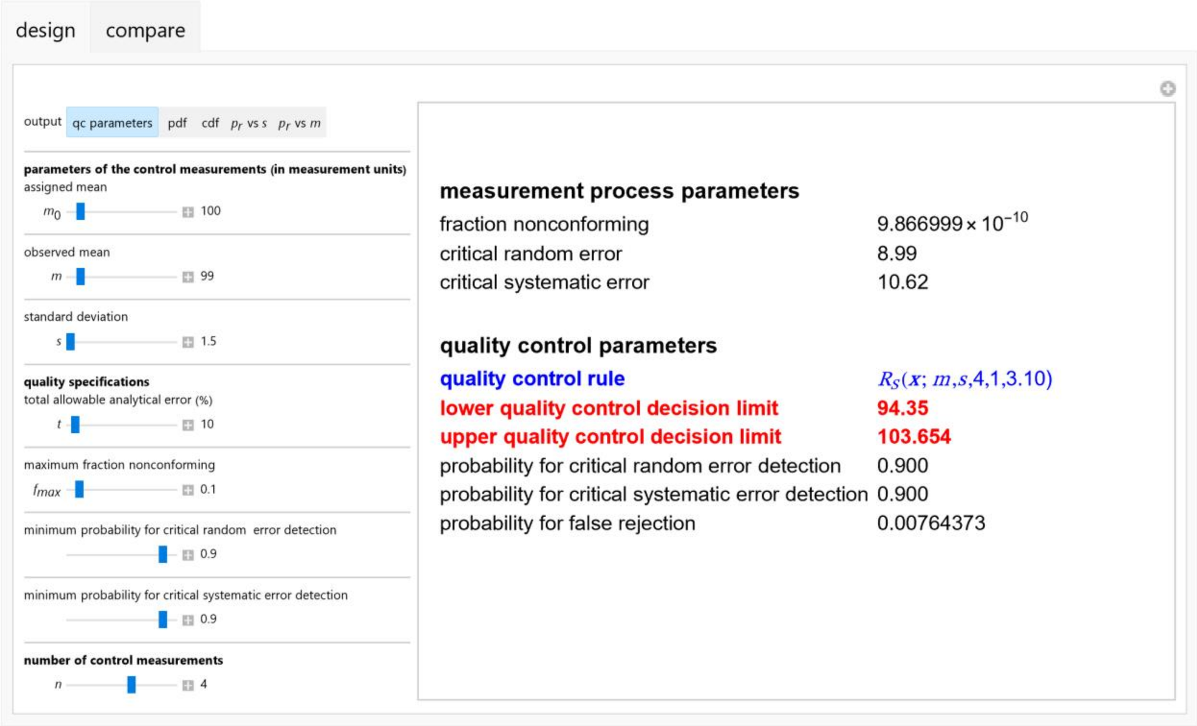


Figure 1: *The measurement process parameters and the quality control parameters of a measurement process, with the settings shown at the left.*

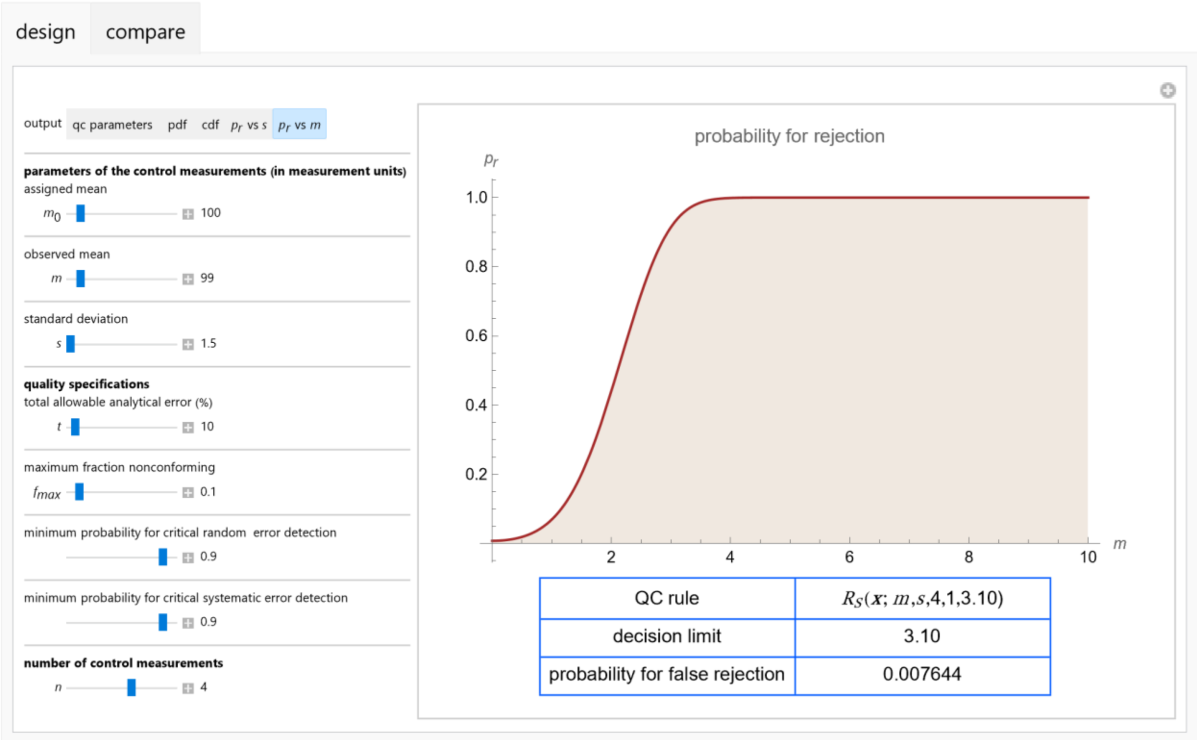


Figure 2: *The probability for rejection of a QC rule vs* the standardized observed mean m *of the control measurements, with the settings shown at the left.*

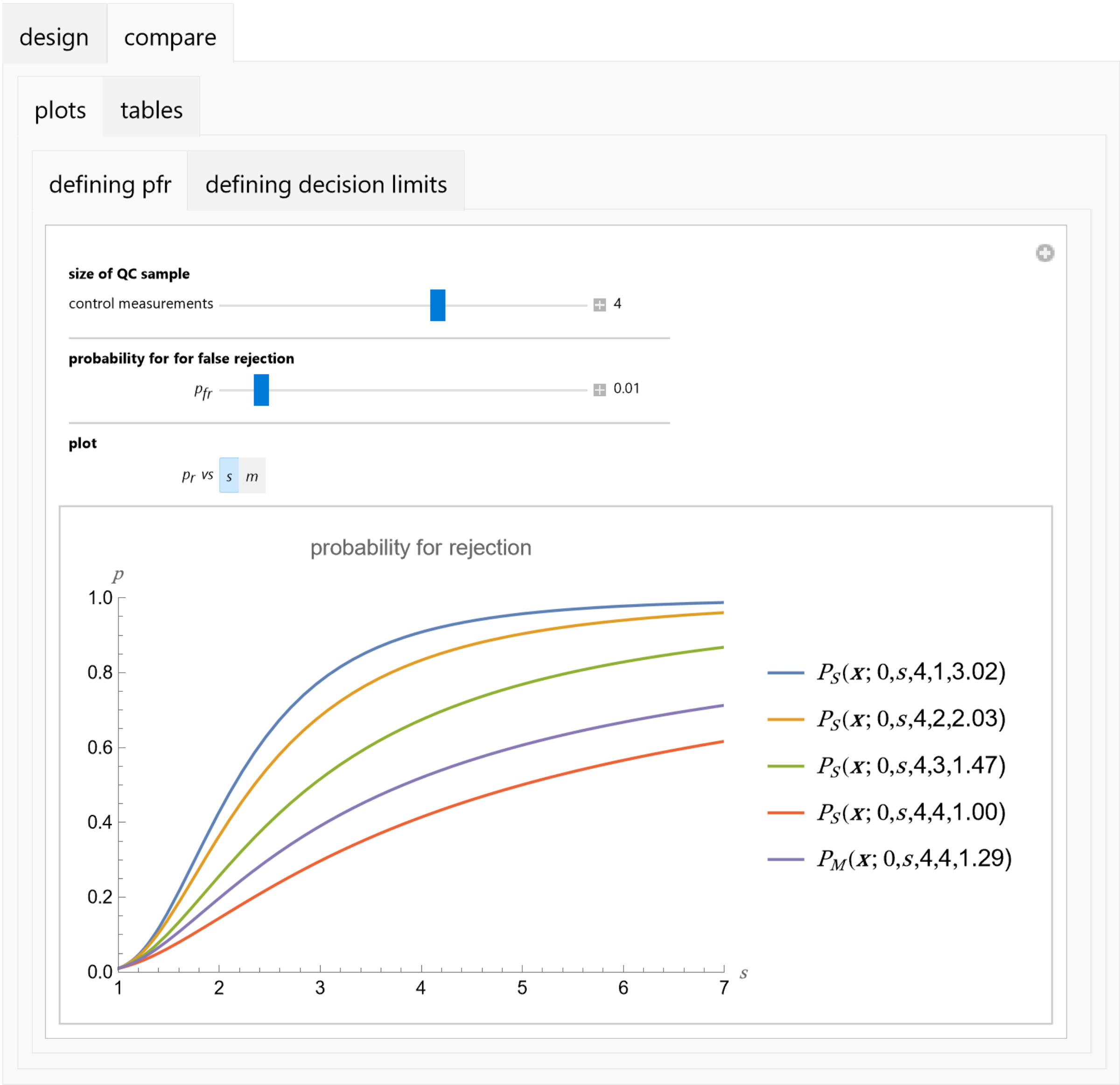
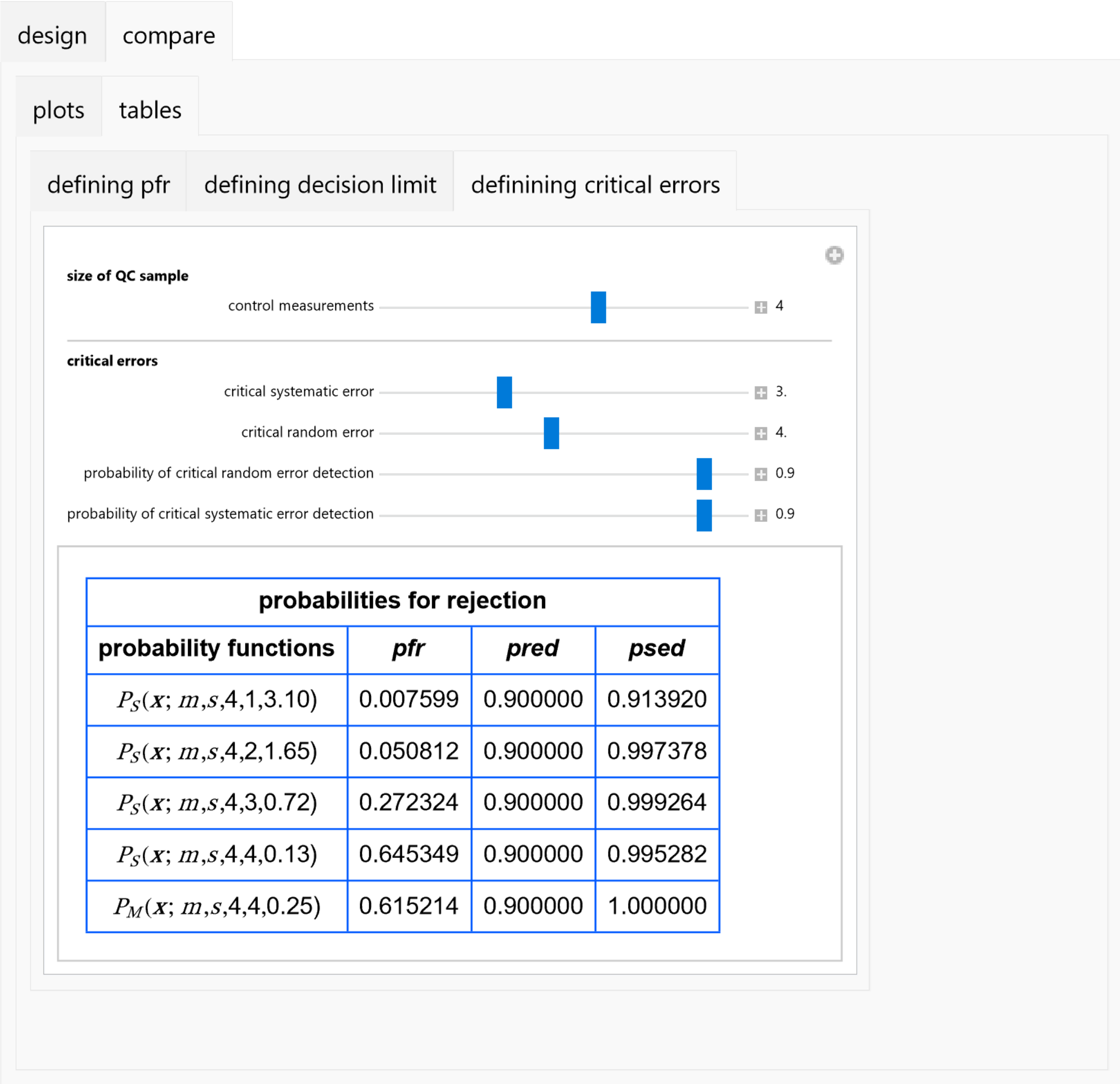


Figure 3: *The probabilities for rejection of the alternative QC rules shown at the right vs* the standardized standard deviation s *of the control measurements, with the settings shown at the top.*



probabilities for rejection			
probability functions	***pfr***	***pred***	***psed***
$P_S(\boldsymbol{x};\, m,s,4,1,3.10)$	0.007599	0.900000	0.913920
$P_S(\boldsymbol{x};\, m,s,4,2,1.65)$	0.050812	0.900000	0.997378
$P_S(\boldsymbol{x};\, m,s,4,3,0.72)$	0.272324	0.900000	0.999264
$P_S(\boldsymbol{x};\, m,s,4,4,0.13)$	0.645349	0.900000	0.995282
$P_M(\boldsymbol{x};\, m,s,4,4,0.25)$	0.615214	0.900000	1.000000

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

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, 4]:

(a) the fraction nonconforming f:

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

(b) the critical random error s_c:

$$\frac{\operatorname{erfc}\left(\frac{\mathrm{m}_0-\mathrm{m}\left(1-\frac{\mathrm{t}}{100}\right)}{s_c\sqrt{2}}\right)+\operatorname{erfc}\left(-\frac{\mathrm{m}_0+\mathrm{m}\left(1+\frac{\mathrm{t}}{100}\right)}{s_c\sqrt{2}}\right)}{2}=f_{max}$$

(c) the critical systematic error m_c:

$$\frac{\operatorname{erfc}\left(\frac{\mathrm{m}_0-(\epsilon\,\mathrm{m_c}-m)\left(1-\frac{\mathrm{t}}{100}\right)}{\mathrm{s}\sqrt{2}}\right)+\operatorname{erfc}\left(-\frac{\mathrm{m}_0+(\epsilon\,\mathrm{m_c}-m)\left(1+\frac{\mathrm{t}}{100}\right)}{\mathrm{s}\sqrt{2}}\right)}{2}=f_{max}$$

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

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

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

$$\frac{1}{k!\,(n-k)!}2^{-n}\left(-1+\operatorname{erf}\left(\frac{ls+\epsilon\,\mathrm{m_c}+m}{\mathrm{s}\sqrt{2}}\right)+erfc\left(\frac{-ls+\epsilon\,\mathrm{m_c}+m}{\mathrm{s}\sqrt{2}}\right)\right)^{n-k}\left(-1+\operatorname{erf}\left(\frac{-ls+\epsilon\,\mathrm{m_c}+m}{\mathrm{s}\sqrt{2}}\right)+erfc\left(\frac{ls+\epsilon\,\mathrm{m_c}+m}{\mathrm{s}\sqrt{2}}\right)\right)^{k}\Gamma(1+n)\;{}_2F_1\left(1,k-n;1+k;1+\frac{2}{\operatorname{erf}\left(\frac{-ls+\epsilon\,\mathrm{m_c}+m}{\mathrm{s}\sqrt{2}}\right)-erf\left(\frac{ls+\epsilon\,\mathrm{m_c}+m}{\mathrm{s}\sqrt{2}}\right)}\right)=p_{\mathrm{m}_c}$$

(e) the factor l of the decision limits $\bar{\mathrm{x}}\pm l\,s$ of the quality control rule $\mathrm{R}_M(\boldsymbol{x};m,s,n,k,l)$ is the minimum solution of both of the following equations for the variable l:

$$\frac{\left(1+\operatorname{erf}\left(\frac{(-ls+m)\sqrt{n}}{s_c\sqrt{2}}\right)+erfc\left(\frac{(ls+m)\sqrt{n}}{s_c\sqrt{2}}\right)\right)}{2}=p_{s_c}$$

$$\frac{\left(1+\operatorname{erf}\left(\frac{(-ls+\epsilon\,\mathrm{m_c}+m)\sqrt{n}}{s\sqrt{2}}\right)+erfc\left(\frac{(ls+\epsilon\,\mathrm{m_c}+m)\sqrt{n}}{s\sqrt{2}}\right)\right)}{2}=p_{\mathrm{m}_c}$$

with ϵ as before in (c),

(f) the probability for rejection for the random error *s* and the systematic error *m* of the quality control rule $P_S(\boldsymbol{x}; m, s, n, k, l)$:

$$P_S(\boldsymbol{x}; m, s, n, k, l) =$$

$$\frac{1}{k!\,(n-k)!}2^{-n}\left(-1+\operatorname{erf}\left(\frac{l+m}{s\sqrt{2}}\right)+erfc\left(\frac{-l+m}{s\sqrt{2}}\right)\right)^{n-k}\left(-1+\operatorname{erf}\left(\frac{-l+m}{s\sqrt{2}}\right)+erfc\left(\frac{l+m}{s\sqrt{2}}\right)\right)^{k}\Gamma(1+n)\;{}_2F_1\left(1,k-n;1+k;1+\frac{2}{\operatorname{erf}\left(\frac{-l+m}{s\sqrt{2}}\right)-erf\left(\frac{l+m}{s\sqrt{2}}\right)}\right)$$

(g) the probability for rejection for the random error *s* and the systematic error *m* of the quality control rule $P_M(\boldsymbol{x}; m, s, n, k, l)$:

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

Conclusion

The program *Quality Control* can be used as an educational or laboratory tool for the design and evaluation of alternative quality control rules for a measurement process.

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[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
pred: probability for random error detection
psed: probability for systematic error detection

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

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

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

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

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

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

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 optimal quality control rule $R_S(\boldsymbol{x}; m, s, n, k, l)$, where $1 \leq k \leq n$, or $R_M(\boldsymbol{x}; m, s, n, n, l)$,

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

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 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 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. Quality control 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 quality control 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 standardized random error (p_r vs s), and

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

of the quality control rules $R_S(\boldsymbol{x}; m, s, n, k, l)$, for $1 \leq k \leq n$, and $R_M(\boldsymbol{x}; m, s, n, n, l)$.

2.1.2. Defining *decision limit*

2.1.2.1. Input.

2.1.2.1.1. Quality control 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 quality control rules $R_S(\boldsymbol{x}; m, s, n, k, l)$, for $1 \leq k \leq n$, and $R_M(\boldsymbol{x}; m, s, n, n, l)$.

2.2. Tables

2.2.1. Defining *pfr*

2.2.1.1. Input.

2.2.1.1.1. Quality control 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 quality control 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 quality control rules $R_S(\boldsymbol{x}; m, s, n, k, l)$, for $1 \leq k \leq n$, and $R_M(\boldsymbol{x}; m, s, n, n, l)$.

2.2.2. Defining *decision limit*

2.2.2.1. Input.

2.2.2.1.1. Quality control 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 quality control rules $R_S(\boldsymbol{x}; m, s, n, k, l)$, for $1 \leq k \leq n$, and $R_M(\boldsymbol{x}; m, s, n, n, l)$.

2.2.3. Defining *pfr*

2.2.3.1. Input.

2.2.3.1.1. Quality control parameters

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

2.2.3.1.2. Critical errors

2.2.3.1.2.1. The critical random error s_c,

2.2.3.1.2.2. The critical systematic error m_c,

2.2.3.1.2.3. The lowest probability for critical random error detection

2.2.3.1.2.4. The lowest 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 random error detection, and

2.2.3.2.1.3. The probabilities for systematic error detection

of the quality control rules $R_S(\boldsymbol{x}; m, s, n, k, l)$, for $1 \le k \le n$, and $R_M(\boldsymbol{x}; m, s, n, n, l)$.

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 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.

Permanent Citation:

Chatzimichail RA, Hatjimihail AT. *Quality Control:* A Software Tool for Statistical Quality Control Design and Evaluation. Drama: Hellenic Complex Systems Laboratory, 2022. Available at: https://www.hcsl.com/Tools/QualityControl/

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First Published: September 9, 2022