ENGINEERS GUIDE TO CALIBRATION MANAGEMENT

A Four step guide to Calibration Management.

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The ENGINEERS GUIDE TO CALIBRATION MANAGEMENT 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 develope a calibration management system.

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Contents:

1. Quality Document System

Planning: Prepare a written validation document

Specifications: Specify what is required and agree the content, using:

- User Requirement.
- Design Qualification.

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

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

Testing: Perform tests and record results, and update:

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

Review: Review results for system performance and conformity to:

- User Requirement.
- Design Qualification.

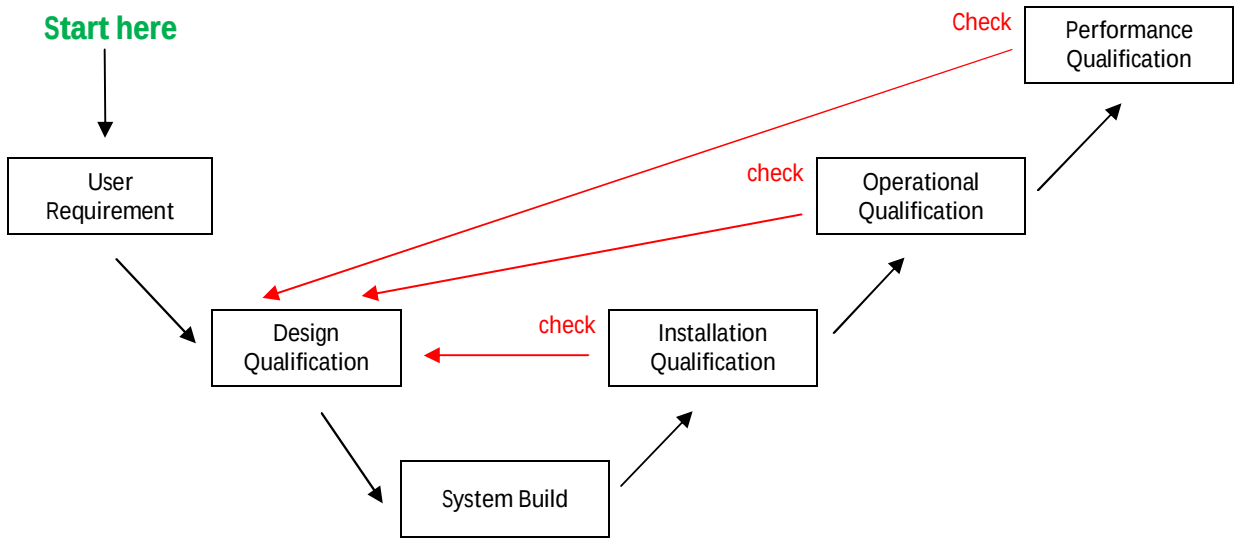

Diagram of the "V" Model.

1.1 User Requirement. The User Requirement defines the basic process requirements to produce a product. The details are:

U.R. table:

Process/Line	Description	Discipline	Eng. Unit	Range	Accuracy
1a/1	Dispensing	Mass	g	10 - 500	100mg

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

1.2 Design Qualification. From the "*User Requirements*" the "*Design Qualification*" is engineered. A description of process with the requirement details of the measuring equipment, as:

D.*Q. table:*

Process and line number	1a/1
Description	Dispensing
Discipline	Mass
Eng. Unit	g
Range of process	10g - 100g
Criticality: *1 Product, 2 Process, 3 Safety, 4 Other*	1
Precision	1%
Resolution of process	100mg
Resolution of measurement	1mg
Calibration Factor	4
As Found Limit	25mg
As Left Limit	6mg

Highlighted figures in the above table are calculated as explained below:

Calculations:

Precision:	= Regulatory	= 1%
Process minimum		= 10g
Resolution of process:	= Process Min. x Precision	= 100mg
Resolution of measurement:	= Res. of process / 100	= 1mg
Calibration Factor:		= 4
As Found Limit:	= Res. of process / Calibration Factor	= 25mg
As Left Limit:	= As Found Limit / Calibration Factor	= 6mg

Highlighted figures in the above are used in the D.Q. table.

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1.3 Installation Qualification. From the *"Design Qualification"* the "Installation Qualification" describes the process and the equipment details specified, as:

- **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: *1 Product, 2 Process, 3 Safety 4 Other***
- **The precision**
- **Process minimum**
- **Calibration factor**
- **As found Limit**
- **As Left Limit**
- **Operating procedure document number**
- **Who Calibrates**
- **Calibration period**

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2. Defining the measurement criteria.

- Process.
- Product.
- Health & Safety.

The documents used for these details are:-

- User requirements.
- Design qualifications.
- Installation qualifications.
- Calibration master lists.
- Operation procedures.

2.1 Defining the limits of accuracy for all measuring instruments. The limits of measurement must be better than the required limits for the product, process and safety. If the measuring instrument fails to meet calibration limits then the product, process or safety could have been compromised. If a factor of two is set, and if the measuring instrument fails calibration there is a margin allowed before any quality issues are raised. The factor should be as large as possible, the larger the factor the greater the safety margin. The setting of the factor often depends upon the repeatability of reading and the errors found during calibration. This factor is called the *"Calibration Factor"* and is applied to many stages in the calibration maintenance process.

2.2 Set the *"Calibration Factor"*. The ideal *"Calibration Factor"* is four, Example: if the product measurement criterion is 100g +/- 1g, then the limit for measurement is 1g / 4, (100g +/- 250mg).

2.3 Set the instrument *"As Found Limit"*. As defined in section 2.2. *Example: 250mg*.

2.4 Set the instrument *"As Left Limit"*. Using the "C*alibration Factor"* of four, the *"As Left Limit'* is defined as: *"As Found Limit"*/4. (*62.5mg*).

2.5* Set the *"Calibration Frequency" (the period between calibrations). The "*Calibration Frequency"* can only be set by having knowledge of the data collated during calibrations; also consideration must be given to the environment where the instrument is used. The results of many calibrations can determine the period of calibration; the period is set given the criteria that the worst case "*As Found result"* is equal to or less than the "*As Found Limit"* at the end of the period. Experience has found that the best unit for calibration frequencies is days, weeks, i.e.; Days (1 thru 7), Weeks (1, 2, 4, 13, 26, 52,104 and so on). When adjusting the calibration period, consider extending by 1 step at a time, or reducing by at least 2 steps at a time.

Note: Check and update the data in the documents:

- User requirements.
- Design qualifications.
- Installation qualifications.
- Calibration master lists.
- Operation procedures.

3. Calibration Support Documents

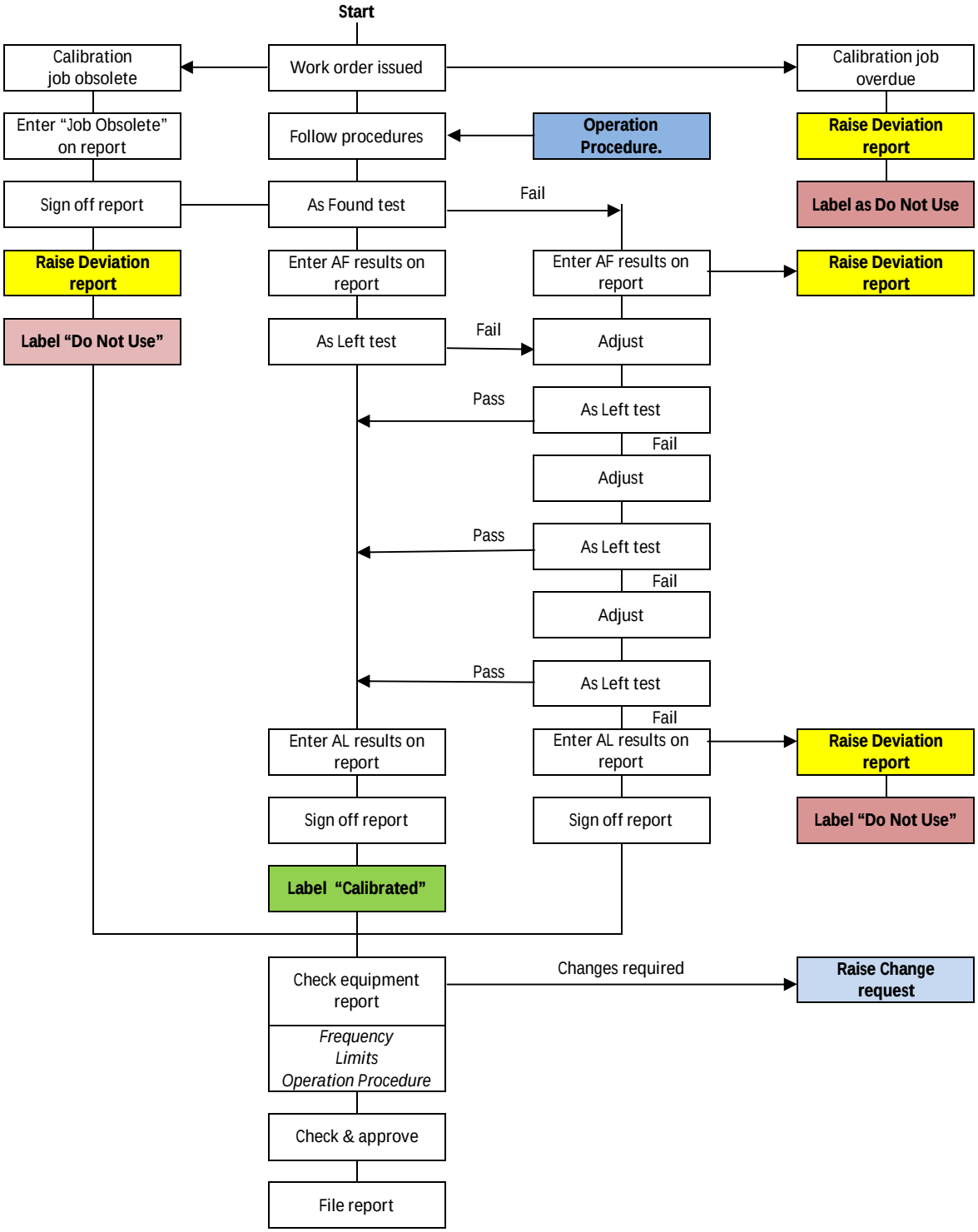
3.1 Calibration Master List.

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: *1 Product, 2 Process, 3 Safety, 4 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.

3.2 Calibration Process Flow Diagram.



3.3 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 calibration label is positioned at the bottom of the equipment identity label within the holder.

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

Equipment Identity Number	
When Calibrated	
Calibration Next Due	
Who Calibrates	
CALIBRATED	

3.4 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 calibration report:

Comparator thresholds

Range uM	Analogue Values	
	Initial mV	Final mV
0.5	121	129

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	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): U 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. #:	
Report Reference Number:	
Report Date:	
Report reviewed by:	
Review checked by:	
Review Date	

3.5 Calibration Deviation Control:

3.5.1 Page 1

CALIBRATION DEVIATION REPORT

Page 1/2

Number to be assigned by Metrology Dept.	*Number:*
Date of Incident:	
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: .....*

Date sent to QA: .....

Send this Deviation Report to the QA Department for action.

3.5.2 Page 2

CALIBRATION DEVIATION REPORT

Page 2/2

Date Received by QA Dept.:	
Received by:	
Responsibility for action given to:	

Date sent to responsible person: .....

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: .....

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

Date Received by QA Dept:	
Approved by:	
Date of approval:	

3.6 Calibration Change Request

3.6.1 Page Header

Calibration Change Request Page <#>/6

Change Request Report Number:	
Title:	

3.6.2 Page 1

User: Name, Requested Change & Detail of intent.

3.6.3 Page 2

Engineering: Defined detail & Technical detail.

3.6.3 Page 3

Q.A.: Detail of impact.

3.6.4 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.

3.6.5 Page 5

Change Action:

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

3.6.6 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.

3.7 Calibration Operation Procedure

3.7.1 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 <#/#>			

3.7.2 Composition of SOP.:

Index:

1. Purpose:
2. Occupational Health and Safety Precautions:
3. Equipment Used:
4. Preparation:
   - 4.1 Initial Inspection:
   - 4.2 Reporting deviation of acceptable condition:
   - 4.3 Cleaning and repairs:
   - 4.4 Warm up time
5. As found:
   - 5.1 As Found Limits:
   - 5.2 Reading and reporting:
   - 5.3 Reporting an As Found Deviation:
6. Correcting & Adjusting:
7. As Left:
   - 7.1 As Left Limits:
   - 7.2 Reading & reporting:
   - 7.3 Reporting an As Left Deviation:
8. Labelling:
9. Signing off Report:
10. SOP training requirements:
11. SOP version control & issue control.

3.8 Calibration Training Documentation.

3.8.1 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 <#/#>			

3.8.2 Overview:

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

3.8.3 Practical Assessment Tasks:

3.8.4 Written Assessment Questions:

3.8.5 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>

3.8.6 Assessment Sign Off:

Assessors Name	Signature	Date

3.8.7 Assessors Kit:

3.8.7.1 Attendance forms:

3.8.7.2 Training forms (this document 1 for each student +1):

3.8.7.3 Written Assessment Answers:

4 Your own Calibration Management System.

An indication of good calibration management is timely corrective adjustment of measuring systems and deviations that only occur for equipment failure.

Some devices require setup before each operation (such as mass weight indicators "balances"), such adjustments should be part of process operational procedures rather than calibration procedures. Such operations should be documented as *"routine checks"*, and not *"calibration"*.

Deviations for *"As found"* readings can normally be corrected by reducing the calibration period. If the calibration process identifies equipment that persistently causes deviation, then the operation of that device or system for the capability of doing the job should be reviewed. Such deviations indicate that in the period since the last calibration, the product, process or safety may have been compromised, so investigation is required to correct any negative consequences.

Deviations for *"As Left"* readings indicate that the equipment or associated system is "not fit for purpose", this should be investigated. Such equipment should not be used.

Finally: If you need more information and/or advice please contact:

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