Appendix 1 Uncertainty of Measurement - Basic Concepts - Part 1

This appendix is in two sections. The first is an example of how Measurement of Uncertainty is applied in the Pharmaceutical Industry and the second provides some examples of uncertainty analysis from the very simplistic to the moderately thorough.

Standard Series	**FUNCTIONAL**	**Number**	**xxxxxx**
Owner	**Name**	**Effective Date**	**date**
Title	**MEASUREMENT UNCERTAINTY CALCULATION AND APPLICATION**		

REVISION HISTORY

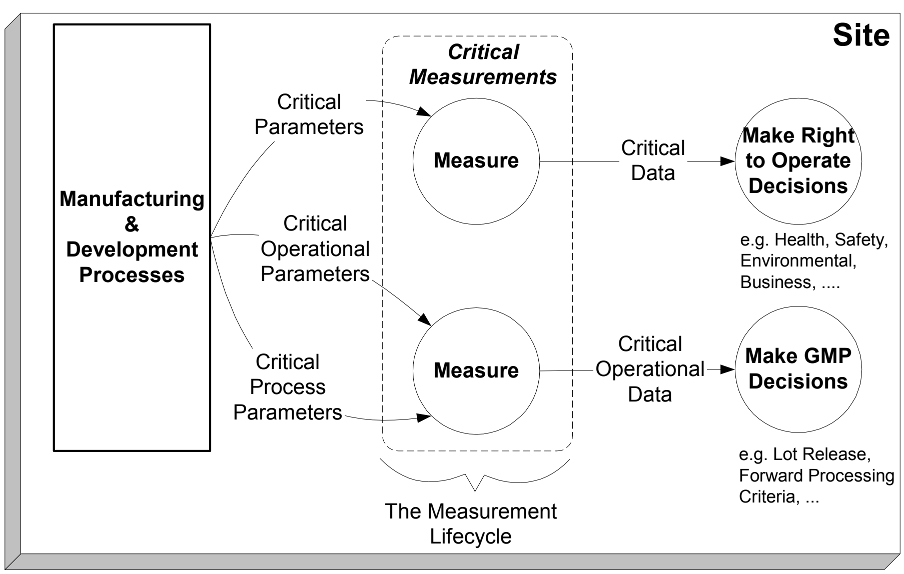
Revision	**Date**	**Revision Description**

KEYWORDS
Alarm, Calibration, Critical Measurement, Critical Operational Data, COD, Critical Process Parameter, CPP, Critical Operational Parameter, COP, Critical Parameter, CP, Critical Data, CD, Data, Decision Limit, Instrumentation, Measurement Uncertainty, MU, PAR, Tolerance.

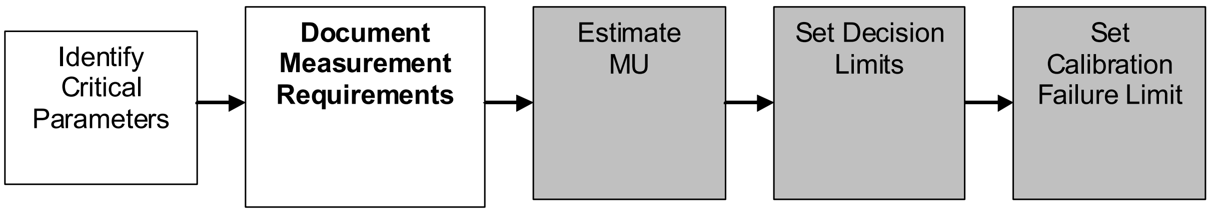
PURPOSE
This document and XYZ, *Critical Measurement*, are designed to assist the sites in responding to Standard XYZ, *Calibration and Measurement*, in a consistent manner.

SCOPE
This document addresses the methodology for documenting the requirements of a Measurement System critical to making operability decisions or Good Manufacturing Practices (GMP) decisions. The Measurement System includes all components of the loop and the standard used to calibrate the loop.

Each site must identify the Measurement Systems requiring a calculated measurement uncertainty (see engineering standard XYZ, *Critical Measurement*). This document covers the requirements for considering Measurement Uncertainty. The requirements apply to any Measurement System used for generating Critical Operational Data (COD) or Critical Data (CD).



Where applicable this standard establishes the requirements for calculating Measurement Uncertainty, determining Decision Limits, and determining Calibration Failure Limits.



APPLICABILITY

This standard will be applied to all Measurement Systems generating COD, CD, or calibration data for COD/CD measurements.

The application of this standard will result in a measurement uncertainty analysis or a rationale for an alternate method. In particular, four (4) situations have pre-existing rationale for an alternate consideration of uncertainty.

They are:

Measurement Systems within the scope of XYZ, *Analytical Equipment*.

Measurement Systems having Method Validation.

Laws of all applicable countries or jurisdictions specify the design and maintenance of the Measurement System.

For example: U.S. EPA requirements for stack carbon monoxide.

The Critical Data are Calculated Values.

Measurements analyzed using SOP XYZ, *Requirements for Establishing Critical Operational Data Measurement and Control Equipment (or Systems) Tolerances, Calibration, and Alarm Limit Determination*, comply with the intent of XYZ, but not this Engineering standard. These measurements are not required to comply with this standard until a change in the Measurement System, or process requirements, would require execution of this standard. This standard, together with XYZ, supersedes the requirements of SOP XYZ.

This standard will be executed on a Measurement System generating COD or CD whenever the design of the Measurement System is changed. This standard will be executed on a Measurement System generating COD or CD whenever a limit (PAR, action, or safe operating limits) for the measurement is changed.

This document does not apply to data that is not COD or CD. The methods in this document may be applied during process development in the laboratory or pilot plant. The methods can be applied to any Measurement System, loop, or instrument to support a Calibration Failure Limit.

This standard applies to xyz and contract personnel involved in calculating and applying Measurement Uncertainty.

The owner (Standard Owner) of this document must review any questions and possible exceptions pertaining to interpretation of the requirements set forth in this Standard. Refer to the Standard Exception process for information regarding approval of exceptions (located in XYZ, *Governance of Engineering Standards*).

REFERENCES

Regulatory

Number	Regulatory Document	Section	Description/Scope

4.1.1	ICH Q7A	5	Process Equipment
4.1.2	21 CFR	211 Sub Part D	Equipment
4.1.3	29 CFR	1910.119	Process Safety Management of Highly Hazardous Chemicals

Industry Guidance/References

Number	Document	Section	Description/Scope
4.2.1	NIST Technical Note 1297		Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results

Number	Document Type	Number	Title

Company documents

DEFINITIONS

The following terms are specific to this Engineering Standard:

Action Limits – The upper and lower limits for parameters (COPs, Environmental, or Business measurements) that when exceeded represent an abnormal situation that requires some sort of action.

Calculated Value – A single piece of data generated by manipulating multiple data points from one or more Measurement Systems.

Calibration Failure Limit – Refer to GMP Glossary

Coverage Factor (k) – A multiplier used with the standard uncertainty (u) to calculate the Measurement Uncertainty (U) to a defined confidence level. (U = k*u)

Critical Data (CD) – Refer to GMP Glossary

Critical Measurement – Refer to XYZ

Critical Operational Data (COD) – Refer to GMP Glossary

Critical Parameter (CP) – Refer to GMP Glossary

Critical Process Parameters (CPP) – Refer to GMP Glossary

Decision Limit (DL) – Refer to GMP Glossary

Guardband Margin (GB) – The expanded uncertainty (U) of a Measurement System used to determine Decision Limits and Calibration Failure Limits.

Measurement Error – The difference between the measured value and the true value of a quantity or parameter.

Measurement System – a collection of individual measurement components connected together, including the calibration system, for measuring a parameter.

Measurement Uncertainty (MU) – Refer to GMP Glossary

Method Validation. – The process of testing a measurement procedure to assess its performance and to validate that performance is acceptable. The magnitudes of the analytical errors are experimentally determined and their acceptability for the application of the method is judged versus defined requirements for quality in the form of maximum allowable errors.

Proven Acceptable Range (PAR) – Refer to GMP Glossary

Required Uncertainty of the Limits (U_{sr}) – The tolerable level of uncertainty allowed at the specified process limits (applies to CPPs, COPs, Action Limits, and Safe Operating Limit).

Safe Operating Limit (SOL) – The safe upper and lower limits for parameters as documented in the Process Safety Information (PSI). The SOL is a measured Critical Parameter (CP) that, when exceeded, defines the transition from safe to unsafe conditions.

RATIONALE

The methodology listed in this document satisfies the intent of the Standard XYZ regarding calibration and maintenance of measurements generating data (COD & CD). This document does not attempt to satisfy all requirements of XYZ. The application of statistics and metrology to processes is complex and non-intuitive. This engineering standard presents a peer reviewed methodology that will foster consistency within areas and across plant sites. The steps denote the minimum effort required to address regulatory and business needs.

STANDARDS

Requirements Summary Matrix

The following Summary Matrix identifies the section numbers, requirements (what must be satisfied; i.e. the "whats"), regulatory/guidance references, required practices (what must be done; i.e. the "hows"), and XYZ references for the systems included in this Engineering Standard. Sample forms are included as appendices to the standard. They are compliant with the standard and can be used. The forms are suggestions only and are not mandatory.

Note: Not all cells of the matrix will contain data (not all requirements will have required practices, regulatory references, XYZ references, etc.). Cells that do not contain data are hatched to indicate that data is not applicable for that cell.

7.1 Determine Measurement Uncertainty Process				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.1.1	This standard must apply to all measurements which generate data (COD & CD).		All measurements that generate data (COD & CD) will generate a documented consideration of uncertainty per a section of this standard. If the remainder of this standard cannot be completed, a rationale for an alternate consideration of Measurement Uncertainty must be documented to meet the requirement. The rationale must be reviewed and approved by Quality Unit for COD parameters. The rationale must be reviewed and approved by a representative of Environmental, Health and Safety, or the Business for CD parameters. An Engineering Manager or above must approve the rationale is technically sound and the alternate method is approved to be implemented. A copy of all rationale approval forms must be given to the Standard Owner. (See Sample Opt Out Rationale Form, Appendix x.)	

7.1 Determine Measurement Uncertainty Process (Continued)				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.1.2	Measurement Systems generating COD or CD, and are maintained by rule of law must meet all legal requirements.		The calibration and maintenance of Measurement Systems having their design and calibration system specified by the law of the local government consider MU by methods outside of this standard. This includes, but is not limited to, Environmental Monitoring Systems governed by the United States Environmental Protection Agency (EPA) or similar entity (at OUS sites). These Measurement Systems must have a documented rationale as described in this standard. The remainder of this standard does not apply to these parameters.	
7.1.3	Measurement systems generating COD or CD, and have been qualified through Method Validation must have documented approval that measurement uncertainty has been considered.		The calibration and maintenance of Measurement Systems within the scope of XYZ, *Analytical Equipment*, or those qualified for use through Method Validation have MU considered by methods outside of this standard. This includes, but is not limited to: Quality Control Lab (QCL) systems. Process Analytical Systems with Method Validation. These COD and CD parameters must have a documented rationale as described in this standard. The remainder of this standard does not apply to these COD and CD parameters.	

7.1 Determine Measurement Uncertainty Process (Continued)				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.1.4	Critical Measurements that are Calculated Values must have must have documented approval that measurement uncertainty has been considered.		It is technically inappropriate to use the methods of this standard for Calculated Values. Any Measurement Systems providing data for a critical Calculated Value must be treated as COD or CD. These COD and CD parameters must have a documented rationale as described in this standard. The remainder of this standard does not apply to Calculated Values. The remainder of this standard does apply to measured parameters from which a Calculated Value is derived.	
7.1.5	Critical Measurement Systems, that cannot meet the design requirements for Measurement Uncertainty, must be approved for use.		These COD and CD parameters must have a documented rationale as described in this standard. The remainder of this standard must be applied to these Measurement Systems. The documentation must be attached to the rationale.	

7.2 **Calculate Measurement Uncertainty**				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.2.1	An uncertainty must be estimated for a Measurement System generating COD or CD.		The Measurement System uncertainty must be estimated with appropriate data sources. Any of the following may be used: Calibration data for the Measurement System. Accuracy specifications from the manufacturer of the Measurement System components. Test data from similar Measurement Systems, generated by a qualified facility. Test data from similar components of the Measurement System, generated by a qualified facility.	
7.2.2	The Measurement Uncertainty must include the contribution of the calibration system.		The Measurement Uncertainty for a Measurement System must include the calibration system (u_{ss}) by either: Using calibration data generated by the Measurement System of interest. Including the Measurement Uncertainty for the calibration system as a component of the Measurement System.	
7.2.3	The estimate of Measurement Uncertainty using component uncertainties must use the root-sum-of-the-squares (RSS) mathematical method.		The calculation to be used to combine uncertainties from multiple sources of error will be: $u_{system} = \sqrt{\sum u_{components}^2}$	

7.2 Calculate Measurement Uncertainty (Continued)				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.2.4	The data and calculations showing estimation of Measurement Uncertainty for COD and CD Parameters must have a technical review and approval.		A set of documents containing all data and calculations used to estimate Measurement Uncertainty must be reviewed and approved. All documents must be reviewed and approved by personnel who have training on this standard. Additionally, at least one approver must be qualified to fulfill the Engineering Role. (See Sample Form, Appendix x)	

7.3 Establish Decision Limits for the Critical Parameter				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.3.1	For each COD and CD parameter, a required uncertainty must be stated at all limits (PAR, Action, or Safe Operating Limits).		The Required Uncertainty of Limits (U_{sr}) must be a design requirement. A value must be stated for each limit of the COD or CD parameter. Acceptable Characteristics of a required uncertainty are: The value can be 0. The rounding rules that apply to the data (COD or CD) can be used to derive a U_{sr}. The value U_{sr} represents an interval outside the limit where the true value must reside with 97.7% confidence or better when the measured value is on the acceptable side of the limit. (See "The Required Uncertainty for COD & CD Parameters", Appendix x.)	

7.3 Establish Decision Limits for the Critical Parameter (Continued)

No.	Requirement (What)	Regulatory/ Guidance Ref.	Required Practice (How)	Ref.
7.3.2	A Guardband Margin must be calculated from the estimate of Measurement Uncertainty.		The Guardband Margin (GB) must be calculated by using the Measurement Uncertainty for a Measurement System. Multiple Measurement Systems may be used to measure all limits of the COD or CD parameter. Only the Measurement System designed to provide COD or CD data at the limit of interest must be used in this calculation. The Guardband Margin must be calculated by multiplying the Measurement Uncertainty (u_{system}) by a coverage factor (k) greater than or equal to 2. $GB = k \times u_{system}, \quad k \geq 2.00$	
7.3.3	A Decision Limit (DL) must be the result of mathematically applying the Required Uncertainty of Limits and the Measurement Uncertainty of the Measurement System to the limit of interest (PAR, Action, or Safe Operating Limits).		If the Guardband Margin is less than the U_{sr}, the Decision Limit (DL) is equal to the limit of interest (PAR, Action, or Safe Operating Limits). If the Guardband Margin is greater than U_{sr}, the Decision Limit is offset from the limit of interest in the direction of acceptability. For a low limit (process operates above): $DL \geq Limit + [GB - U_{sr}]$ For a high limit (process operates below): $DL \leq Limit - [GB - U_{sr}]$	

7.3 Establish Decision Limits for the Critical Parameter (Continued)				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.3.4	The data and calculations showing consideration of Measurement Uncertainty in the calculation of a Decision Limit must have a technical review and approval.		A set of documents containing all data and calculations used to define the Decision Limits for a Critical Measurement must be reviewed and approved. All documents must be reviewed and approved by personnel who have training on this standard. Additionally, at least one approver must be qualified to fulfill the Engineering Role. (See Sample Decision Limit Rationale Form, Appendix x)	

7.4 Verify the Measurement System is Capable				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.4.1	Where there are two Decision Limits for a COD or CD parameter, there must be an operating range between the Decision Limits.		Where there are two Decision Limits for a COD or CD parameter, a Measurement System design must result in Decision Limits (DL) that have an operating range between them. $DL_{Hi} - DL_{Lo} > 0$ It is highly recommended for business reasons that the range between the Decision Limits is greater than the Guardband Margin.	
7.4.2	The Measurement System must be capable of measuring all the limits for a COD or CD parameter.		The Measurement System(s) designed for the COD or CD parameter must be configured to show the value of all limits. This requirement can be met with multiple measurement devices.	

7.4 Verify the Measurement System is Capable (Continued)				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.4.3	For COD or CD parameters with one limit, the Measurement System(s) must be able to measure continuously between the limit and the target for a COD or CD parameter.		For COD or CD parameters with one limit, the Measurement System(s) design must be configured to show all values between the limit and the target for the COD or CD parameter. It is recommended that the Measurement System be able to measure all values in the normal operating range. This requirement can be met with multiple measurement devices.	
7.4.4	For COD or CD parameters with two limits, the Measurement System(s) must be able to measure continuously between the highest and lowest limits for a COD or CD parameter.		For COD or CD parameters with two limits, the Measurement System(s) design for the COD or CD parameter must be configured to show all values between the highest and lowest limits. This requirement can be met with multiple measurement devices.	

7.5 Establish Calibration Failure Limit

No.	Requirement (What)	Regulatory/ Guidance Ref.	Required Practice (How)	Ref.
7.5.1	A Calibration Failure Limit for a COD or CD Measurement System will have a confidence of 95.4% to 99.7% that the failure is a true change in the Measurement System.		Where a measurement system is calibrated in sections, each component calibration must have a CFL allowable range. u_{system} must be the Measurement Uncertainty or its components used to determine the Decision Limits. Calculate the allowable range for the Calibration Failure Limit (CFL) $CFL = k \times u_{system}, \quad 2.00 \le k \le 3.00$ $CFL_{\min} = 2.00 \times u_{system} \quad (95.4\%)$ $CFL_{\max} = 3.00 \times u_{system} \quad (99.7\%)$ Verify the CFL is at or between CFL_{min} and CFL_{max}.	
7.5.2	The data and calculations showing consideration of Measurement Uncertainty in the calculation of the Calibration Failure Limit must have a technical review and approval.		A set of documents containing all data and calculations used to define the Calibration Failure Limit for a COD or CD Measurement System must be reviewed and approved. All documents must be reviewed and approved by personnel who have training on this standard. Additionally, at least one approver must be qualified to fulfill the Engineering Role.	

7.6 Approve Decision Limits				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.6.1	A Decision Limit must be calculated for each limit (PAR, Action, or Safe Operating Limits).		The Required Uncertainty of the Limits, the Measurement Uncertainty, and the calculation of a Decision Limit must be recorded and approved. The approvers must include Engineering and Quality Unit.	

7.7 Retention of Data and Documents				
No.	**Requirement (What)**	**Regulatory/ Guidance Ref.**	**Required Practice (How)**	**Ref.**
7.7.1	The data and calculations showing consideration of Measurement Uncertainty for COD and CD parameters must be retained.		These documents are historical and should be stored in a secure environment that can be easily accessed in the future.	

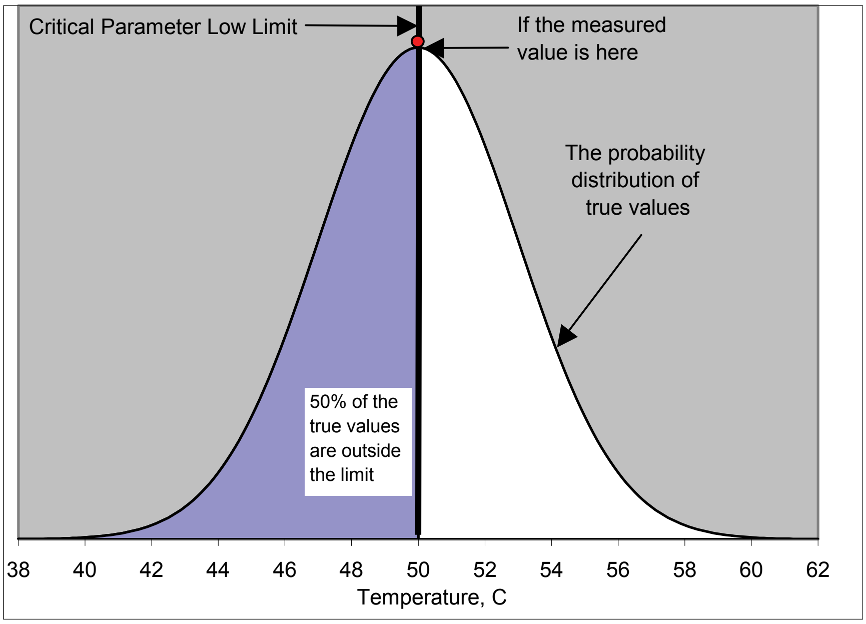
APPENDICES

The Required Uncertainty for COD & CD Parameters

A COD or CD parameter will have acceptable limits. When the measured values from a COD or CD Parameter are in acceptable ranges relative to the limits, a process is meeting requirements.
The uncertainty of the Measurement System can impact the quality control system for the process under consideration. The probability of falsely accepting a measurement as good when the true value is beyond limits can be estimated for every value in the acceptable range of operation. The point with the largest probability of falsely accepting the measurement is at the limit itself. The probability is 50% that the true value is beyond the limit.
The Required Uncertainty of a Limit is a value that conveys the process owner's sensitivity to error in a measurement when a process is operating near a limit. Since Measurement Systems cannot be designed without error, a specification must be established which can be used to design an appropriate Measurement System. The Required Uncertainty of a Limit is based on good scientific judgment and knowledge of the process.

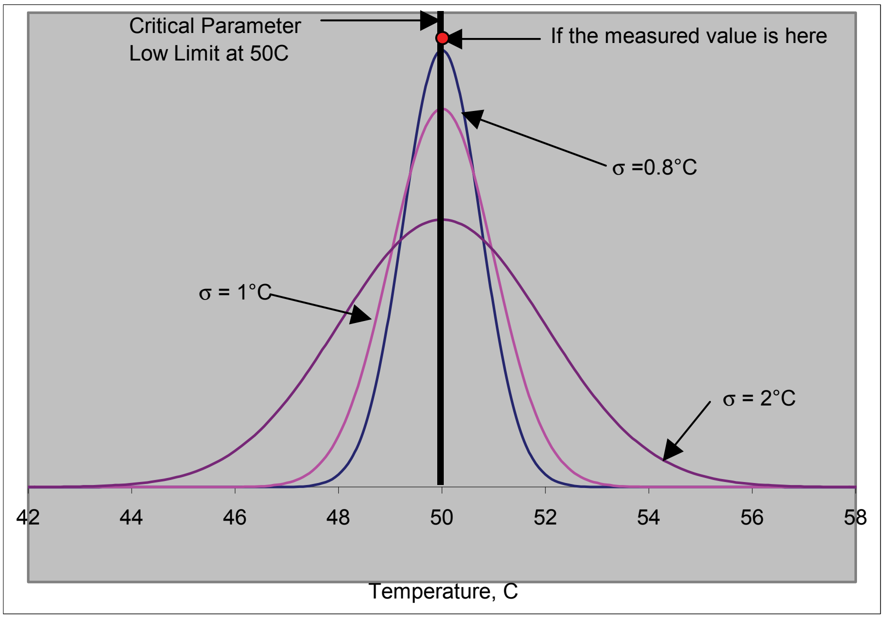
False Accept Rate at a Limit

Note: False accept rate, as used in this document, is the more general statistical term and is not the definition applied in the GMP Glossary.
Measurement Systems will have an error. When a measurement is at a limit, the probability that the true value is outside the limit reaches 50%. There is only one true value, which is unknown. The likelihood of the true value is described by a normal probability distribution. The probability of this true value decreases as the difference between the true and measured value increases. 50% of the probable values also lie in the acceptable area of operation. It can be said that there is a 50% false accept rate when operating at a limit.



<u>Designing a Measurement System</u>

The use of a false accept rate does not convey the impact that Measurement Error has on the process. A normal distribution centered on a limit can take many shapes based on the standard deviation of the measurement uncertainty distribution.



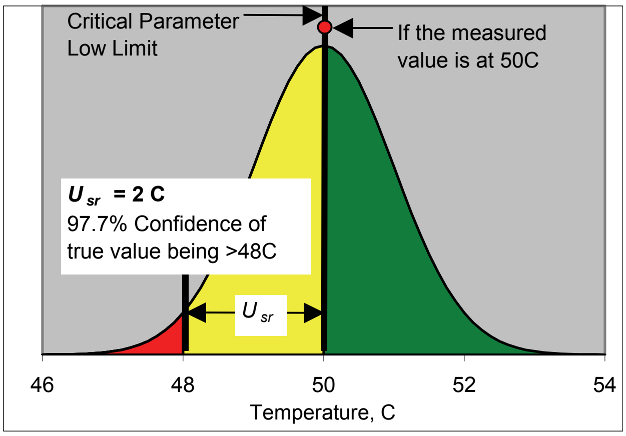
The standard deviation can be used to define a process owner's requirement for the level of confidence that the Measurement System must provide to prevent an unrecognized impact on the process. A value that conveys a confidence for a given standard deviation is the expanded probability. When translated to a Measurement System, the expanded probability is the Required Uncertainty of a Limit, U_{sr}. The standard deviation of a Measurement System is the Measurement Uncertainty, u_{system}.

This engineering standard establishes 97.7% confidence interval as sufficient to consider a Measurement System capable of meeting process requirements. This sets the Coverage Factor between U_{sr} and u_{system} equal to 2.00. The examples below show the impact of the Required Uncertainty of a Limit on the confidence interval for a COD or CD parameter.

> **CAUTION:** An understanding of standard statistical variables U, k, and u is recommended. The use of the U_{sr} (an expanded uncertainty), u_{system} (a standard uncertainty), and a coverage factor can lead to math errors. The general equation $U = k \quad u$ is to be used. The example below demonstrates why a $u_{system} = U_{sr}$ is not sufficient to meet process requirements. The coverage factor, k, must always be understood. i.e. a 2 C device is not sufficient if the Required Uncertainty of the Limit is 2 C.

Example 1: A MS&T chemist has a PAR low limit on a reactor temperature of 50 C. For valid scientific reasons, an excursion to 48 C would have little impact on the product impurity profile. The Measurement System for this application can be designed to produce standard uncertainties of 0.8 C, 1 C or 2 C. Which Measurement System is capable of meeting process requirements?

Analysis:
There is sufficient scientific rationale to establish U_{sr} at 2 C. This indicates that when the measured value is just at the PAR (50 C), the true value can be, unknown to all, at 48 C with an appropriate level of risk to product quality. The goal of the engineer is to design a Measurement System with a confidence greater than or equal to 97.7% (k=2.00) have a true value within 2 C of the measured value at the limit.



<u>Choice 1, 2 C</u> -Starting with the highest uncertainty device is typically the most cost effective Measurement System.

$$\frac{U_{sr}}{u_{system}} = \frac{2°C}{2°C} = 1$$

The U_{sr} equals one standard deviation. This standard requires the U_{sr} to be at least two standard deviations of the system uncertainty.
Using a Standard Normal, Cumulative Probability table:

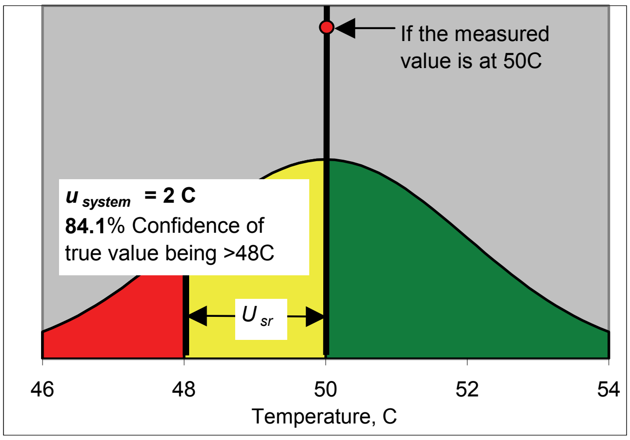
$$z = \frac{x - mean}{\sigma} = \frac{48 - 50}{2} = -1$$

$$\Pr(z \le -1) = 0.1587$$

$$\Pr(z > -1) = 1 - 0.1587 = 0.8413 = 84.1\%$$

The confidence for the Measurement System with u_{system} = 2 C is 84.1% that the true value is greater than 48 C.

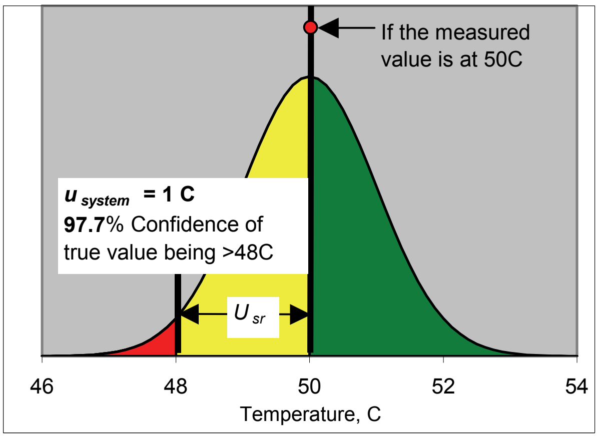
This is an unacceptable system for a Decision Limit at the PAR. The Guardband Margin may be used to determine Decision Limits that allow the use of this Measurement System. See the next section, "Decision Limits and Guardbanding".



Choice 2, 1 C -The 1 C system is more expensive and harder to maintain. It is considered the most common method for monitoring temperature in applications of this type.

$$\frac{U_{sr}}{u_{system}} = \frac{2°C}{1°C} = 2$$

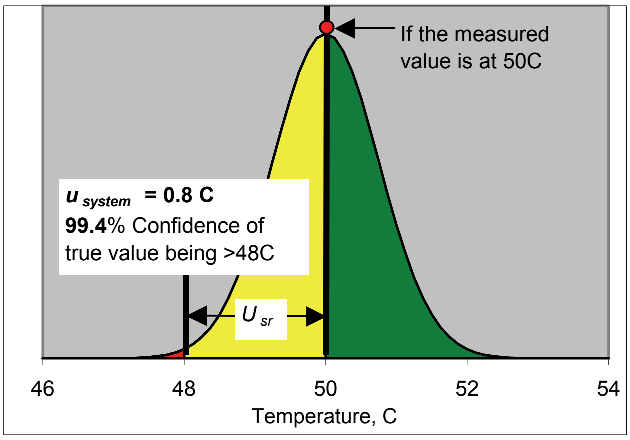
The U_{sr} equals two standard deviations. This standard requires the U_{sr} to be at least two standard deviations of the system uncertainty.
Using a Standard Normal, Cumulative Probability table, the confidence for the Measurement System with an uncertainty of 1 C is 97.7% that the true value is greater than 48 C.
This is an acceptable system that permits the Decision Limit to be at the PAR.



Choice 3, 0.8 C -The 0.8 C system is two orders of magnitude more expensive than the 1 C system. It is considered the best available technology for monitoring temperature in applications of this type.

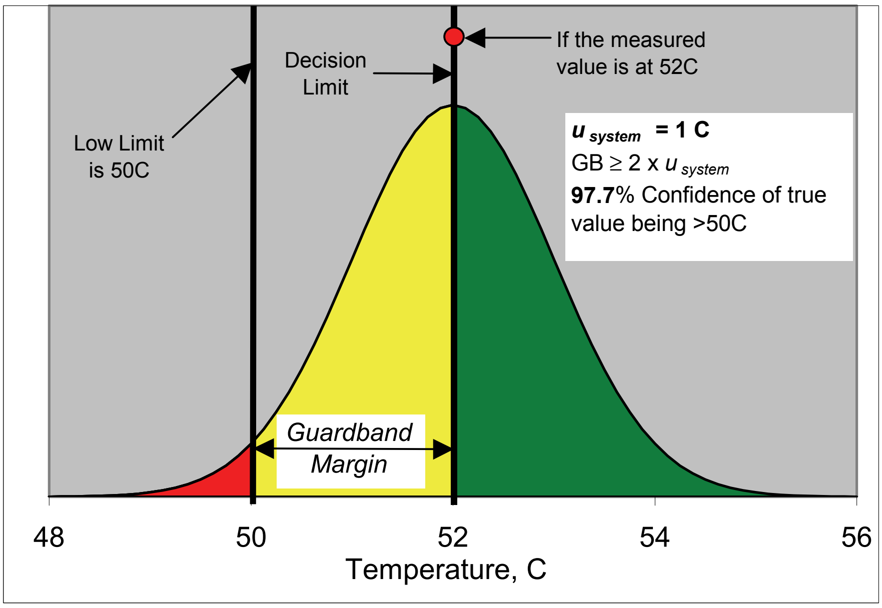
$$\frac{U_{sr}}{u_{system}} = \frac{2°C}{0.8°C} = 2.5$$

The U_{sr} equals two and a half standard deviations. This standard requires the U_{sr} to be at least two standard deviations of the system uncertainty.
Using a Standard Normal, Cumulative Probability table, the confidence for the Measurement System with an uncertainty of 0.8 C is 99.4% that the true value is greater than 48 C.
This is an acceptable system that permits the Decision Limit to be at the PAR.

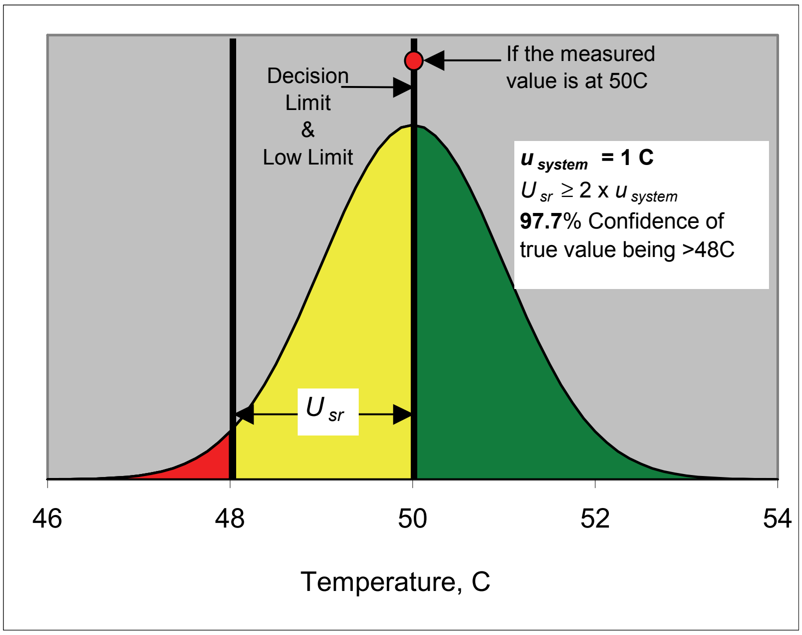


Decision Limits and Guardbanding

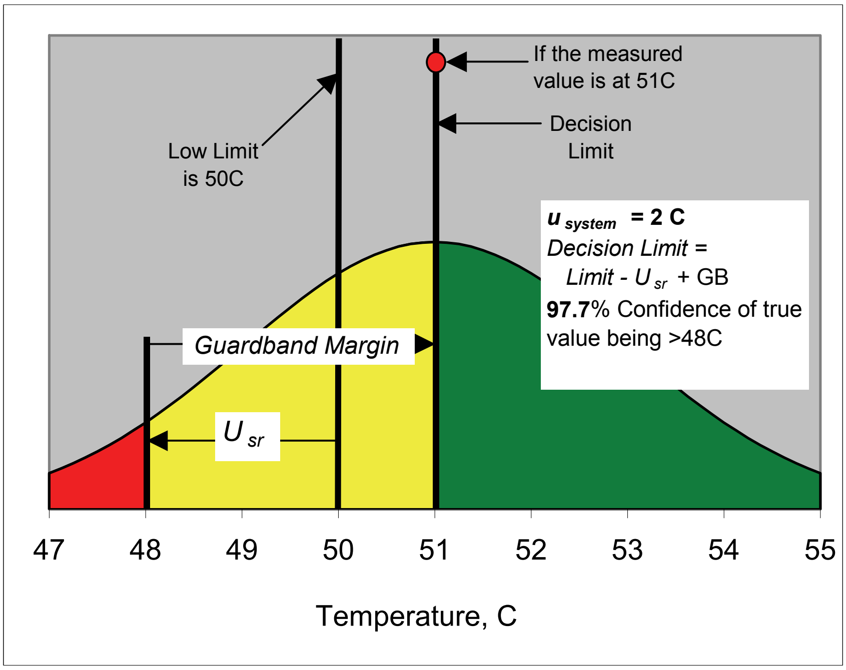
Prior to designing a Measurement System, the Decision Limits are the PARs, Action Limits, and Safe Operating Limits. In order to consider Measurement Uncertainty, corrections to the Decision Limits may be necessary to make sure that the risk posed by measurement uncertainty is acceptable to the process owner.
When a limit such as a PAR is understood to be a limit of failure, it is unacceptable to have a true value beyond this limit. The required uncertainty (U_{sr}) is zero. In such cases, the uncertainty of the Measurement System has an immediate and real impact when the true value is past the limit but the measured value is not.
In order to make good risk based decisions, the designed uncertainty must be accounted for by guardbanding. A Guardband Margin is an interval based on the Measurement Uncertainty that, when used to modify the Decision Limits, results in lower risk of a true value exceeding a limit without an intervention. By its nature, a Guardband Margin increases false rejects and decreases false accepts on a Measurement System. This engineering standard requires, if employed, that a Guardband Margin be no smaller than twice the Measurement Uncertainty of the Measurement System (u_{system}).
In the example shown in the figure below, if the Guardband Margin is used to adjust the Decision Limit from 50 C to 52°C, the probability that the true value is 50°C or greater becomes 97.7% when the measured temperature is 52°C. If the Decision Limit remains 50°C, the probability of a true value less than 50°C occurring at the limit is 50%.



When a limit, such as a PAR is a limit of acceptance, the region of acceptable performance is not fully defined. Scientific judgment and data can be used to determine an interval outside the limit where success is a reasonable conclusion. The Required Uncertainty of a Limit defines a region of expected success. The Decision Limit can exist at the PAR if the Measurement System can guarantee with a high confidence (97.7%) that the true value is in the region of success.



Finally, if a Measurement System cannot meet the requirements for a limit of acceptance, it is possible to apply a Guardband Margin and a U_{sr} to obtain a Decision Limit which is between the critical limit and a fully guardbanded process.



Considerations for Establishing Decision Limits

This standard establishes the least conservative values for Decision Limits. The Decision Limits for a COD or CD parameter may be different than the calculations in this standard provide.

For COD parameters, quality may be affected by sudden changes in operation outside of norms. A process that is tightly controlled relative to a limit may justify movement of a Decision Limit to reflect the degree of control. When process variability is low, any change that results in an excursion outside norms may need investigation. The use of statistical process control may identify alternative Decision Limits. The Decision Limits must meet the requirements of this standard.

For COD parameters, the use of a measurement to detect equipment failure or human error is common. The use of Decision Limits to codify this function is highly discouraged. This will result in the quality system responding to changes in equipment that have not actually compromised the process. The Calibration system is designed for this function.

CD parameters may be used to detect imminent equipment failure. In this case, the Decision Limits established by this standard are sufficient. The acceptable range and Required Uncertainty at a Limit, if correctly identified, will result in the correct Decision Limits.

Sample OPT Out Rationale Form

See Attachment 15

Sample OPT Out Rationale Data Entry Guide

DATA	DESCRIPTION
Site (A)	Enter the Manufacturing site here
Building (B)	Enter the actual building number if there is one
Process (C)	Enter the process name
Item Code (D)	Enter the ticket number If there is no ticket number, enter N/A.
Instrument ID (E)	Enter the instrument Tag number If there are multiple instruments that are used to measure the same parameter for this step and they are identical, list all of them.
COD/CD List Source (F)	Enter the Title and Approval Date of the COD/CD List used in this analysis.
Rationale (G)	Record a rationale for not using this engineering standard on this Measurement System to Set Decision Limits.
Prepared by Signature (H)	The person filling out the form signs here. (Your signature indicates that you prepared this document following the applicable standards and procedures.)
Engineering (I)	The engineer responsible for the Process Step that this measurement system resides in. (Your signature indicates that you have reviewed this document and agree with the information contained herein.)
Technical Service (J)	For COD: Thexyz Representative responsible for the Process Step that this measurement system resides in. (Your signature indicates that you have reviewed this document and agree with the information contained herein.) Not Required for CD.
Signatures: Approver (K)	For COD: The Quality Unit signs here. For CD: The Health & Safety Representative for Health & Safety Data; The Environmental representative for Environmental Data; or the Appropriate Leader for Business Data.

	(Your signature indicates that you agree with the rationale.)
Engineering Management (L)	An Engineering Manager or above must agree with the rationale and give approval to implement an alternate method of uncertainty consideration. (Your signature indicates that the rationale is technically sound and the alternate method of uncertainty consideration may be implemented.)

Sample CML Form

See Attachment 16

Sample CML Data Entry Guide

DATA	DESCRIPTION
Site (A)	Record the Site Details here.. This information will be included in the COD data.
Building (B)	Record the Building # here. This information will be included in the COD data.
Process (C)	Record the process name from the ticket. This information will be included in the COD data.
Item Code (D)	Record the item code, ticket number or utility, e.g., Purified Water. Record N/A if this is related to air pollution or wastewater treatment (CD).
Instrument ID (E)	Record the instrument Tag number If there are multiple instruments that are used to measure the same parameter for this step and they are identical, list all of them.
Step (F)	Record the step ID or description (e.g. 4, D-3). If there is no step ID, then record a description of when the measurement is critical, or a description of the utility process if the measurement is on a utility.
IF u_{system} is being estimated based on performance data	
XYZ (G)	Record the equipment number of the transmitter or primary loop element or instrument for this COD or CD measurement. This record is where the Loop Calibration Failure Limit will be stored. (PM Tolerance, Equipment Tolerance) Record N/A if this has not been assigned.
u_{system} (H)	The uncertainty of the measurement system based on performance data.
$u_{secondary\_standard}$ (I)	The uncertainty of the secondary standard that was used to measure the performance of the measurement system.
IF u_{system} is being estimated using vendor data	
XYZ (G)	Record the equipment number of the transmitter or primary loop element or instrument for this critical measurement. This is where the Loop Calibration Failure Limit will be stored. (PM Tolerance, Equipment Tolerance) Record N/A if this has not been assigned.

DATA	DESCRIPTION
Loop: Sensor: (J) Manufacturer Model number Component Uncertainty	Record the following: Manufacturer, not vendor Complete model number including options. Calculated or verified Component Uncertainty or Calibration Failure Limit **Note**: Some of this data will be available from the Computerized Maintenance Management System or paper based maintenance record. All data retrieved from these systems must be verified.
Loop: Transmitter: (K) Manufacturer Model number Component Uncertainty	Record the following: Manufacturer, not vendor Complete model number including options. Calculated or verified Component Uncertainty or Calibration Failure Limit **Note**: Some of this data will be available from the Computerized Maintenance Management System or paper based maintenance record. All data retrieved from these systems must be verified.
Loop: I/O module: (L) Manufacturer Model number Component Uncertainty	Record the following: Manufacturer, not vendor Complete model number including options. Calculated or verified Component Uncertainty or Calibration Failure Limit.
$u_{combined}$ (M)	The combined uncertainty of all of the components of the measurement system.
$u_{secondary\_standard}$ (N)	The uncertainty of the secondary standard used to calibrate the measurement system.
u_{system} (P)	The uncertainty of the measurement system.
Once u_{system} has been calculated	
Minimum Calibration Failure Limit (Q)	Minimum Calibration Failure Limit = 2 * u_{system}
Signatures: MU Team member (R)	The person filling out the form signs here. (Your signature indicates that you prepared this document following the applicable standards and procedures.)
Signatures: Engineering (S)	The engineer responsible for the Process Step that this measurement system resides in. (Your signature indicates that you have reviewed this document and agree with the information contained herein.)

Sample Decision Limit Rationale Form

Site:	A	**Item Code:**	D
Building:	B	**Instrument ID:**	E
Process:	C	**COD/CD List Source:**	F

Measurement System Requirements						
Step	Description	Process Limit High	Required Uncertainty of the High Limit (U_{sr})	Process Limit Low	Required Uncertainty of the Low Limit (U_{sr})	Eng Units
G	H	I	J	K	L	M

Measurement System Design Attributes							**Decision Limits**				
Instrument ID	Source	u_{system}	Guardband	Is Guardband Margin / u_{system} > = 2 ? (Yes or No)	Instrument Range High (IRH)	Instrument Range Low (IRL)	High	Target (applicable for single sided limits only)	Low	Rationale	Do the Decision Limits/Target fall between IRH & IRL? (Yes or No)
N	O	P	Q	R	S	T	U	V	W	X	Y

Prepared By:	Z	**Title:**	Z	**Date:**
	(Your signature indicates that you prepared this document following the applicable standards and procedures)			
Engineering:	AA	**Title:**	AA	**Date:**
	(Your signature indicates that you have reviewed this document and agree with the information contained herein)			
Tech Services:	AB	**Title:**	AB	**Date:**
	(Your signature indicates that you have reviewed this document and agree with the information contained herein)			
Approver:	AC	**Title:**	AC	**Date:**
	(Your signature verifies that measurement uncertainty has been considered for decision limits and that you agree with the rationale)			

Sample Decision Limit Rationale Data Entry Guide

DATA	DESCRIPTION
Site (A)	Enter the Manufacturing site here
Building (B)	Enter the actual building number if there is one
Process (C)	Enter the process name
Item Code (D)	Enter the ticket number If there is no ticket number, enter N/A.
Instrument ID (E)	Enter the instrument Tag number If there are multiple instruments that are used to measure the same parameter for this step and they are identical, list all of them.
COD/CD List Source (F)	Enter the Title and Approval Date of the COD/CD List used in this analysis.
Step (G)	Enter the step ID or description (e.g. 4, D-3). If there is no step ID, then enter a description of when the measurement is critical, or a description of the utility process if the measurement is on a utility.
Description (H)	Process Description for the parameter
Measurement System Requirements (I, J, K, L, M)	Enter the High and Low Process Limits (i.e. PARs/Action Limits/Safe Operating Limits) with the required uncertainty at those limits (U_{sr}) & engineering units.
Measurement System Design Attributes (N, O, P, Q, R, S, T)	N - Enter the instrument Tag number. If there are multiple instruments that are used to measure the same parameter for this step and they are identical, list all of them. O - Enter the Title and Approval Date used in this analysis. P - Enter the Measurement Uncertainty of the Measurement System Q – the calculated Guardband Margin of the instrument R – Verification that the ratio between the Guardband Margin and u_{system} must be at least 2 to 1. S, T – the range of the instrument (in terms of the units specified in M) IF there is more than one instrument required to measure the process limits, fill out one row for each measurement.

DATA	DESCRIPTION
Decision Limits (U, V, W, X, Y)	Enter the established decision limits for each measurement per ABC (U, V, W), how they were calculated (X), and whether or not the instrument range (S, T) covers the entire range of the decision limits.
Prepared by Signature (Z)	The person filling out the form signs here. (Your signature indicates that you prepared this document following the applicable standards and procedures.)
Engineering (AA)	The engineer responsible for the Process Step that this measurement system resides in. (Your signature indicates that you have reviewed this document and agree with the information contained herein.)
Technical Service (AB)	For COD: The XYZ Representative responsible for the Process Step that this measurement system resides in. (Your signature indicates that you have reviewed this document and agree with the information contained herein.) Not Required for CD.
Signatures: Approver (AC)	For COD: The Quality Unit signs here. For CD: The Health & Safety Representative for Health & Safety Data; The Environmental Representative for Environmental Data; or the Appropriate Leader for Business Data. (Your signature verifies that measurement uncertainty has been considered for decision limits and that you agree with the rationale.)