RISK-BASED CONTROL LIMITS[1]

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Abstract *- A methodology is presented for the development of SPC control limits for measurement processes. The methodology employs both Bayesian and traditional measurement decision risk concepts to establish control limits that flag whether measuring processes are in or out of control relative to the specifications of the artifacts they measure. The methodology has particular relevance for calibration and testing.*

INTRODUCTION

Ordinarily, control limits for evaluating measuring processes that are employed in testing or calibration are established either as fixed (often arbitrary) limits or as confidence limits computed from a history of process control data. In compiling a control history, a check standard of some assumed value is measured by the process. If the difference between the assumed value of the standard and the value measured by the process lies outside the control limits, the process is said to be out of control.

Clearly, such a proclamation is without value if the control limits are not in some way related to the specifications of the parameters that are calibrated or tested by the process or if these limits fail to accommodate whatever test or calibration quality requirements are in place. Obviously, a process may be considered to be in control if it is used to test or calibrate parameters with wide tolerances and, at the same time, be judged as out of control if used to test or calibrate parameters with tight tolerances.

These considerations notwithstanding, it has been common practice to establish control limits that have no relationship to the tolerance limits or other requirements of the items that the measuring process is measuring. This is primarily because a method has not been available for doing otherwise. The presentation of such a method is the subject of this paper.

STATEMENT OF THE PROBLEM

A measurement process is evaluated using a check standard with an assumed value. The check standard is measured by the process and a deviation of the measured value from the standard's assumed value is noted. Given the assumed value of the standard, an estimate of the standard's uncertainty, and an estimate of the measuring process uncertainty, we desire to determine the minimum measured deviation that corresponds to an unacceptable risk that the measuring process will falsely accept or reject a given measurand or "subject parameter." If the measured deviation exceeds this deviation, the process can be said to be out of control with respect to calibrating or testing the parameter of interest.

NOTATION AND TERMINOLOGY

x	-	random variable representing subject parameter deviations from nominal
y	-	random variable representing measured values of x
ε_x	-	bias (deviation from nominal) in the population of subject parameter values
u_x	-	estimated standard uncertainty in ε_x

[1] Presented January 19 at the 2001 Measurement Science Conference, Anaheim. Minor corrections made later under "Statement of the Problem" and to Eq. (7).

ε_y	-	estimated bias in the measurement process
u_y	-	estimated standard uncertainty in ε_y
ε_s	-	estimated bias in the check standard
u_s	-	estimated standard uncertainty in ε_s
ε_c	-	critical bias for the measurement process
L_1	-	lower tolerance offset for the subject parameter
L_2	-	upper tolerance offset for the subject parameter
P_x	-	in-tolerance probability for the subject parameter at the time of measurement
$f_x(x)$	-	pdf for the subject parameter at the time of measurement
$f_y(y\|x)$	-	pdf for measured values of the subject parameter
P_{xy}	-	joint probability that the subject parameter will both be in-tolerance and observed to be in-tolerance
P_y	-	probability that subject parameter values will be observed to be in-tolerance
X_0	-	assumed value for the check standard
X_s	-	actual value of the check standard
Y	-	a specific measurement of x made by the measurement process
FA	-	false accept risk
FR	-	false reject risk
r	-	ratio of u_y to u_s.

In these definitions, the adjective "assumed" indicates a value provided by some agency or authority. The adjective "estimated" indicates a value determined by Bayesian estimation.

RELEVANT FUNCTIONS

Before developing the methodology for risk-based limits, it will be beneficial to review the various functions that will be employed. These functions include the probability density functions (pdfs), the probability functions and the risk functions.

Probability Density Functions

The probability density functions are those of the measurement process and of the subject parameter.

Measurement Process

The conditional pdf $f_y(y|x)$ is usually assumed to be normal:

$$f_y(y\,|\,x) = \frac{1}{\sqrt{2\pi}u_y} e^{-(y-x-\varepsilon_y)^2/2u_y^2}\,, \qquad (1)$$

where u_y is the measurement process standard uncertainty and ε_y is the measurement process bias. The pdf is shown in Figure 1.

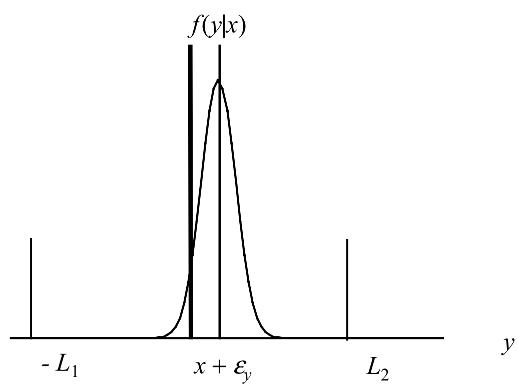

Figure 1. The pdf for measurements of a subject parameter, given a specific value of x and a bias ε_y in the measurement process. The limits $-L_1$ and L_2 are tolerance offsets for the subject parameter.

Subject Parameter (*Measurand*)

In performing the integrations for the probability functions, various alternatives for $f_x(x)$ will be encountered in practice. In this paper, we will select the normal distribution to illustrate the methodology. The appropriate pdf is

$$f_x(x) = \frac{1}{\sqrt{2\pi}u_x} e^{-(x-\varepsilon_x)^2/2u_x^2}\,, \qquad (2)$$

where ε_x is the bias in the subject parameter population and u_x is the standard uncertainty in this bias. In most instances, ε_x is unknown and is taken to be zero.[2] The pdf is shown in Figure 2.

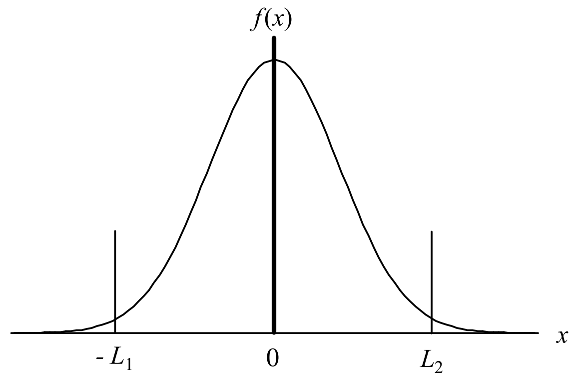

Figure 2. The pdf for subject parameter deviations from nominal for an unbiased population ($\varepsilon_x = 0$).

Probability Functions

The probability functions are written

$$
\begin{aligned}
P_x &= \int_{-L_1}^{L_2} f_x(x)dx \\
P_{xy} &= \int_{-L_1}^{L_2} dx\, f_x(x) \int_{-L_1}^{L_2} dy\, f_y(y\,|\,x) \qquad (3) \\
P_y &= \int_{-\infty}^{\infty} dx\, f_x(x) \int_{-L_1}^{L_2} dy\, f_y(y\,|\,x).
\end{aligned}
$$

As stated earlier, the pdf $f_x(x)$ may take on a variety of forms. Those most often encountered are the normal, lognormal, uniform, triangular, exponential, cosine, half-cosine, quadratic, and U-shaped [1]. In this paper, we use the pdf for the normal distribution exclusively.

Risk Functions

The risk functions are given by

$$
\begin{aligned}
FA &= \begin{cases} 1 - P_{xy}/P_y, & \text{consumer option} \\ P_y - P_{xy}, & \text{producer option} \end{cases} \\
FR &= P_x - P_{xy}\,,
\end{aligned} \qquad (4)
$$

where *FA* and *FR* are, respectively, the *false accept* and *false reject* risks associated with testing or calibrating the subject parameter of interest. For false accept risk, the *consumer option* represents false accept risk from the point of view of the recipient of the tested or calibrated parameter. It is the probability that an accepted parameter will be out-of-tolerance. The *producer option* represent false accept risk from the point of view of the calibrating or testing organization. This is the probability that an out-of-tolerance parameter will be falsely observed to be in-tolerance. False reject risk is the probability that an in-tolerance parameter will be falsely observed to out-of-tolerance.

SOLVING FOR RISK-BASED LIMITS

Let FA_c and FR_c denote critical (not to exceed) criteria for false accept and false reject risk, respectively, for testing or calibrating a subject parameter of interest. We use either one of these criteria to solve for ε_y. Denoting this solution by ε_c, the control limits are established as limits for the perceived difference $Y - X_0$. To establish these limits, we must first solve for the measurement process bias, based on *a priori* knowledge and on the results of measurement.

Estimating the Measurement Process Bias

The bias in the measurement process is estimated using a Bayesian method [2-6]. With this method, we start with *a priori* estimates for ε_y, u_y, ε_s and u_s and employ measurement results to refine these estimates.

As above, let *Y* represent the result of measuring the check standard with the measuring process. This result may be due to a single measurement or may be the mean value of a sample of measurements. If we assume *a priori* that the

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[2] The uncertainty u_x can often be estimated from subject parameter tolerance limits and end-of-period in-tolerance probabilities [8-9].

biases in the measuring process and the check standard are normally distributed with zero means and standard deviations u_y and u_s, respectively, then an estimate of ε_y can be obtained from measurement results according to

$$\varepsilon_y = \frac{r^2}{1+r^2}\left(Y - X_0\right), \tag{5}$$

where

$$r = u_y / u_s . \tag{6}$$

Estimating the Check Standard Bias

Estimating the bias of the check standard follows the same approach as the analysis of the measuring process bias. The expression to use is

$$\varepsilon_s = \frac{(1/r)^2}{1+(1/r)^2}\left(X_0 - Y\right), \tag{7}$$

Solving for ε_c

The solution begins with a statement of the maximum allowable risk for using the measuring process to test or calibrate a particular parameter of interest. This risk is labeled FA_c, if risks are keyed to false accept risk or FR_c, if risks are keyed to false reject risk. Next, we solve for the value of ε_y that corresponds to FA_c or FR_c and equate ε_c to this value. The solution is obtained using the Newton-Raphson method. If process control is keyed to false accept risk, the base function is

$$F = FA - FA_c . \tag{8}$$

If process control if keyed to false reject risk, then the base function is

$$F = FR - FR_c . \tag{9}$$

Using Eqs. (2) – (4), and assuming $\varepsilon_x = 0$, we can develop the probability functions needed to compute FA and FR in Eq. (4):

$$\begin{aligned} P_x &= \int_{-L_1}^{L_2} f_x(x)dx \\ &= \frac{1}{\sqrt{2\pi}u_x}\int_{-L_1}^{L_2} e^{-x^2/2u_x^2}dx \\ &= \Phi\left(\frac{L_1}{u_x}\right) + \Phi\left(\frac{L_2}{u_x}\right) - 1 , \end{aligned} \tag{10}$$

$$\begin{aligned} P_{xy} &= \int_{-L_1}^{L_2} dx\, f_x(x) \int_{-L_1}^{L_2} dy\, f_y(y\,|\,x) \\ &= \frac{1}{2\pi u_x u_y}\int_{-L_1}^{L_2} dx\, e^{-x^2/2u_x^2}\int_{-L_1}^{L_2} dy\, e^{-(y-x-\varepsilon_y)^2/2u_y^2} \\ &= \frac{1}{\sqrt{2\pi}}\int_{-L_1/u_x}^{L_2/u_x} e^{-\zeta^2/2}\left[\Phi\left(\frac{L_1+\varepsilon_y+u_x\zeta}{u_y}\right) + \Phi\left(\frac{L_2-\varepsilon_y-u_x\zeta}{u_y}\right) - 1\right] d\zeta , \end{aligned} \tag{11}$$

and

$$
\begin{aligned}
P_y &= \int_{-\infty}^{\infty} dx\, f_x(x) \int_{-L_1}^{L_2} dy\, f_y(y\,|\,x) \\
&= \frac{1}{2\pi u_x u_y} \int_{-\infty}^{\infty} dx\, e^{-x^2/2u_x^2} \int_{-L_1}^{L_2} dy\, e^{-(y-x-\varepsilon_y)^2/2u_y^2} \\
&= \Phi\left(\frac{L_1+\varepsilon_y}{u}\right) + \Phi\left(\frac{L_2-\varepsilon_y}{u}\right) - 1,
\end{aligned} \tag{12}
$$

where

$$
u = \sqrt{u_x^2 + u_y^2}\ . \tag{13}
$$

Newton-Raphson Iteration

We use the Newton-Raphson method to solve for ε_y iteratively. The solution for the *i*th iteration is

$$
\varepsilon_{y,i} = \varepsilon_{y,i-1} - \frac{F}{F'}, \tag{14}
$$

where F is given in Eq. (8) or (9) and F' is given by

$$
F' = \begin{cases} P_y' - P_{xy}', & \text{If keyed to False Accept (Producer Option)} \\ 1 + \dfrac{(1-FA)P_y' - P_{xy}'}{P_y}, & \text{If keyed to False Accept (Consumer Option)} \\ -P_{xy}', & \text{If keyed to False Reject}, \end{cases} \tag{15}
$$

where the primes indicate taking derivatives with respect to ε_y. The derivatives in Eq. (15) are given by

$$
\begin{aligned}
P_{xy}' = \frac{1}{\sqrt{2\pi}u}\Bigg(& e^{-\zeta_1^2/2u^2}\left\{\Phi\left[\frac{u}{u_x u_y}\left(L_2 + \frac{u_x^2}{u^2}\zeta_1\right)\right] + \Phi\left[\frac{u}{u_x u_y}\left(L_1 - \frac{u_x^2}{u^2}\zeta_1\right)\right] - 1\right\} \\
& - e^{-\zeta_2^2/2u^2}\left\{\Phi\left[\frac{u}{u_x u_y}\left(L_2 + \frac{u_x^2}{u^2}\zeta_2\right)\right] + \Phi\left[\frac{u}{u_x u_y}\left(L_1 - \frac{u_x^2}{u^2}\zeta_2\right)\right] - 1\right\}\Bigg),
\end{aligned}
$$

and

$$
P_y' = \frac{1}{\sqrt{2\pi}u}\left(e^{-\zeta_1^2/2u^2} - e^{-\zeta_2^2/2u^2}\right),
$$

where

$$
\zeta_1 = \varepsilon_{y,i-1} + L_1
$$

and

$$
\zeta_2 = \varepsilon_{y,i-1} - L_2\,.
$$

The iteration process is halted when we reach a point where $|(F/F')\ /\ \varepsilon_y| < \delta$, where δ is some pre-set level of precision (e.g., 10^{-6}). At this point, we set $\varepsilon_c = \varepsilon_y$.

SETTING THE CONTROL LIMITS

The result of a measurement or sample of measurements of the check standard is an observed deviation $Y - X_0$. A "critical" deviation Δ, associated with unacceptable measurement decision risk in testing or calibrating the parameter discussed in the previous section, corresponds to the critical value ε_c. Accordingly, we can invoke Eq. (5) and write

$$\Delta = (Y - X_0)_c$$
$$= \frac{1+r^2}{r^2}\varepsilon_c \, ,$$

where r is defined in Eq. (6). From this result, we can establish upper and lower control limits for $Y - X_0$ of

$$UCL = \frac{1+r^2}{r^2} | \varepsilon_c | \, ,$$

and

$$LCL = -\frac{1+r^2}{r^2} | \varepsilon_c | \, .$$

Note that, if different consequences result from having a positively biased measurement process as opposed to a negatively biased process, it may be desired to use different upper and lower values for ε_c in setting *UCL* and *LCL*. This is done by employing different upper limit and lower limit values for FA_c or FR_c in solving for ε_c.

RESULTS

Results obtained with four levels of measurement process uncertainty and various levels of maximum allowable false accept risk are shown in Tables 1 and 2. Table 1 shows results obtained by keying to the producer option. Table 2 shows results for the consumer option. Table 3 shows results obtained by keying to false reject risk.

The UUT of interest is a subject parameter with tolerance offsets of L_1 = -10, and L_2 = +10 and an in-tolerance probability of 85% prior to measurement. The total standard uncertainty in the test system is 1.2755. This corresponds to a nominal 4:1 TAR between the UUT tolerances and the measurement process. The nominal TAR is obtained by setting the UUT in-tolerance probability to 95%. The assumed check standard value is X_0 = 100, and, in all cases shown, the *a priori* standard uncertainty in this value is u_s = 0.3189. This is about 25% of the measurement process standard uncertainty.

Keying to False Accept Risk

For each measurement scenario, a minimum level of false accept risk exists that cannot be bettered regardless of measurement process bias. This is because, even though the bias may be zero, there is still uncertainty in the measuring process. This means that, if there are out-of-tolerance parameters in the UUT population, there is a finite probability that some will be erroneously accepted. As can be seen from Tables 1 and 2, other things being equal, the lower the accuracy of the measuring process, the higher the minimum false accept level.

We also find that, with the producer option, for a given scenario, there exists a maximum level of false accept risk that will not be exceeded regardless of the value of the measuring process bias. This occurs because the producer option false accept risk is the joint probability that a parameter will both be out-of-tolerance and accepted. Since there is a limit to the out-of-tolerance probability, there is also a limit to the joint out-of-tolerance + accepted probability.

This is not the case for the consumer option, since this option is defined as the conditional probability that an item will be out-of-tolerance *given* that it was accepted. As the magnitude of the measurement process bias increases, it becomes possible that all or virtually all accepted items will be out-of-tolerance. Hence, there is no upper limit shown in Table 2.

By comparing Tables 1 and 2, it is apparent that selecting the consumer option for false accept risk yields smaller UCL and LCL values than selecting the producer option. The need for tighter control limits in the consumer option case is due to the fact that the computed false accept risk is higher for the consumer option than for the producer option.

Keying to False Reject Risk

When keying limits to false reject risk, we again see a minimum possible risk, corresponding to zero bias. Note the tighter control limits when keying to false reject risk as opposed to false accept risk. This effect is due to the fact that, for UUT parameter in-tolerance percentages higher than 50%, false reject risk is higher than false accept risk.

In addition, with false reject risk, the upper risk cutoff is roughly equal to the UUT parameter *a priori* in-tolerance probability. This is because false reject risk is the joint probability that a parameter will both be in-tolerance and rejected. As the magnitude of the measuring process bias increases, it reaches a point where virtually all in-tolerance UUT parameters will be rejected.

CONCLUSION

The methodology presented in this paper allows us to determine control limits for a measurement process that are relevant to what the process measures, i.e., its UUT workload. Such control limits consist of risk-based bounds for observed differences between a measured value for a check standard and the check standard's assumed value. Since these bounds can be adjusted to apply to specific workload items, we satisfy ISO/IEC 17025 [10] requirements for controlling testing and calibration processes commensurate with intended applications.

Table 1

Measurement Process Biases and Control Limits Keyed to False Accept Risk (Producer Option)

UUT Lower Tolerance (L1)	UUT Upper Tolerance (L2)	UUT Standard Deviation	A Priori Meas Process Uncertainty	Effective Accuracy Ratio	Assumed Check Std Value	Max Allowable Risk	Assumed Check Std Uncertainty	Control Limits for Measured Deviations
10	10	6.9467	1.2755	4:1	100	0.017572†	0.3189	±0.0000
10	10	6.9467	1.2755	4:1	100	0.02	0.3189	±0.7943
10	10	6.9467	1.2755	4:1	100	0.03	0.3189	±1.9637
10	10	6.9467	1.2755	4:1	100	0.04	0.3189	±2.9455
10	10	6.9467	1.2755	4:1	100	0.05	0.3189	±4.0807
10	10	6.9467	1.2755	4:1	100	0.071903*	0.3189	± 9.9164
10	10	6.9467	1.7007	3:1	100	0.022190†	0.3189	±0.0000
10	10	6.9467	1.7007	3:1	100	0.03	0.3189	±1.7702
10	10	6.9467	1.7007	3:1	100	0.04	0.3189	±2.9315
10	10	6.9467	1.7007	3:1	100	0.05	0.3189	±4.1305
10	10	6.9467	1.7007	3:1	100	0.074780*	0.3189	± 16.1706
10	10	6.9467	2.5511	2:1	100	0.029938†	0.3189	±0.0000
10	10	6.9467	2.5511	2:1	100	0.03	0.3189	±0.2007
10	10	6.9467	2.5511	2:1	100	0.04	0.3189	±2.7654
10	10	6.9467	2.5511	2:1	100	0.05	0.3189	±4.3128
10	10	6.9467	2.5511	2:1	100	0.074900*	0.3189	± 13.9591
10	10	6.9467	5.1021	1:1	100	0.044903†	0.3189	±0.0000
10	10	6.9467	5.1021	1:1	100	0.05	0.3189	±3.7249
10	10	6.9467	5.1021	1:1	100	0.069155*	0.3189	± 14.4370

† Minimum attainable risk
* Maximum attainable risk

Table 2

Measurement Process Biases and Control Limits Keyed to False Accept Risk (Consumer Option)

UUT Lower Tolerance (L1)	UUT Upper Tolerance (L2)	UUT Standard Deviation	A Priori Meas Process Uncertainty	Effective Accuracy Ratio	Assumed Check Std Value	Max Allowable Risk	Assumed Check Std Uncertainty	Control Limits for Measured Deviations
10	10	6.9467	1.2755	4:1	100	0.020840†	0.3189	± 0.0000
10	10	6.9467	1.2755	4:1	100	0.03	0.3189	± 1.4559
10	10	6.9467	1.2755	4:1	100	0.04	0.3189	± 2.2541
10	10	6.9467	1.2755	4:1	100	0.05	0.3189	± 2.9993
10	10	6.9467	1.7007	3:1	100	0.026480†	0.3189	± 0.0000
10	10	6.9467	1.7007	3:1	100	0.03	0.3189	± 1.0246
10	10	6.9467	1.7007	3:1	100	0.04	0.3189	± 2.1172
10	10	6.9467	1.7007	3:1	100	0.05	0.3189	± 2.9591
10	10	6.9467	2.5511	2:1	100	0.036359†	0.3189	± 0.0000
10	10	6.9467	2.5511	2:1	100	0.04	0.3189	± 1.3560
10	10	6.9467	2.5511	2:1	100	0.05	0.3189	± 2.7272
10	10	6.9467	5.1021	1:1	100	0.059551†	0.3189	± 0.0000

†Minimum attainable risk

Table 3

Measurement Process Biases and Control Limits Keyed to False Reject Risk

UUT Lower Tolerance (L1)	UUT Upper Tolerance (L2)	UUT Standard Deviation	A Priori Meas Process Uncertainty	Effective Accuracy Ratio	Assumed Check Std Value	Max Allowable Risk	Assumed Check Std Uncertainty	Control Limits for Measured Deviations
10	10	6.9467	1.2755	4:1	100	0.024388†	0.0319	± 0.0000
10	10	6.9467	1.2755	4:1	100	0.03	0.0319	± 0.8651
10	10	6.9467	1.2755	4:1	100	0.04	0.0319	± 1.4732
10	10	6.9467	1.2755	4:1	100	0.05	0.0319	± 1.9254
10	10	6.9467	1.2755	4:1	100	0.85*	0.0319	± 26.6855
10	10	6.9467	1.7007	3:1	100	0.034232†	0.0319	± 0.0000
10	10	6.9467	1.7007	3:1	100	0.04	0.0319	± 0.9395
10	10	6.9467	1.7007	3:1	100	0.05	0.0319	± 1.5737
10	10	6.9467	1.7007	3:1	100	0.85*	0.0319	± 27.8841
10	10	6.9467	2.5511	2:1	100	0.056540†	0.0319	± 0.0000
10	10	6.9467	2.5511	2:1	100	0.85*	0.0319	± 31.1317
10	10	6.9467	5.1021	1:1	100	0.85*	0.0319	± 42.3343

† Minimum attainable risk
* Maximum attainable risk

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