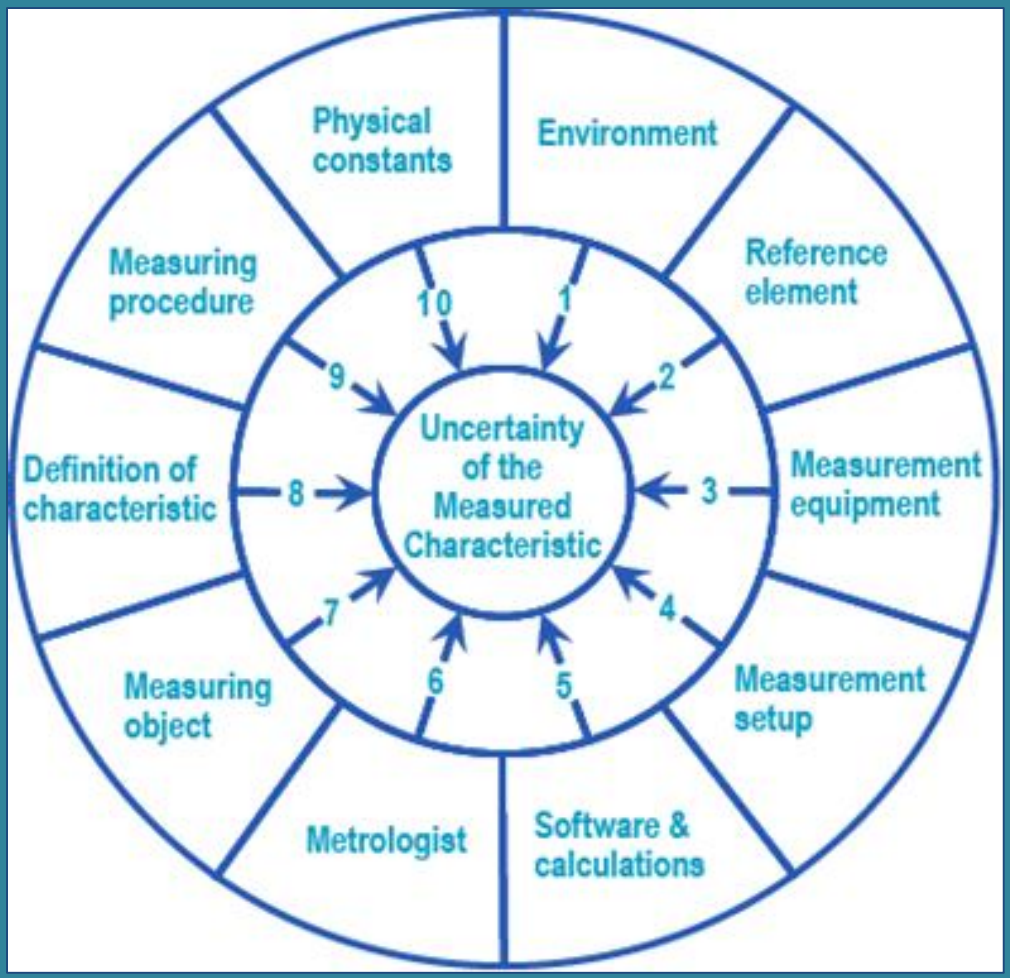
Measuring Up

A Calibration Management System



By Pat Fogwill

MEASURING UP

Calibration Management

Pat Fogwill (c)

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DISCLAIMER OF LIABILTY.

MEASURING UP written from the experience of many years in the manufacturing and service industries and has been published as an aid for those who wish to maintain or develop a calibration management system.

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Foreword:

Every day we make measurements, yet, do we consider the accuracy of that measurement?

If you are a provider of service or product then this publication will help you to take your quality systems to levels that can save you time and money, improving your methodology and giving you a clearer understanding on how to measure up.

In many cases measurements are made as a guide for approximating, therefore in this case the measurement is loose or not accurate, but we still have an expectation of a limit as to the uncertainty of that measurement. The degree of uncertainty is what we frequently determine (even in our minds) as acceptable. The level of uncertainty or accuracy depends on the purpose for the measurement. When manufacturing a product the quality depends upon its size or content, and any error in measurement results in something of poor quality or totally useless.

The scope for making measurements is enormous, and most with wide-ranging consequence, such as Occupational Health and Safety, Hygiene, Product Quality and Product Safety issues. My background is engineering & engineering management in the industries of: Defence, Telecommunications and Pharmaceutical, so I have seen, experienced and had to sort the most awful "stuff-ups".

This book outlines the methods for developing and maintaining your measurement systems, showing how to determine and apply acceptable limits, ensuring that measurements are applied and used with total confidence. The language used in this book does not mean that you have to be a scientist or engineer to understand the methodology; it is a simple guide that takes you through the different steps enabling you work and produce a quality service or quality product. Many of the steps you may have completed to some degree even just in the mind, but the contents show you what is required and the documenting of your procedures.

In the end you can have a measurement system that is structurally sound, that can be reviewed and modified at any time, producing a calibration management system that ensures timely corrective actions minimising errors and cost, and that will withstand audit. You will be able demonstrate by documents and documented history that shows, "what you do is what you say you do", and "what you do meets the required standard".

If your measurement is uncertain then so are your processes and products.

Contents:

Calibration:

Definition:

- Determining the uncertainty of measurement.
- To determine the difference between a measured value and the accepted true value.
- The term is often used to describe the process of adjustment of measuring instruments to align with a standard.

Traceability:

An essential function and should always be followed, if your measurement is not based upon the accepted true value the results are bound to cause issues.

In many cases It is a requirement that measurements are traceable i.e.: Each measurement can be traced through known standards up to an acceptable standard; such as "National", "International" or "Physical" Standards.

New technologies are enabling the metrology industry to declare standards based upon physical standards, such as the number of atoms of carbon = 1kg. (This is not a figure I personally carry in my head, nor would I want to, but you can see from such an example how the physical standards are being defined).

For clarity of understanding and management there is a need to keep the number of traceable steps to a minimum, below is a typical step by step traceable path you could adopt.

- **Process**: - The limits applied for good quality of a product or service.
- **Process measurement**: - Usually determined on or near the production line is the most hard-worked equipment, subjected to and influenced by the close proximity of interference (electrical, radio frequency, thermal, humidity, mechanical vibration), and should be installed and maintained in order to ensure the limits of process are not exceeded. Traceability is taken from the transfer measurement equipment.
- **Transfer measurement**: - The equipment for calibrating the process measuring equipment is used frequently and submitted to environmental changes, and installed and maintained in order to ensure the limits of the process measurement equipment are not exceeded. Traceability is taken from the site standard measurement equipment.
- **Site Standard measurement**: - Master measuring instrument for your site, used for calibrating your transfer measurement equipment, usually located in an environmentally stable room, free from any influencing properties, usually a Laboratory, and maintained in order to ensure that the limits of the transfer standard equipment are not exceeded. Traceability is taken from the test house measurement equipment.

- **Test House**: - The equipment used for calibrating your equipment, usually by a third party (preferably regulated by a testing authority) . This equipment must be traceable and documented linked to the acceptable standard.

Important: Each step from the "product" to the "Site Standard" is maintained by equipment with lesser uncertainties than itself.

Setting the Limits:

As Found & As Left Limits:

"As Found Limit" - Definition:

- The maximum deviation level permitted between the measured value and the accepted true value prior to any adjustment.
- If this limit is exceeded the process / product quality may have been compromised for some or all of the period since the last calibration.

"As Left Limit' – Definition:

- The maximum deviation level permitted between the measured value and the accepted true value immediately following any adjustment.
- This level also is the point at which you determine if adjustment is required; if the deviation between the measured value and accepted true value is less than the "As Left Limit" then no adjustment is required.
- If this limit cannot be met immediately following adjustment then this indicates that the equipment is not fit for purpose and should not be used and should be repaired or replaced.

Before setting the limits for accepted uncertainties, you must understand your requirements for the product / process accepted quality limits:

Let's say that the process is "to sterilize by steam, the containment for your product and that this is a statutory requirement", the sterilization temperatures must be 121.1 degrees Celsius with an uncertainty of 1 degree Celsius.

Defining the limits for process measurement:

The process measuring equipment uncertainties for the value of 121.1 degrees Celsius must be less than +/-1 degree.

The requirement is for the process measuring equipment to always be operational with uncertainties equal or less than the "As Found Limit".

- The worst case difference between the measured value and the accepted true value is the "As Found Limit".
- Service is only required when the "As Left Limit" is exceeded.

Calculating the **" As Found Limit"** is determined as ½ of the process limit, then the "As Found Limit" is +/- 0.5 degree Celsius (500mK).

Calculating the **"As Left Limit"** is determined as ½ of the "As Found Limit", then the "As Left Limit" is 250mK.

Conclusion: The process measuring equipment will operate with the uncertainties up to 500mK and will require service when the uncertainties exceed 250mK.

Defining the limits for the transfer measurement:

The transfer measuring equipment uncertainties for the value of 121.1 degrees Celsius must be less than 250mK.

The requirement is for the transfer measuring equipment to always be operational within or less than the "As Found Limit" and the "As Left Limit".

- The worst case difference between the measured value and the accepted true value is the "As Found Limit".
- Service only required when the "As Left Limit" is exceeded.

Calculating the **"As Found Limit"** is determined as ½ of process measurement limit, then the limit is 125mK.

Calculating the **"As Left Limit"** is determined as ½ of the "As Found Limit", then the limit is 62mK.

Conclusion: The Transfer Standard measuring equipment will operate with the uncertainties up to 125mK and will require service when the uncertainties exceed 62mK.

Defining the limits for the site standard measurement:

The Site Standard measuring equipment uncertainties for the value of 121.1 degrees Celsius must be less than 62mK.

The requirement is for the Site Standard measuring equipment to always be operational within or less than the "As Found Limit" and the" As Left Limit".

- The worst case difference between the measured value and the accepted true value is the "As Found Limit".
- Service / adjustment only required when the "As Left Limit" is exceeded.

Calculating the **"As Found Limit"** is determined as ½ of transfer measurement equipment limit, then the limit is 31mK.

Calculating the **"As Left Limit"** is determined as ½ of the "As Found Limit", then the limit is 15mK.

Conclusion: The Site Standard measuring equipment will operate with the uncertainties up to 31mK and will require service when the uncertainties exceed 15mK.

Calibration Factor:

The examples given above use a factor of two between each step of the measurement maintenance processes and is known as the "Calibration Factor". A factor of 2, 4 or greater can be applied, the greater the number the safer your system, but the greater the number the more difficult it becomes to fit the required steps to the limits of the appropriate standards, i.e.:

Where AF="As Found Limits" & AL="As Left Limits".

Using the previous example, we can easily calculate:

Using a Calibration Factor of 2

- **Process requirement**: - 1000mK.
- **Process measurement**: - AF = 500mK. AL=250mK.
- **Transfer measurement**: - AF=125mK. AL=62mK.
- **Site Standard measurement**: - AF=31mK. AL=15mK.
- **Test House requirement**: - 7mK.

Using a Calibration Factor of 4

- **Process requirement**: - 1000mK
- **Process measurement**: - AF = 250mK. AL=60mK.
- **Transfer measurement**: - AF=15mK. AL=4mK.
- **Site Standard measurement**: - AF=1mK. AL=0.25mK.
- **Test House requirement**: - 0.06mK.

Most test houses could not offer traceability with uncertainties this small, whereas 5mK is possible. This example demonstrates that the calibration factor of 2 would work, where the factor of 4 would not. The calculations using the factor of 3 would also demonstrate that this factor would not work.

It has been found by many years experience that the Calibration Factors of between 2 and 4 work well and have produced world leading results.

Conclusion: Some critical processes may require some process control adjustment due to the derived accepted uncertainties. The example shown is for the sterilisation by steam, using the control parameters of 121.1 degree Celsius for 20 minutes. The actual temperature of the set point for the process should now be set for 121.6 degree Celsius, allowing for the uncertainty of 500mK. For greater certainty for the delivery of the sterilisation lethal dose, the time can be extended to 30 minutes. The process control parameters would now be 121.6 degree Celsius for 30 minutes. Therefore the process parameters would now be 121.1 degree Celsius to 122.1 degree Celsius for 30 minutes.

Calibration Period:

The calibration period is the period between each calibration. At each calibration the measuring equipment is checked and the uncertainty of the measured value is compared with the accepted true value to confirm that the equipment has been operating within the "As Found Limits", and if required the equipment adjusted / corrected to uncertainties less than the "As Left Limits".

In adopting the correct calibration period it is expected that the measuring equipment uncertainties lie within the determined limits, and the only time these limits are exceeded would be as a result of equipment failure.

Depending upon the type of equipment being maintained and the working environment of the equipment, the period can be set from days to weeks or even years. Experienced has demonstrated that the best management period should not be set based upon calendar dates, as these are not fixed periods, but by using the number of days or weeks or the multiples of weeks as: 1, 2, 4, 13, 26, 52 or multiples of 52 weeks, or periods in days set as 1, 2 or 3.

The management for setting the period should be flexible, that allows:

- Extension of the period if the results of calibration indicate no adjustment required for up to three calibration periods,
- Reduction of the period if the calibration results indicated that limits have been exceeded once.

It is obvious that prior knowledge is required in order to make decisions for setting calibration periods. Here are three suggested methods:

1 Seek advice from the manufacturer or supplier.

2 Seek professional advice from instrument engineers, metrology consultants, or experienced technicians.

3 Always plan and document test runs.

Whatever your decision, the period should always be tested, usually by being cautious and selecting periods less than expectations, then modifying them based upon the results of calibration.

If the period selected is too long then product, process or occupational health and safety could be compromised.

If the period is too short you are demonstrating that time and money is being lost due to unnecessary maintenance and equipment over handling that can reduce the life expectancy of that equipment.

If equipment demonstrates erratic behaviour between calibrations, the cause can be either; incorrect selection of equipment, incorrect installation, incorrect maintenance procedures, system inconsistencies or influence quantities from the equipment surrounding environment, i.e.; Temperature fluctuation, humidity, pressure changes, radio, electrical or magnetic radiation or electrostatic, just to mention a few. Whatever the cause, you will need to plan and make a thorough investigation for several possible scenarios.

Calibration Management Lifecycle:

Quality Document System:

The process of installing and maintaining any measurement system must be managed using a clear step by step documented regime, which facilitates review in order for decision making, and demonstration that all equipment selected can be maintained and is fit for purpose.

Planning: Prepare a written validation document:

Specifications: Specify what is required:

- User Requirement.
- Design Qualification.

Test Planning: Document how the equipment is to be tested:

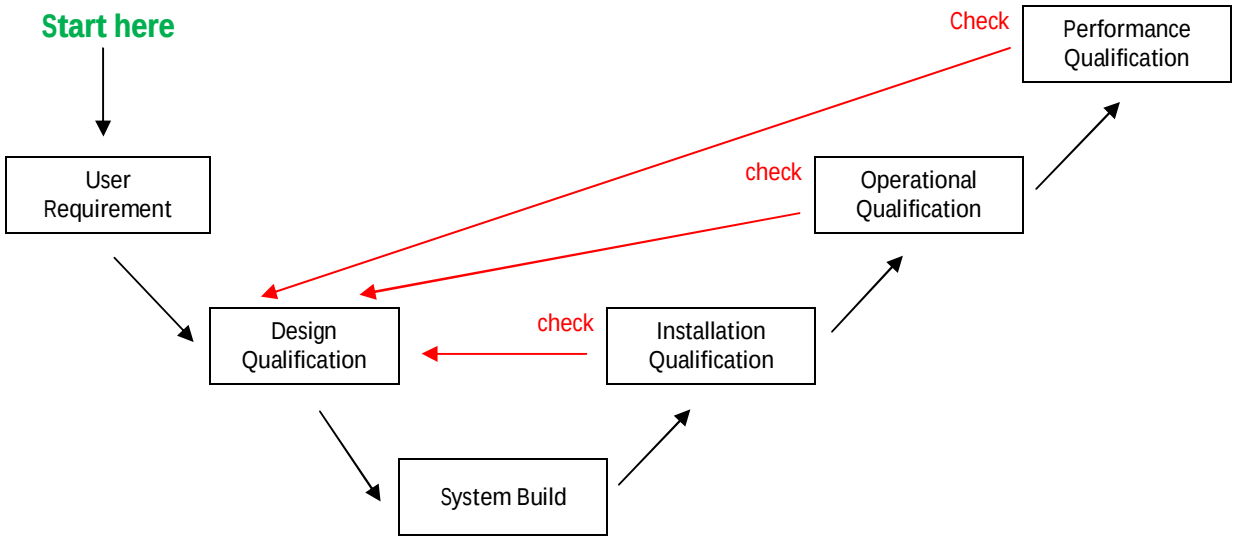
- Operational Qualification.
- Performance Qualification.
- Installation Qualification.

Testing: Perform tests and record results:

- Installation Qualification.
- Operational Qualification.
- Performance Qualification.

Review: Review results for system performance:

- User Requirement.
- Design Qualification.
- Installation Qualification.



The "V" Model.

The above documents are normally stored for easy access in a library, with files sorted by the Location, Line, Machine, Equipment identity number. And remain active for the life of the equipment, or as defined by regulatory bodies.

In the event of quality audits, reviews or product recall, investigations will require the information contained in these files.

User Requirement:

This document is generated to show and explain the basic requirements for the production of a quality product/service:

The contents:

- Product description / purpose. (What it is and what it does).
- Regulatory controls.
- Recipe / components of the product. (Details to include maximum and minimum limits permitted).
- Process steps and process descriptions. (How the product is made including the limits of process or other influencing limits i.e.: Occupational health and safety, environment, packaging, handling, and product life).
- Expected production run sizes / batches / quantity, frequency and timelines for manufacture.
- A table for each process stage showing :
    - Process line title,
    - Description of process,
    - Measurement discipline,
    - Engineering units used for each discipline,
    - Range of measurements,
    - Permitted tolerances.
    - Special notes.

This document is to be:

- Signed and dated by the User/Owner.
- Reviewed, questioned and challenged by design group (User/Owner, Engineering, Quality assurance). The User/ Owner to amend / update as required. Repeated review following updates.
- Engineering acceptance sign-off and dated as definitive and clear in content to be able to establish the design phase.
- Quality Assurance acceptance sign-off and dated as definitive and clear in content, conforming to regulatory and quality standards, giving approval for establishment of the design phase.
- This document to be version controlled, capturing details and purpose for amendments and updates.

Design Qualification:

This document is a detailed plan generated from the user requirement showing and explaining how the product is to be manufactured or service provided from the raw material to the final product, including the machinery, locations, services, environment, and manpower in order for the production of a quality product/service to be delivered within the expected timeline:

The contents:

- Product/service description/purpose. (What it is and what it does).
- Regulatory controls.
- Recipe/components of the product/service. (Details to include maximum and minimum limits permitted).
- A breakdown detail of all the process steps, from the obtaining of raw material to the final product, to include all of the process descriptions, equipment required, and manpower required. (How the product/service is made, where it is to be stored, manufactured or provided, including the limits of process or other influencing limits i.e.: Occupational health and Safety, environment, packaging, handling, and product /service life).
- Expected production run sizes / batches / quantity, frequency and timelines for manufacture or provision.
- Required environment (temperature, humidity, cleanliness, other; magnetic, electrostatic, light, radiation protection etc.).
- A table for <u>each process</u> showing :
    - Process line title,
    - Process line location,
    - Description of process,
    - Equipment description,
    - Measurement discipline,
    - Engineering units used for each discipline,
    - Range of measurements,
    - Permitted tolerances.
    - Special notes. (Identifying any precautions taken from experience or advice given, example: some chemicals demonstrate a tendency to be effected by electrostatic charges causing “clumping” and errors of measurement due to magnetic influence. You will need to define the methodology to minimise such effects).

This document is to be:

- Signed and dated by the responsible Engineer, and Engineering Management.
- Reviewed, questioned and challenged by design group (User/Owner, Engineering, Quality assurance). The responsible engineer to amend / update as required. Repeated review following updates.
- Engineering acceptance sign-off and dated as definitive and clear in content to be able to establish the Installation phase.
- User /Owner acceptance sign-off and dated as definitive and clear in content to be able to establish the installation phase.
- Quality Assurance acceptance sign-off and dated as definitive and clear in content, conforming to regulatory and quality standards, giving approval for establishment of the installation phase.

This document to be version controlled, capturing details and purpose for amendments and updates, remaining a live document for the life of the equipment / process.

Operational Qualification:

From the Design Qualification an itemised list of all required equipment is specified. This document is later reviewed and updated following the development of the performance Qualification and again following the Installation Qualification.

The purpose of this document is to identify the detailed operational requirements of each piece of equipment and following the Installation Qualification how it is to be used, maintained and what services are required for it to operate.

Initially the itemised list of equipment will identify maximum limits (operation frequency, measurement limits, maintenance functions and limits) to be applied and the basis for those limits.

This document is to be:

- Signed and dated by the responsible Engineer, and Engineering Management.
- Reviewed, questioned and challenged by design group (User/Owner, Engineering, Quality assurance). The responsible engineer to amend / update as required. Repeated review following updates.
- Engineering acceptance sign-off and dated as definitive and clear in content to be able to establish the Installation phase.
- User /Owner acceptance sign-off and dated as definitive and clear in content to be able to establish the installation phase.
- Quality Assurance acceptance sign-off and dated as definitive and clear in content, conforming to regulatory and quality standards, giving approval for establishment of the installation phase.

This document to be version controlled will be always a live document throughout the life of the equipment, being updated and maintained based upon the history of operation.

Performance Qualification:

Initially from the Operation Qualification this document itemises the actual limits expected to be applied to each item of equipment. Then reviewed and updated to show that the actual uncertainties and limits are within the defined limits as identified in operational qualification. The review and update occur when testing during the equipment assessment and installation stage, and then at regular periods through the equipment life. The data content of this document should reflect the absolute capability of the equipment.

This document is to be:

- Signed and dated by the responsible Engineer, and Engineering Management.
- Reviewed, questioned and challenged by design group (User/Owner, Engineering, Quality assurance). The responsible engineer to amend / update as required. Repeated review following updates.
- Engineering acceptance sign-off and dated as definitive and clear in content to be able to establish the Installation phase.
- User /Owner acceptance sign-off and dated as definitive and clear in content to be able to establish the installation phase.
- Quality Assurance acceptance sign-off and dated as definitive and clear in content, conforming to regulatory and quality standards, giving approval for establishment of the installation phase.

This document is version controlled and indicates that the equipment is fit for purpose for the stages of selection, installation, operation and maintenance, therefore remains a live document for the life of the equipment.

Installation qualification:

From the initial Operational and Performance Qualification documents this document is developed during the equipment selection stage, through to the final installed stage, and indicates the equipment components (Title, Model, and Serial Numbers etc.), process stage, Manufacturer, Supplier, Services details (Energy sources and distribution), applied limits, frequency and type of maintenance and identification of Standard operation procedures to be used for operation and maintenance.

This document is to be:

- Signed and dated by the responsible Engineer, and Engineering Management.
- Reviewed, questioned and challenged by design group (User/Owner, Engineering, Quality assurance). The responsible engineer to amend / update as required. Repeated review following updates.
- Engineering acceptance sign-off and dated as definitive and clear in content to be able to establish the ongoing operations.
- User /Owner acceptance sign-off and dated as definitive and clear in content to be able to establish the ongoing operations.
- Maintenance Engineering acceptance sign-off and dated as definitive and clear in content to be able to maintain the equipment.

This document is version controlled and amended and updated as required as a live document for the life of the equipment.

Calibration Documentation:

- Calibration Master List:
- Calibration Flow Diagram:
- Equipment Labelling:
- Calibration Reports:
- Calibration Support Documents:
- Calibration Deviation Reports:
- Calibration Change Request:
- Calibration Operation Procedures:
- Calibration Training Documents:
- Company Quality Statement for Calibration:

The above documents are normally stored for easy access in a library, with files sorted by the machine/ equipment identity number. And remain active for the life of the equipment, or as defined by regulation.

In the event of quality audits, reviews or product recall, investigations will require the information contained in these files.

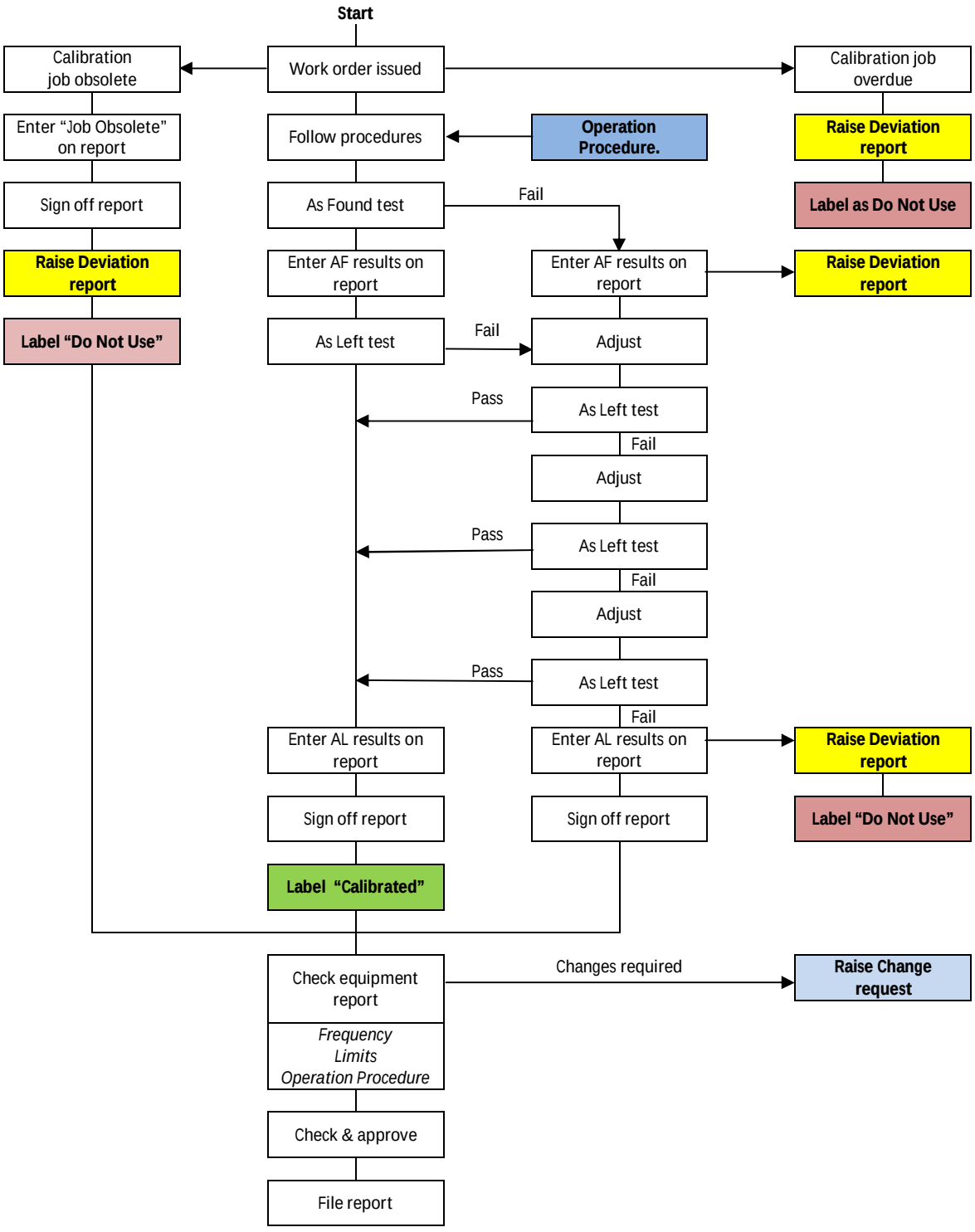
Calibration Master List:

From the "Installation Qualification" the detail for the "Master Calibration List" is defined, and the equipment details are:

- Location: Building/Department/Line Number
- Equipment Identity Number
- Description of Equipment
- The measurement discipline
- The measurement engineering unit
- The range of equipment
- The resolution of equipment
- The accuracy of the equipment
- Make of equipment
- Model of equipment
- Serial Number of equipment
- The criticality:
    - *Product*
    - *Process*
    - *Safety*
    - *Other*
- The precision
- Process minimum
- Calibration Factor
- As found Limit
- As Left Limit
- Operating procedure document number
- Who Calibrates
- Calibration period

This document should be dated with the approval signatories of the User/owner, Engineering management and Quality Assurance management, and should be version controlled.

Calibration Process Flow Diagram:



This document should be dated with the approval signatories of the User/owner, Engineering management and Quality Assurance management, and should be version controlled.

Equipment Labelling:

All equipment that is defined as critical must be identified using a label attached to the equipment. The label to indicate:

- Owner Company.
- Location: Department/Line.
- Equipment Identity Number.
- Equipment Criticality.
- Equipment Description.

All critical measuring equipment must have a calibration status label attached indicating:

- Equipment Identity Number.
- When Calibrated.
- Calibration next due.
- Who calibrates. (Name of responsible person or contracting organisation).

The above criteria are best contained in a single clear label holder, below shows a template for the labels, where the calibrated label is positioned at the bottom of the equipment identity label within the holder.

Label 1/2

Equipment Owner	
Location: Dept / Line	
Equipment Identity Number	
Criticality	
Description	
DO NOT USE	

Label 2/2

Equipment Identity Number	
When Calibrated	
Calibration Next Due	
Who Calibrates	
CALIBRATED	

The completed calibrated label is positioned at the bottom of the equipment identity label within the holder, covering the "DO NOT USE" section.

Equipment Owner	
Location: Dept / Line	
Equipment Identity Number	
Criticality	
Description	

DO	Equipment Identity Number	
	When Calibrated	
	Calibration Next Due	
	Who Calibrates	
	CALIBRATED	

Calibration Reports:

Calibration Report

Page <#>/<#>

Equipment I.D. #	Work Order #	Date	SOP

Description

Department	Location

Equipment used:

Equipment I.D.#	Description

As Found Results:

Warm up time Confirmed ☐

Reference Value	DUT value	Error	Limit	Pass/Fail

Calibration Report

Equipment I.D	Work Order #	Date	Page <#>/<#>

As Left Results

Warm up time confirmed ☐

Reference Value	DUT value	Error	Limit	Pass/Fail

Comments:

.....

.....

.....

.....

.....

.....

.....

Calibrated By:		Date:	
Checked By:		Date:	

This document should be version controlled, ideally as a part of an Operation Procedure.

Calibration Report – Support Documents:

Some calibration reports may be from external contractors. Some of these may not show the Pass/Fail status based to your limits. You will be required to generate calibration support documents to show the equipment calibration status based upon your limits. Below is an example of support documentation for a particle counter:

Data from the contractor calibration report:

1. Comparator thresholds

Range uM	Analogue Values	
	Initial mV	Final mV
0.5	121	129

2. Particle Response

Nominal uM	Particle data			Median Response		
	GMD uM	Lot #	U uM	Initial mV	Final mV	Sensitivity uM/V
0.5	0.499	1234567	0.005	129	129	3.87

The above table shows that the report findings report errors in mV.

The applied limits for the particle size errors should use the engineering unit of uM; therefore, a new table is required that calculates the errors in uM using the data in the contractor calibration report.

Generated table for conversion of mV results to uM.

Calculated errors in uM from data in the calibration report

Applied Limits		Initial sensitivity uM /mV	Final sensitivity uM/mV	Initial Counter response uM	Final Counter Response uM	Initial Error uM	Final Error uM
Initial +/- uM	Final +/- uM						
0.025	0.006	0.003868	0.003868	0.468	0.499	0.031 (Failed)	0

The calculations used in the table above:

- Initial Sensitivity: GMD particle size / Initial Median Response.
- Final Sensitivity: GMD particle size / Final Median Response.
- Initial Counter Response: Initial sensitivity x Initial comparator response.
- Final Counter Response: Final sensitivity x Final comparator response.
- Initial Error: Initial counter response – GMD particle size.
- Final Error: Final counter response – GMD particle size.
- Final Applied limit (As Left Limit): Final uM + LSD. (0.005+0.001)
- Initial Applied Limit (As Found Limit): As Left Limit x calibration factor (4).

Conclusion:

The Initial Error value is greater than the Initial Applied Limit; therefore = Fail.

(An "As found" Deviation Report will be required).

The Final Error value is less than the Final Applied Limit; therefore = Pass.

The Footer of document:

Equipment I.D. #:	<ID #>
Report Reference Number:	*<Contractor report number>.*
Report Date:	*<Contractor report date>.*
Report reviewed by:	*<Signature of the calibration support document author>.*
Review checked by:	*<Signature of person checking calibration support document>.*
Review Date	<dd/mm/yyyy>

Calibration Deviation Control:

Page 1

CALIBRATION DEVIATION REPORT

Page 1/2

Number to be assigned by Metrology Dept.	*Number:*
Date of Incident:	*<dd/mm/yyyy>.*
Equipment owner department:	
Reported by:	
Equipment I.D. number:	
Equipment description:	

Type of deviation (circle appropriate)

Exceeded As found Limits *Exceeded As Left Limits* *Other*

Description of deviation: .....
.....

Recommended Action: .....
.....

Signed: ..... *Date: ..... <dd/mm/yyyy>. .....*

Date sent to QA: .... <dd/mm/yyyy>. .....

Send this Deviation Report to the QA Department for action.

Page 2

CALIBRATION DEVIATION REPORT

Page 2/2

Date Received by QA Dept.:	*<dd/mm/yyy>.*
Received by:	
Responsibility for action given to:	

Date sent to responsible person: ..... <dd/mm/yyyy>. .....

Send this Deviation Report to the responsible person for action.

Date Received for action:	
Received by:	

Recommendations for prevention of repetition: .....
.....

Change request raised (circle the appropriate) Yes No
Change request Number: .....
Date sent: ..... .<dd/mm/yyyy>. .....

Send this Deviation Report together with any Change Request to QA for action.

Date Received by QA Dept:	
Approved by:	
Date of approval:	*<dd/mm/yyyy>.*

Calibration Change Request:

Page Header

Calibration Change Request Page <#>/6

Change Request Report Number:	
Title:	

Page 1

User: *<Name, Requested Change & Detail of intent>.*

Page 2

Engineering: *<Defined detail & Technical detail>.*

Page 3

Q.A.: *<Detail of impact>.*

Page 4

Change Approval:

- User: - *<Name, Title, Signature & Date>.*
- Owner: - *<Name, Title, Signature & Date>.*
- Engineering: - *<Name, Title, Signature & Date>.*
- Q.A.: - *<Name, Title, Signature & Date>.*

Page 5

Change Action:

- Change maker: - *<Method of change, Documentation of change, Signature & Date>.*

Page 6

Change Sign-off:

- Change maker: - *<Name, Title, Signature & Date>.*
- User: - *<Name, Title, Signature & Date>.*
- Owner: - *<Name, Title, Signature & Date>.*
- Engineering:- *<Name, Title, Signature & Date>.*
- QA: - *<Name, Title, Signature & Date>.*

Calibration Operation Procedure:

Page Header:

Standard Operating Procedure			
Title: Calibration procedure for <equipment>			
SOP <#>	Version <#>	Effective Date	<dd/mm/yyyy>
Approved: <Name of authorised Person>		Review Date	<dd/mm/yyyy>
Page <#/#>			

Composition of SOP.:

- Index:
- Purpose: *<Show the details of: Equipment being calibrated: Make, Model, Defined limits, where to be maintained (in situ or Laboratory)>.*
- Occupational Health and Safety Precautions: *<Identify the associated risks>.*
- Equipment Used: *<Identify all equipment used to perform the process>.*
- *Preparation:*
  - Initial Inspection: *<General condition>.*
  - Reporting acceptable deviation: *<Cleanliness, useability, safe>.*
  - Cleaning and repairs: *< cleaning materials, reference documentation>.*
  - Warm up time *<Minimum time required for warm up>.*
- As found:
  - As Found Limits:
  - Reading and reporting*: <How to enter data to the calibration report>.*
  - Reporting an As Found Deviation: *<What to do for failed "As found" results>.*
  - Correcting & Adjusting: *<Adjustment parameters and how to>.*
- As Left:
  - As Left Limits:
  - Reading & reporting: *<How to enter data to the calibration report>.*
  - Reporting an As Left Deviation: *<What to do for failed "As Left" results>.*
  - Labelling: *<How to enter data onto the label>.*
- Signing off Report:
- SOP training requirements: *<Identify the training resource document>.*
- SOP version control & issue control. *<The version detail (date, Number)>.*

Calibration Training Documentation:

Page Header:

Training Resource			
Title: <Course Title>			
Course Number<#>	Version <#>	Effective Date	<dd/mm/yyyy>
Approved: <Name of authorised Person>		Review Date	<dd/mm/yyyy>
Page <#/#>			

Overview:

Objective:	<details>
Target Audience:	<details>
Duration:	<details>
Required Equipment and materials	<details>
Lesson Plan	<details>
Assessment Method	<practical and or written>
Assessment	<details>

Practical Assessment Tasks: Description of tasks.

Written Assessment Questions: Questions.

Assessment Summary:

Practical Assessment	Pass Mark	Required: < #%>	Achieved: <#% Pass or Fail>
	Action upon Failure		
	Follow-up Pass Mark	Required: < #%>	Achieved: <#% Pass or Fail>
Written Assessment	Pass Mark	Required: < #%>	Achieved: <#% Pass or Fail>
	Action upon Failure		
	Follow-up Pass Mark	Required: < #%>	Achieved: <#% Pass or Fail>

Assessment Sign-Off:

Assessors Name	Signature	Date

Assessors Kit:

- Attendance forms:
- Training forms (this document 1 for each student +1):
- Written Assessment Answers:

Company Quality Statement for Calibration:

This document is generated and used for the purpose of indicating the company's attitude towards calibration and is a general document summarising that you have adopted and used a quality system with the identified terms of reference.

Example:

Header:

<COMPANY NAME> - Quality Policy – Calibration.

Content:

Date: <day, month, year>

Rationale: Product quality can be adversely affected by incorrect information generated from out of calibration equipment.

Purpose: To ensure that calibration, control, measuring, monitoring and test equipment used in manufacture and distribution is appropriately selected, installed, calibrated and maintained.

Scope: This policy applies to all sites and companies manufacturing or distributing materials or products for use or sale by, or use by <COMPANY NAME>.

Summary of Revision:

This is the first issue in the <COMPANY NAME> Quality Management System.

Requirements:

1. All instruments and testing equipment is assessed for calibration requirements. The assessment differentiates between the instrumentation and test equipment needing routine calibration and equipment not needing routine calibration, and is documented.

2. Based upon the assessment, all instruments and test equipment is permanently and uniquely identified by a label attached to the equipment.

3. All equipment requiring calibration is calibrated in a way which is appropriate to the actual operation and use of the equipment.

4. All calibrations are described in procedures that specify: Methods used, Standards used, acceptable limits of accuracy and where applicable precision, Records to be kept, Calibration frequencies and basis of frequency determination, Actions to be taken for non-compliance.

5. Changes are controlled by change control procedures.

6. Calibrations are performed by trained personnel or approved third parties.

7. Records include: Name of person who completed the calibration, date of calibration completion, data containing deviations as found and after adjustment.

8. Date of the next due calibration.

9. Calibrations are carried out using approved reference equipment that is traceable to: National, International or Physical Standard.

10. Calibration records are kept for the life of the equipment or seven years (whichever is the longest).

11. Systems are in place for the isolation or withdrawal of equipment that is non-compliant to: Calibration due date, Calibration Limits or not fit for purpose.

Signed: <QA. Manager Signature>

Name: <Printed name of QA Manager>

Title: Quality Assurance Manager

Date: <dd. Month. Year>

Audit:

- Audits can occur as a regular quality function from within the organisation or from a regulatory body, or from a customer, and are made to show that you are compliant to the appropriate requirements, checking all components of your practices, including external support organisations.

  "What you do is what you say you do" and "what you do meets the required standard".

- If your company uses third party support, you should audit that organisation if their service impacts upon the quality or occupational health and safety of your product.

Audit Readiness:

If you have done the right thing and maintained your system, audits need not be a difficult process, and can often lead to improvements to that system. So your approach should be taken with an open and honest attitude.

Audit Checklist:

1. Company Quality Statement – Calibration
2. All equipment assessed for criticality.
3. All critical devices labelled with unique identity.
4. All critical devices display a status label.
5. All critical device labels up-to date.
6. All critical devices shown in Design Qualifications.
7. All Design Qualifications are up-to date and signed-off and approved.
8. All critical devices shown in Installation Qualifications.
9. All Installation Qualifications are up-to date and signed-off and approved.
10. All critical devices shown in Operational Qualifications.
11. All Operational Qualifications are up-to date and signed-off and approved.
12. All critical devices shown in the Calibration Master List.
13. All critical devices have limits of calibration.
14. All critical device calibration limits have been assessed and tested.
15. All critical devices have been scheduled for calibration.
16. All critical device calibration schedules have been tested and validated.
17. All calibration procedures are documented in Calibration Operation Procedures.
18. All calibration Operation Procedures are up to date, approved and signed-off.
19. All Calibration Operation Procedures appear in the Operation Procedure Register.
20. All calibrations are traceable to an acceptable standard.
21. The Calibration Master List contains: Calibration Limits, Frequency of calibration, Identity of the Calibration Operation Procedure, Criticality, Who calibrates, for all devices.
22. There is a permanent library for all calibration record history.
23. All critical devices are identified in Performance Qualifications.
24. All Performance Qualifications are up-to date, signed-off and approved.
25. All calibration personnel are trained and approved.
26. All calibration training records are up-to date, signed-off and approved.
27. Records for calibration non-compliance are up to date.
28. Records for calibration change control.

Audit Lifecycle:

Audit Notification:

Auditor gives notice of audit with:

- Audit date.
- Audit content.
- Audit agenda.

Auditee Response:

Gives notice to the auditor with:

- Confirmation of proposed dates or preferred dates.
- Confirmation of agenda with any additional comments.
- Audit preparation:
  - Review audit checklist.
  - Appoint support team:
    - **Audit recorders**:- The personnel who will be responsible for recording all questions and responses.
    - **Audit document log**:- The personnel who will be responsible for logging all auditor requests for personnel and documents.
    - **Callers**: - The personnel who will be responsible for notifying the requirements of the auditor to:
      - Summoned personnel.
      - Searchers.
      - Runners.
    - **Runners**: - The personnel who will be responsible for supplying and returning required documentation during the audit.
    - **Searchers**: - The personnel who will be responsible for locating and passing the requested documents for the runners.
    - **Audit team**:- The personnel who are to be in attendance of the auditor at all times of the audit session.
      - Quality Management.
      - Project Management.
      - Calibration Management.
  - Preparation of the audit room:
    - Tables and seating.
    - Telephones.
    - Refreshment area (light refreshments i.e.; water, tea, coffee, soft drinks, biscuits).
    - Waiting and document collating area (separate room to the audit room):
      - Desks and seating.
      - Telephones.
      - In and out trays for documents.
  - Notice to all employees of the audit and protocols.

Audit Process:

- Auditor welcome and confirmation of agenda.
- Introductions.
- Auditor tour of facilities:
  - Manufacturing areas.
  - Maintenance areas.
  - Canteen facilities.
  - Rest areas.
  - Audit room.
- Presentations:
  - Auditor:- Explanation of non-compliance and actionable observations forms and the expected response timescales.
  - Auditee:-
    - Confirmation of the agenda and approximate times of breaks.
    - Introduction of the attending team.
- Review of previous audits
  - Audit non-compliance status.
  - Audit actionable observation status.

(Note: The audit would cover all areas of operations, but, the interest of this book is calibration).

- Calibration:
  - Project Phase:
    - User requirements.
    - Design Qualifications.
    - Installation Qualifications.
    - Calibration Master List.
    - Calibration process.
    - Labelling.
  - Pre-operational Phase:
    - Operational Qualifications.
    - Performance Qualifications.
  - Operational Phase:
    - Calibration process.
    - Calibration records:
    - Procedures.
    - Training.
- Auditor Findings
- Auditee response.

Audit Aftermath:

Formal minutes are drawn-up and circulated to all personnel who fronted the auditor and others who have played an active role in the audit.

A meeting is called for all who fronted the auditor and others who have played an active role in the audit.

All documentation used in the audit is checked off the check list generated at the time of the audit, and updated if required.

All documentation that is not subject to any actions required out of the audit is returned to the source libraries.

From the auditors' verbal summary, the meeting attendees are requested to prepare written responses.

Upon receipt of the written report from the auditor, the company must immediately acknowledge the receipt of the report.

A meeting is called for Managers to attend in order to review and decide actions, responsibilities and timeline.

An audit response is despatched to the auditor with immediate responses and challenges, together with details of proposed activities and timelines.

Timely corrective action for Audit Actionable Observations and Non-compliance notices should be actioned by the appointed personnel, based upon the timelines as identified in the initial response to the audit report.

All corrective actions must be project based and follow the calibration lifecycle phases.

Upon completion of corrective actions, the auditor is to be notified in writing together with support documentation.

Audit Documents:

Audit Actionable Observation Report:

These reports are records for identifying processes or actions that are not non-compliant, but could escalate to non-compliance if not corrected. These observations should be treated seriously and immediate action for correction should be taken. A template of such a report is shown below.

Audit Actionable Observation Report

Audit Reference Number:	***Observation Reference Number:***	***Date:***
Audited Organisation:		
Audit Reference Documents / Standards: (if applicable)		
Description of Observation:		
Auditor Signature:	***Auditee Signature:***	
Action Complete Target Date:	***Action Owner Name:***	
Auditee Signature:	***Action Owner Signature:***	
Action Review and Closure (To be completed by the Auditor).		
Accepted: (Auditor Signature).	***Date Accepted:***	

Audit Non-Compliance Report:

These reports can be very serious and have far reaching consequences upon your business, i.e.: If you are a manufacturer of pharmaceuticals you could lose your licence to manufacture. The non-compliance issues raised in these reports require your immediate attention and should be corrected in the shortest possible time.

Audit Non-Compliance Report

Audit Reference Number:	***Non-compliance Reference Number:***	***Date:***
Audited Organisation:		
Audit Reference Documents / Standards: (if applicable)		
Non-compliance reference in contract or standard (clause or section):		
Description of Non-compliance:		
Auditor Signature:	***Auditee Signature:***	
Cause Investigation: Isolated / symptomatic (underline appropriate)		
Proposed Action: (To be completed by the Auditee).		
Action Complete Target Date:	***Action Owner Name:***	
Auditee Signature:	***Action Owner Signature:***	
Action Review and Closure (To be completed by the Auditor).		
Accepted: (Auditor Signature).	***Date Accepted:***	

Audit Report Summary Sheet:

Audit Summary Report

Audit Reference Number:	***Date:***
Audited Organisation:	
Audit Contract Reference – Title – Description:	
Auditor Signature:	***Auditee Signature:***
Summary of Audit Findings	
Non-Compliances:. ***Reference No Description***	
Actionable Observations: ***Reference No. Description***	
Accepted: (Auditee Signature).	***Date Accepted:***

Summary

Thank you for your time to read this book. I hope that you have gained the knowledge to help you and your organisation improve your product, furthering customer satisfaction.

The cost of setting up and maintaining a calibration management system is nothing compared with the cost of dealing with the issues of a product failure.

If you still believe that it is a waste of time, because you don't have a calibration system and have never needed one, then think again – If you have never faced a potential disaster you have been lucky.

So remember:

If your measurement is uncertain then so are your processes and products.

Pat Fogwill