

- 1.1 This procedure defines the processes for calibration program which ensure the accuracy, maintainability and repeatability of inspection, measuring and test equipment (including Testing Systems) used in Flex Manufacturing against requirements of FDA 21 CFR 820.72 and ISO13485 7.6.

2.0 REQUIREMENTS

FDA 21 CFR Part 820

21 CFR 820.72

- (a) *Control of inspection, measuring, and test equipment.* Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.
- (b) *Calibration.* Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.
- (1) *Calibration standards.* Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.
- (2) *Calibration records.* The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

International Standard

ISO 13485, Clause 7.6 Control of monitoring and measuring equipment

ISO 9001, Clause 7.1.5 Monitoring and measuring resources

Guideline, Industry, Professional & Customer References

Not Applicable

3.0 SCOPE

- 3.1 Organization: Applicable to Flex Manufacturing (S) Pte. Ltd.
- 3.2 Services and Products: Applicable to all testing, monitoring and measuring equipment, comparative references (gauges, templates, software, etc.) and test software used in the design, manufacturing, installation, and servicing activities for verification of product conformity and for controlling processes.

4.0 GENERAL INFORMATION

4.1 Reference documents:

Document Number	Document Title
SKW-QMD2004-00	Problem Notification And Recall
SKW-QMD2011-00	Corrective Action Procedure
SKW-QMD2012-00	Preventive Action Procedure
SKW-QMD2006-00	Nonconforming Material Procedure
SKW-SQM2003-00	Service Qualification Procedure
SKW-MFG2004-00	Deviation Procedure
SKW-MFG4004-00	Calibration Specification Template
SKW-MFG4003-00	Calibration Master List Template
SKW-MFG4010-00	Equipment Removal <u>or</u> Release for Use <u>or</u> Calibration Not Required Form
SKW-EQM2001-00	Preventive <u>and</u> Predictive Maintenance For Machine <u>or</u> Equipments
SKW-MFG4001-00	Calibration Evaluation Form
SKW-MFG4002-00	Calibration Interval Assessment Form
SKW-MFG4009-00	Equipment Activation <u>or</u> Deactivation Form
SKW-FIT3001-00	FlexFlow Standard Operating Procedure

4.2 Record Retention Requirement:

4.2.1 This section describes the minimum requirement for the retention of records, where the records are retained and the duration for which the records shall be maintained.

No	Document Number / Name	Retention Period	Storage Location	Protection	Disposition
1	SKW-MFG4010-00 / Equipment Removal / Release for Use / Calibration Not Required Form	A minimum of 3 years for non-medical account A minimum of 5 years upon product obsolescence for medical account	Calibration Cabinet	Locked cabinet	Shred
2	Calibration Reports / Certificate / Records	<u>Minimum 2 years</u>	Calibration Cabinet	Locked cabinet	Seek Customer approval for disposition
		<u>Refer to SKW-PGM3003-00</u>	<u>Off Site</u>	<u>By Off Site</u>	<u>Seek Customer approval for disposition</u>
3	SKW-MFG4004-00 / Calibration Specification Template	A minimum of 3 years for non-medical account A minimum of 5 years upon product obsolescence for medical account	Calibration Cabinet	Locked cabinet	Shred
4	SKW-MFG4003-00 / Calibration Master List Template	Current	Calibration Cabinet	Locked cabinet	Shred
5	SKW-MFG4001-00 / Calibration Evaluation Form	A minimum of 3 years for non-medical account A minimum of 5 years upon product obsolescence for medical account	Calibration Cabinet	Locked cabinet	Shred

No	Document Number / Name	Retention Period	Storage Location	Protection	Disposition
6	SKW-MFG4002-00 / Calibration Interval Assessment Form	A minimum of 3 years for non-medical account A minimum of 5 years upon product obsolescence for medical account	Calibration Cabinet	Locked cabinet	Shred
7	SKW-MFG4009-00 / Equipment Activation/ Deactivation Form	A minimum of 3 years for non-medical account A minimum of 5 years upon product obsolescence for medical account	Calibration Cabinet	Locked cabinet	Shred

4.3 Systems: Supporting Systems and Tools:

System Name	Access
FlexQ	https://flexq-medical.flextronics.com/Account/Login (Access via User Login and Password)

4.4 Affected Functions and Responsibility

Function	Task
IMTE Owner	- To liaise with calibration personnel related to registration of new IMTE and provide all required documents including the IMTE specification, calibration interval assessment (for purchased or transferred IMTE), IMTE manual and Calibration Certificates (if available). - To liaise with calibration personnel about the collection of the IMTE by vendor that will be due for calibration. - To raise the "Equipment Removal <u>or</u> Release for Use <u>or</u> Calibration Not Required Form" when calibration is not performed by the due date. The necessary approval by Calibration Personnel, Quality Manager and Superior of the IMTE owner is required. - To review all previous <u>affected</u> product inspection, measuring and test results <u>for</u> out of specification IMTE <u>which used</u> during the affected period. - To inform their immediate superior and the calibration personnel when the IMTE is suspected as faulty or out of specification so that containment action can be taken.

Function	Task
	• To take necessary action to analyses the impact to the product once the IMTE is found faulty or out of specification before or after calibration. • To inform the calibration personnel when IMTE is to be removed/ relocated or transferred to another location so that necessary action can be arranged. • To liaise with calibration personnel for deactivation and activation of any IMTE (specific project) in the FlexFlow system, <u>and safe keeping the record for traceability.</u> • To ensure all IMTE are affixed with latest “In House Calibration” Labels (Calibration, Conditional Accept, Limited Range Calibration, Do Not Use or Calibration Not Required) and the conditions of the labels are legible and not torn or tampered prior to using the IMTE. • To ensure those IMTE affixed with “Do Not Use” label is quarantined from use. • To ensure the limitation of usage range of the IMTE affixed with “Calibration Not Required” label. • To notify calibration personnel any IMTE affected by manufacturing/quality process/application changes that requires recalibration. • To register under Preventive Maintenance for Calibration Not Required IMTE. • To complete the Deviation Form after impact assessment (if any). • To complete the NCMR raised by the calibration personnel (if any). • Sign off the calibration certificate after verified the calibrated IMTE and verified the calibration label received. • To ensure the safeguard / calibration void sticker is affixed on the IMTE (when applicable). • To raise the “Calibration Not Required Form”, SKW-MFG4010-00 when calibration is not required for the IMTE. The necessary approval by Calibration Personnel, Quality Manager and Superior of the IMTE owner is required.
Calibration Personnel	• To maintain the latest Calibration Master List and monthly approved by Engineer/Quality Manager. • To arrange collection of IMTE with various owners and vendor prior to calibration due. • To ensure calibration is performed for IMTE by the stipulated due date per the Monthly Calibration Due list. • To ensure all IMTE is sent to the approved external laboratories. • To review the Calibration Report/Certificate to ensure the IMTE meets the calibration specification and all elements of Calibration

Function	Task
	Specification Form. • To issue the “In-house Calibration” label upon approval of the calibration report / certification. • Has the authority to suspend the use of IMTE that are not calibrated.
Calibration Personnel	• To raise the Equipment Removal Form (SKW-MFG4010-00) and Calibration Evaluation Form to IMTE Owner for impact assessment for IMTE that is out of calibration specification. • To raise NCMR to IMTE Owner if evaluation indicates that the out of specification affects the product and processes associated on the use of the IMTE. • To issue the reference number for “Equipment Removal / Release for Use / Calibration Not Required” Form. • To issue the “Do Not Use” label upon requesting of reference number for the “Equipment Removal” Form from IMTE Owner. • To liaise with IMTE owner for any IMTE deactivation and activation in FlexFlow system. • To issue the “Calibration Not Required” label to IMTE owner upon approval of Calibration Not Required Form, SKW-MFG4010-00.
Department Manager of IMTE Owner	• To review and approve all IMTE issue raised by IMTE owner and also impact of the faulty/ out of specification IMTE to the product. • To recall and hold back all products affected by IMTE that is determined as calibration out-of-specification per the NCMR process.
Quality Manager	• Overall responsible for calibration out of specification identification, segregation, containment, investigation and corrective action per the NCMR process, corrective Action process and Preventive Action process. • To approve all related calibration documentations.

4.5 DEFINITIONS and ABBREVIATIONS

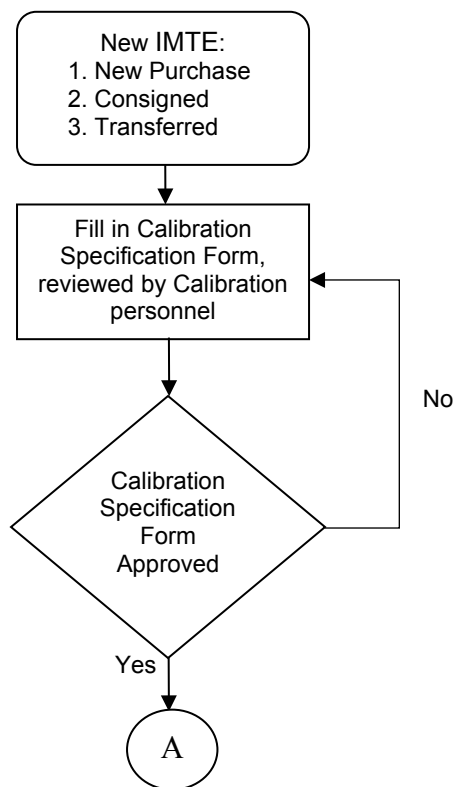
- 4.5.1 IMTE – Inspection, Measuring and Testing Equipment
- 4.5.2 PM – Preventive Maintenance
- 4.5.3 CFT – Customer Focus Team
- 4.5.4 OEM – Original Equipment Manufacturer
- 4.5.5 EQ ID – Equipment ID
- 4.5.6 CR – Calibration Report
- 4.5.7 Cust ID – Customer ID (Applicable for consigned IMTE)

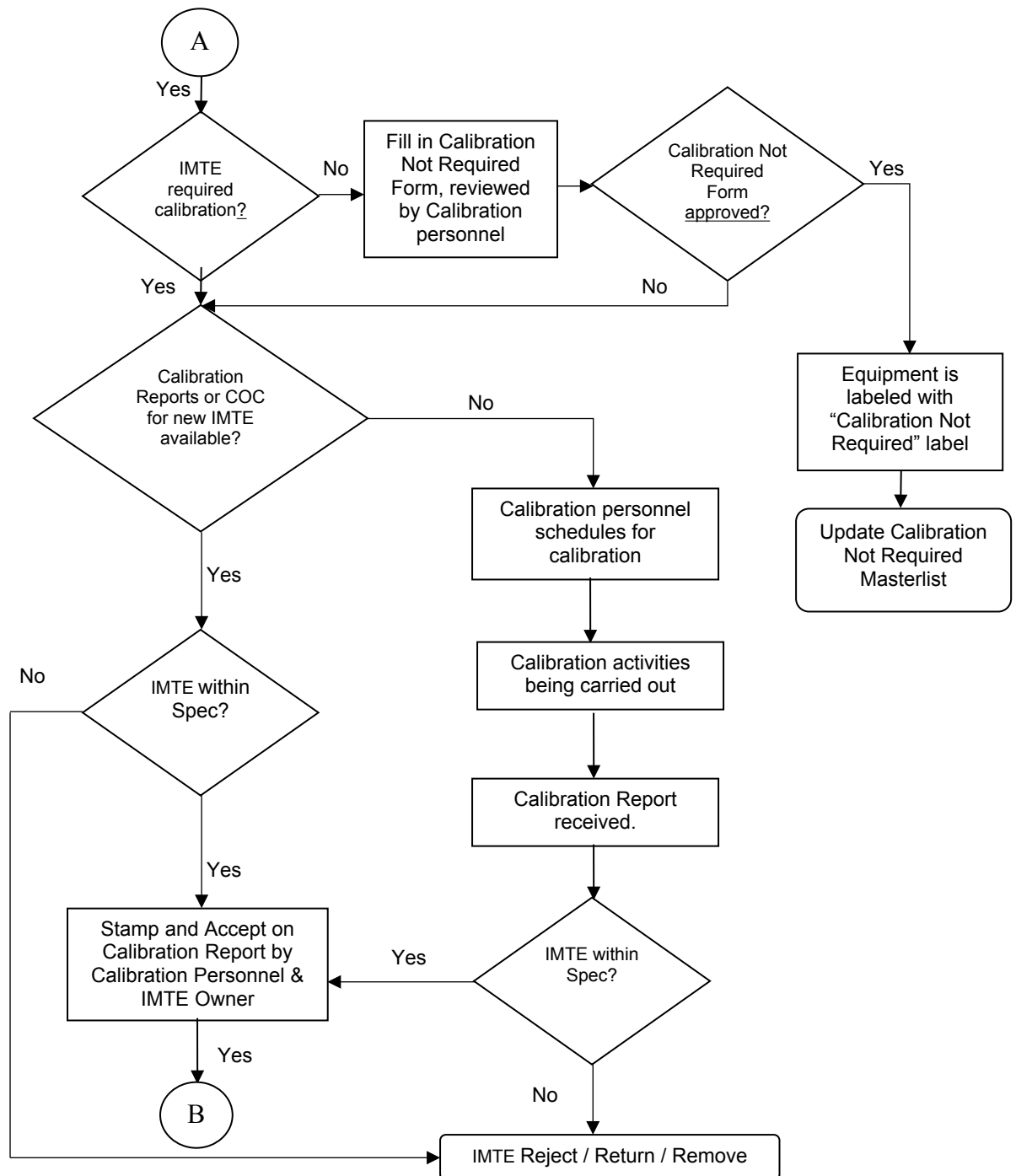
- 4.5.8 Reference Equipment – Equipment/tools which used to perform calibration.
- 4.5.9 Accuracy - degree of closeness of measurements of a quantity to its actual (true) value
- 4.5.10 Repeatability – is the variation in measurements taken by a single person or instrument on the same item and under the same conditions
- 4.5.11 Precision – degree to which repeated measurements under unchanged conditions show the same results
- 4.5.12 As-found Value – The value of calibration point versus reference equipment input before any adjustments are made during a calibration procedure. Often referred to as Pre-calibration values
- 4.5.13 As-left Value – The value of calibration point versus reference equipment input after any adjustments are made during a calibration procedure. If no adjustment was made, then the as-left value equal to as-found value. Often referred to as Post-calibration values.
- 4.5.14 Monthly Calibration Due List – Is a list to inform the owner of the IMTE that the IMTE is due for calibration and the owner need to start arranging for it.
- 4.5.15 NIST – National Institute of Standards and Technology (USA)
- 4.5.16 COC – Certificate of Conformity
- 4.5.17 NCMR – Nonconformance Material Report – A controlled document generated when nonconformity is identified.
- 4.5.18 AC/DC – Alternating Current and Direct Current – A type of electric motor that runs on AC or DC.
- 4.5.19 ISO/IEC – International Organization for Standardization and International Electrotechnical Commission
- 4.5.20 Spec – Specification
- 4.5.21 Calibration – Comparison to a known standard and subsequent realigning of equipment to bring its measurement accuracy within specified tolerances.
- 4.5.22 IMTE Owner – Owner of the IMTE which can be Engineer, Engineer Assistant or Technician.
- 4.5.23 Obtained Error – The obtained error is referring to the total error from the combination of accuracy specification and additional error which deviated from the established accuracy specification range of the equipment.

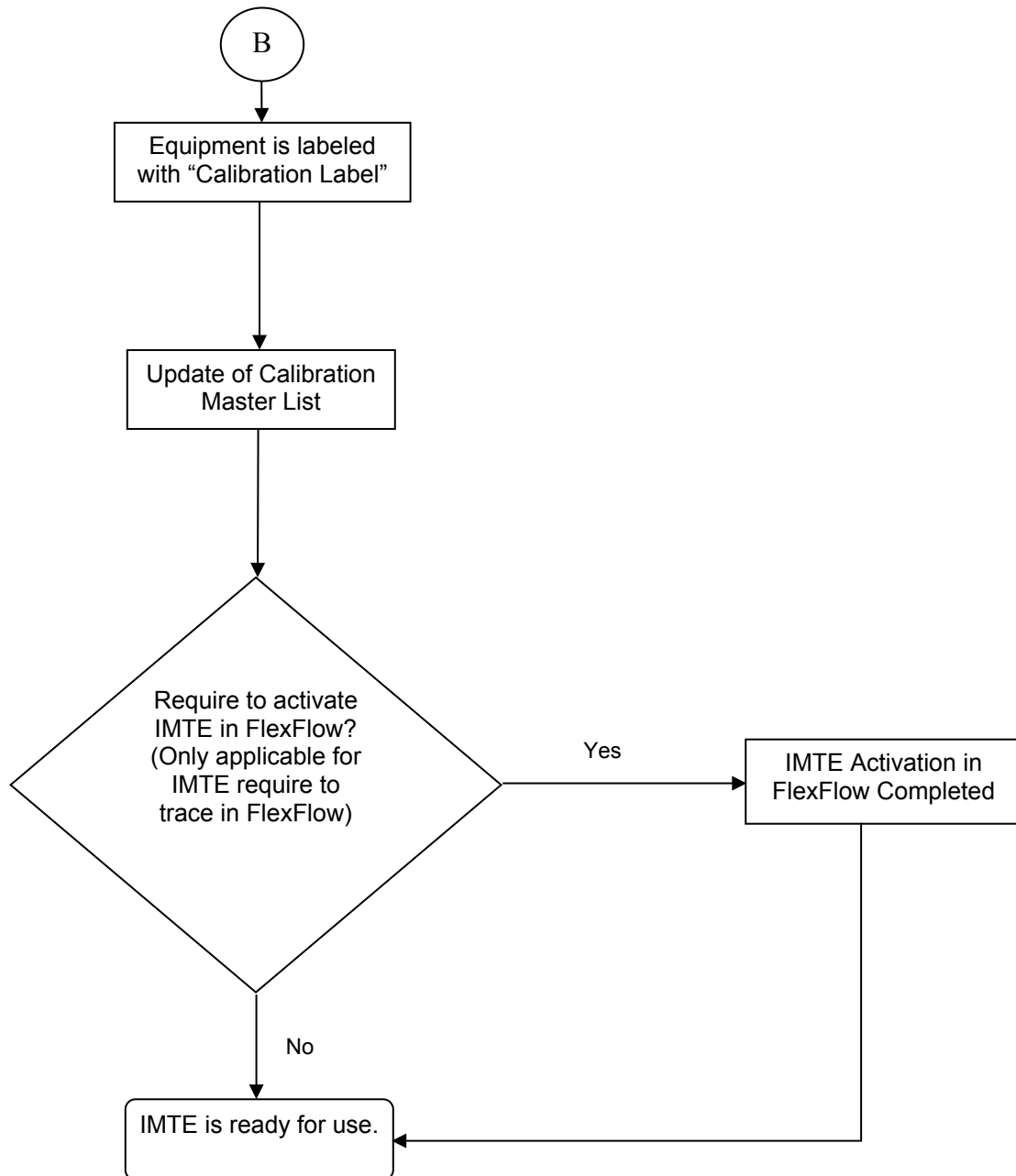
- 4.5.24 Out of Specification – During a calibration some calibration point(s) failed to meet the required tolerance level. This causes the result of the calibration to be out of tolerance or, as often referred, that it was an out of specification.

5.0 PROCESS FLOW CHART

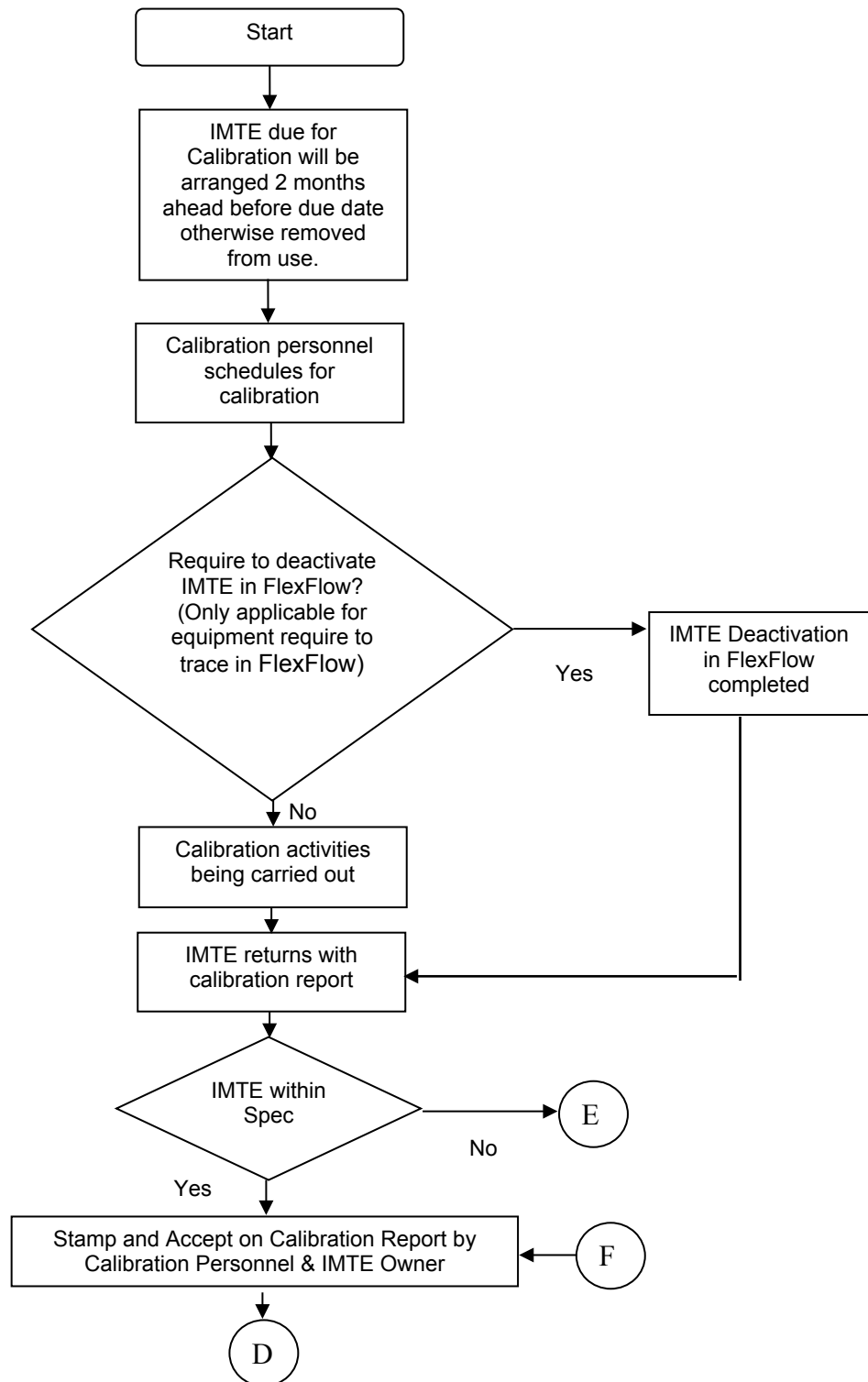
5.1 Calibration Process Flow

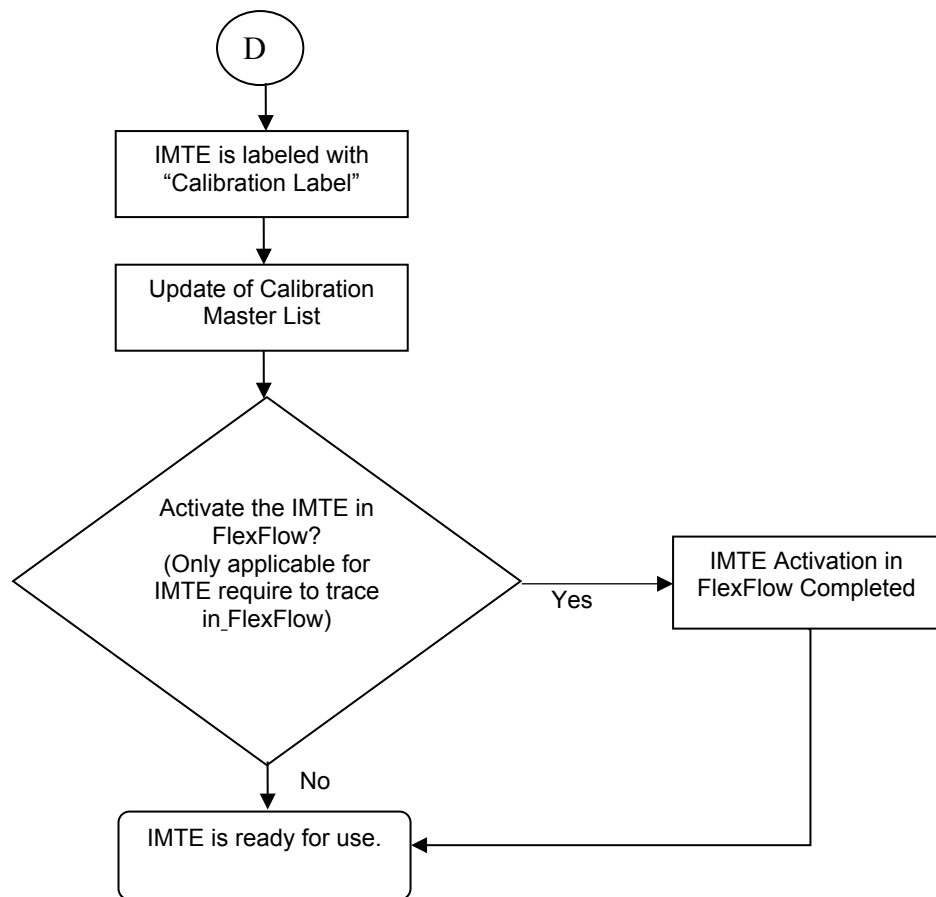


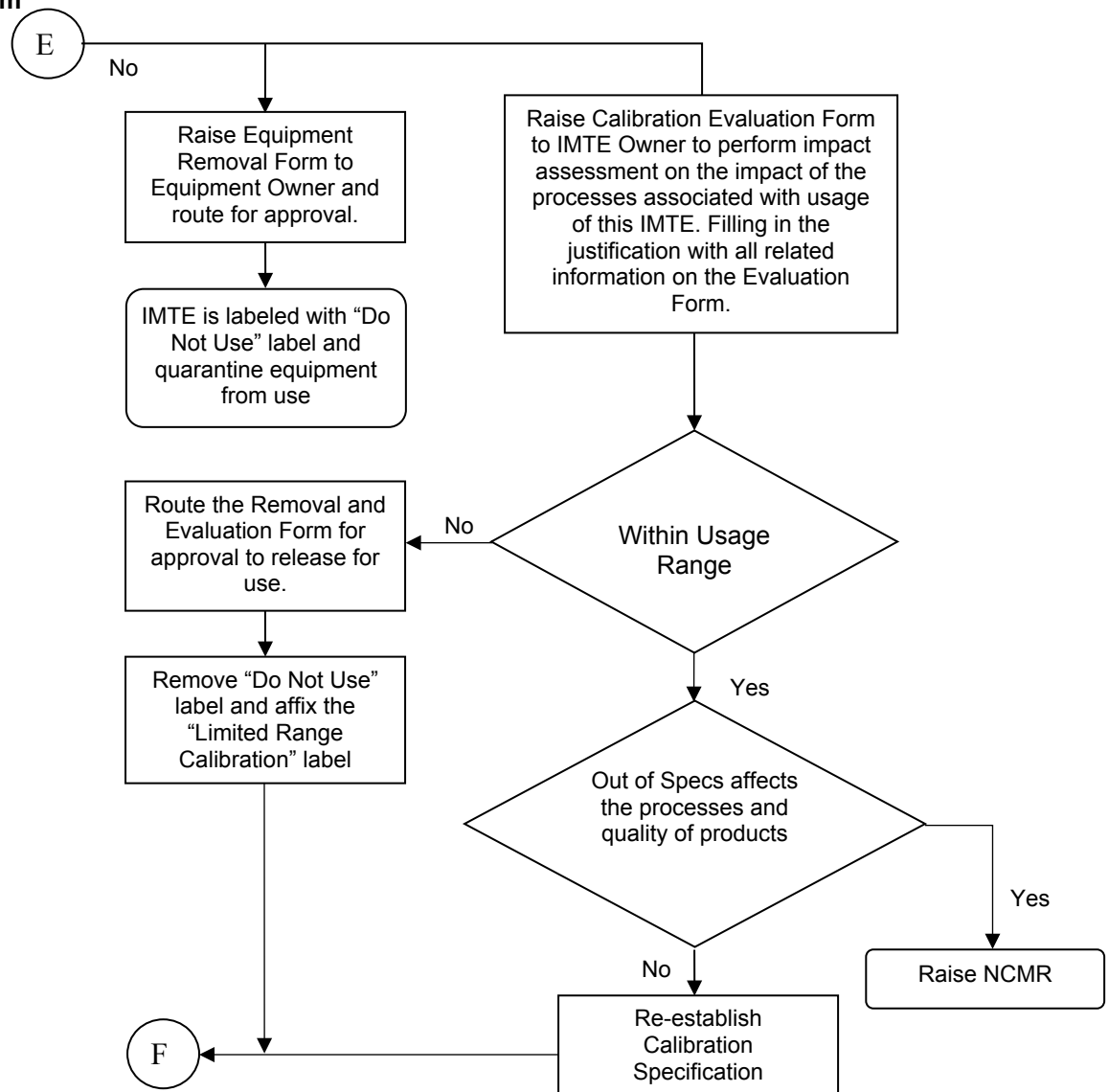




5.2 Calibration Process Flow (routine cycle)







6.0 PROCEDURE

- 6.1 Calibration shall apply to IMTE that fulfill the below criteria or as specified by customer.
 - 6.1.1 Used directly to assure quality of products and services delivered to customers.
 - 6.1.2 Used to demonstrate conformance of product to specification.
 - 6.1.3 Used for product and process validation.
 - 6.1.4 Receiving, in-process, and final inspections testing.

- 6.1.5 Verification of system operation during servicing (installation, maintenance, and / or repair).
- 6.2 Calibration Specification Form SKW-MFG4004-00 must be raised for all equipment categorized as IMTE. Calibration Not Required Form SKW-MFG4010-00 must be filled in for all IMTE where calibration is not required for the IMTE. Calibration shall not be required for:
 - 6.2.1 IMTE that are not used to verify the functionality or operational characteristics of the product / material, and where no tolerance is specified.
 - 6.2.2 IMTE that are not used for acceptance activity.
- 6.3 For IMTE which assessed with Calibration Not Required, shall followed according to Preventive & Predictive Maintenance For Machine or Equipments, SKW-EQM2001-00.
- 6.4 New IMTE:
 - 6.4.1 IMTE shall be selected and acquired according to:
 - 6.4.1.1 IMTE capabilities and functions
 - 6.4.1.2 Specified range for measurements or usage range
 - 6.4.1.3 Future services support (e.g. calibration, repair, etc.)
 - 6.4.1.4 Required accuracy for its intended use
 - 6.4.1.5 Required repeatability and/or precision for its intended use wherever applicable
 - 6.4.2 Owner must provide the following details to the personnel responsible for calibration for the updating of Calibration Master List. The information is to be captured in the form SKW-MFG4004-00 - Calibration Specification Template. The form is to be approved by the IMTE Owner's Superior and Quality Manager. The details (elements) are but not limited to:
 - 6.4.2.1 IMTE Description
 - 6.4.2.2 IMTE Manufacturer
 - 6.4.2.3 Customer and Customer ID number
 - 6.4.2.4 IMTE Model, Serial number
 - 6.4.2.5 IMTE Owner
 - 6.4.2.6 Calibration Interval (in month) not exceeding the interval recommended by the manufacturer, the customer or determined by SKW-MFG4002-00 Calibration Interval Assessment Form

- 6.4.2.7 Location of the IMTE (if any), for usage in multiple locations will be identify as Portable
- 6.4.2.8 Brief description of how/where the IMTE is used
- 6.4.2.9 IMTE range
- 6.4.2.10 Usage range
- 6.4.2.11 Calibration specifications:
 - 6.4.2.11.1 Calibration range (It is reference to minimally cover the usage range including possible errors)
 - 6.4.2.11.2 IMTE accuracy (specification/ tolerance limit, or maximum permissible error)
 - 6.4.2.11.3 IMTE repeatability or precision (specification/ tolerance limit, or maximum permissible error), if applicable.
- 6.4.2.12 Calibration Standard to which the IMTE is to be calibrated if applicable.
- 6.4.2.13 Any changes made to the Calibration Specification (refer to section 6.4.2.11), impact assessment shall be performed using Calibration Evaluation Form (SKW-MFG4001-00).
- 6.4.3 Calibration range, accuracy specification, repeatability specification, and calibration standard in the Calibration Specification, SKW-MFG4004-00 will not be applicable to OEM for calibration purposes.
- 6.5 Equipment ID
 - 6.5.1 IMTE requiring calibration has a distinct equipment ID assigned to it which shall be issued by Calibration personnel.
 - 6.5.2 Equipment ID shall be assigned to the IMTE using below system: -
 - EQ ID: ZZZZ (For Kallang Assets)
 - ZZZZ = Sequence number (Starting from 0001)
- 6.6 Calibration Process
 - 6.6.1 Each type of IMTE or individual IMTE must have a calibration specification (inclusive of information as provided per 6.4.2) (Form SKW-MFG4004-00).
 - 6.6.2 For new IMTE belongs to Flex, the calibration interval shall be reviewed based on Calibration Interval Assessment Form (SKW-MFG4002-00). For customer's consigned IMTE, calibration interval will be as define based on customer's interval or else will run through the same assessment. Quality Manager shall approve the calibration interval.

- 6.6.3 A “Monthly Calibration Due List” shall be issued ahead in the current month to all IMTE owners informing them of the IMTE that will be due for calibration in 2 months’ time based on monthly Calibration Master List, using SKW-MFG4003-00 prepared by Calibration personnel.
- 6.6.4 All IMTE requiring external calibration will be arranged and collected prior to due dates by vendor responsible for calibration except for those IMTE requiring on-site calibration.
- 6.6.5 In the event that calibration of IMTE cannot be collected / performed before the due date, Owner shall raise the Calibration Removal Form and the IMTE shall be affixed with ‘Do Not Use’ label and quarantined from use until it can be calibrated unless an interval extension has been approved via Deviation process per SKW-MFG2004-00.
- 6.6.6 The calibration personnel responsible for calibration shall liaise with approved external calibration laboratories.
 - 6.6.6.1 All external calibration laboratories are qualified per Service Qualification process SKW-SQM2003-00 and updated in the Approved Vendor List and must have the proper capabilities, IMTE, procedures for the requested calibration services.
 - 6.6.6.2 External calibration laboratory standard must be certified to ISO/IEC 17025 or traceable to recognized National Metrology/Standard Laboratories, customer approved laboratories or IMTE OEM. The scope of calibration shall be defined by laboratories to ensure the capability to perform the required calibration.
- 6.6.7 The calibration specification shall be sent to the identified approved external calibration laboratories as part of the service requisition process. The calibration service shall proceed only with calibration laboratories that are able to provide the required calibration services meeting the calibration specification (Calibration Lab Information) of the intended IMTE.
- 6.6.8 All IMTE requiring internal calibration, IMTE Owner will have their trained personnel to carry out the internal calibration based on their In-house procedure (Customer’s procedure / Instructions / Standard) of that IMTE.
- 6.6.9 Upon IMTE calibration completion, the new calibration report shall be received by calibration personnel. The calibration report shall be reviewed against the calibration specification SKW-MFG4004-00 to

ensure it is meeting all specifications as stated and signed off by the calibration personnel on the report.

6.6.10 Calibration Report / Certificate shall include the following minimum information:

6.6.10.1 IMTE Name

6.6.10.2 IMTE Model (if applicable)

6.6.10.3 IMTE Serial number (if applicable)

6.6.10.4 IMTE specification / range

6.6.10.5 Date of calibration performed

6.6.10.6 Calibration due date of Reference Equipment used to calibrate the IMTE.

6.6.10.7 Calibration points

6.6.10.8 As-found values

6.6.10.9 As left values (If applicable, if repair or adjustments made)

6.6.10.10 Description of any remedial action/adjustments and/repairs made

6.6.10.11 Signature/date of whom performed the calibration

6.6.10.12 Accredited Logo is applicable for:

- AC/DC Hi-Pot
- Leakage Current Tester
- Electrical Safety Analyzer
- Ground Bond Tester
- AC/DC Withstand Voltage Tester
- Multimeter which are used during the safety testing measurement.
- Load Box

6.6.11 If an observation on consistent increased on the obtained error from calibration out of specification event is found during calibration reports review, Calibration personnel will dictate the increased calibration frequency accordingly.

6.6.12 For passed equipment, Calibration personnel shall review the calibration result against with accuracy specification and documented the outcome in SKW-MFG4002-00.

6.6.13 If the calibration report indicates the IMTE meets the requirement, the IMTE shall be affixed with an "In-house Calibration" label (refer

Page 17 of 23

Appendix 7) and the equipment ID shall be indicated in the report approval stamp.

- 6.6.14 If the calibration was done in a limited condition (range, mode, etc.) and the IMTE meets the requirement, the IMTE shall be affixed with the “Limited Range Calibration” label (refer Appendix 7) and comments needed to be written on the calibration report.
- 6.6.15 If IMTE is newly purchased, Factory Certificate of Conformity will be accepted with IMTE serial number indication.
- 6.6.16 The IMTE is ready for use once the IMTE owner received the calibration label from calibration personnel after calibration certificate approval and shall affix the label to the IMTE.
- 6.6.17 IMTE Owner require to verify (e.g., calibration date and due date) and sign off the report the IMTE received is free from any damage after calibration personnel signed off the report. IMTE Owner also require to verify the calibration label(s) issued are readable and correct.
- 6.6.18 The Calibration Master List shall be updated with the latest calibration disposition by Calibration Personnel and shall be monthly approved by Calibration Engineer/Quality Manager.
- 6.6.19 All calibration report / certification shall be filed by Calibration personnel for retention for a period of time as per section 4.2.
- 6.7 IMTE Calibration for IMTE registered in FlexFlow system (specific project).
 - 6.7.1 This section only applicable for IMTE login in FlexFlow system only.
 - 6.7.2 Any IMTE required to be registered in FlexFlow system, IMTE owner shall raise IMTE Activation/Deactivation Form SKW-MFG4009-00.
 - 6.7.3 If the IMTE is sent out for calibration, the IMTE owner shall raise Equipment Activation/Deactivation Form SKW-MFG4009-00 to deactivate the IMTE in FlexFlow system.
 - 6.7.4 The information is to be captured on form SKW-MFG4009-00 – Equipment Activation/Deactivation Form. The details are as follows but not limited to:
 - IMTE ID number
 - IMTE Type
 - IMTE Owner
 - 6.7.5 The calibration personnel shall deactivate the IMTE and acknowledged by the requestor.

- 6.7.6 For new IMTE or IMTE returned from calibration, once the new calibration date has been approved by calibration department, the requestor shall issue the activation of the IMTE in the system using Equipment Activation/Deactivation Form SKW-MFG4009-00.
- 6.7.7 Calibration personnel will update the status in FlexFlow system according to the approved calibration certificate.
- 6.7.8 The requestor shall verify all information in the FlexFlow system is correct.
- 6.7.9 Calibration personnel will activate the IMTE in the system and acknowledged by the requestor for the IMTE is ready to be use.
- 6.8 Calibration out of specification and deviation:
 - 6.8.1 When calibration result is out of specification, calibration personnel will raise Equipment Removal Form (SKW-MFG4010-00) and Calibration Evaluation Form (SKW-MFG4001-00) to the IMTE owner to perform impact assessment as follows:
 - 6.8.1.1 An evaluation on the out of specification IMTE, which accuracy and repeatability specification are not met, IMTE will be needed to assess the impact on the processes associated with the usage of this IMTE whether there was any adverse effect on product quality.
 - 6.8.1.2 If the review of the out of specification falls outside the usage range, the IMTE can be release and approved for use with the 'Limited Range Calibration' label affixed.
 - 6.8.1.3 If the review of the out of specification falls within the usage range but does not affects the processes and quality of product, the calibration specification will be re-established for acceptance of IMTE to use.
 - 6.8.1.4 If evaluation indicates that the out of specification affects the processes associated on the use of the IMTE, the relevant functions (i.e. customer focused team) and the Quality Manager shall be involved in the review, investigation and action as per the Nonconforming Material Procedure (NCMR) SKW-QMD2006-00 and Problem Notification And Recall SKW-QMD2004-00. All previous product inspection, measuring and test results performed using the affected IMTE and the affected physical product / inventory shall be

handled via the nonconforming (NCMR) system including identification, segregation and containment.

6.8.2 Customer shall be informed if the investigation results showed that the quality or reliability of any product produced is potentially affected.

6.8.2.1 Product Disposition "Use As Is" shall be made with adequate technical justifications and/or customer's concurrence.

6.8.3 Any corrective action or preventive action required as a result of the investigation shall be handled via the NCMR system, the Corrective Action Procedure per SKW-QMD2011-00 and the Preventive Action Procedure per SKW-QMD2012-00.

6.9 Inactivation of IMTE from usage

6.9.1 Equipment Removal / Release for Use / Calibration Not Required Form (SKW-MFG4010-00) shall be raised to inactivate any IMTE from use if:

- IMTE is removed/relocated or transferred to another location
- IMTE is no longer required to be in used
- IMTE is past calibration due date
- IMTE is faulty
- Calibration results not satisfactory (out of specification)
- IMTE is permanently removed physically and from the FlexFlow system (deactivated).

6.9.2 Upon approval, "Equipment Removal / Release for Use / Calibration Not Required Form" shall be filed by calibration personnel and the Calibration Master List shall be updated.

6.9.3 A post calibration will be required for all calibrated IMTE to confirm the accuracy and precision of the IMTE to assess the impact of its measurements taken since the last calibration before it can be removed/ relocated or transferred from their existing usage. A justification is required if no post calibration is required.

6.9.4 For IMTE that is faulty, impact assessment need to be done by using Calibration Evaluation Form (SKW-MFG4001-00).

6.9.5 A "Do Not Use" label shall be affixed onto the IMTE in the interim. The IMTE owner shall determine disposition of the IMTE to remove, inactivate or to recalibrate.

- 6.9.6 All inactivated IMTE would not trigger any need for calibration unless reactivation request is made through as per Equipment Removal Form of that IMTE.
- 6.9.7 Reference number for "Equipment Removal / Release for Use / Calibration Not Required Form" shall be issued by the Calibration personnel.
 - Reference No. RE/BBB/CC
 - RE = Representing Removal
 - BBB = Sequence Number, starting from 001 (Kallang)
 - CC = Year, e.g. 06 representing Year 2006
- 6.9.8 If IMTE is to be completely removed physically and from the system (FlexFlow), the IMTE owner shall raise Equipment Removal / Release for Use / Calibration Not Required Form, SKW-MFG4001-00 and Equipment Activation/Deactivation Form, SKW-MFG4009-00.
- 6.10 Recalibration:
 - 6.10.1 For any IMTE that is affected by manufacturing/quality process changes (e.g. shifting of stationary IMTE where the shift impacts calibration such as a balance) and/or application (e.g. the process change results in a change to the calibration specifications), IMTE Owner need to notify calibration personnel that the affected IMTE shall be recalibrated.
 - 6.10.2 Affected IMTE recalibration process shall follow as section 6.5 and 6.6.
 - 6.10.3 If recalibration is deem not require as in 6.9.1, a verification on the IMTE using a known standard (best sample with known measurement data, calibrated gauge blocks, etc.) should be performed by IMTE owner.
- 6.11 IMTE care and storage
 - 6.11.1 The IMTE is maintained, secured/stored and handled in such a way as to preserve its accuracy and fitness for use. IMTE that is out of calibration specification or otherwise not fit for use shall be inactivated and shall be handled per section 6.7 and 6.8.

7.0 ATTACHMENT/APPENDICES

7.1 Labels

7.1.1 "Calibration" label

← 53 mm (for reference only) →

Calibration	
EQID : _____	
S/No : _____	
Cal Date : _____	
Due Date : _____	
Remark : _____	

↑ 28 mm
(for reference only)
↓

7.1.2 "Do Not Use" label

Do Not Use	
Ref No. : RE / _____	
EQID : _____	
S/No : _____	
Date : _____	
Remark : _____	

7.1.3 "Conditional Accept" label

Conditional Accept	
EQID : _____	
S/No : _____	
Cal Date : _____	
Due Date : _____	
Remark : _____	

7.1.4 "Limited Range Calibration"

Limited Range Calibration	
EQID	: _____ 
S/No	: _____
Cal Date	: _____
Due Date	: _____
Remark	: _____

7.1.5 "Calibration Not Required" label

Calibration Not Required	
Ref. No.	: RE/ _____
EQID	: _____ 
Date	: _____

**** End of document ****



REVISION HISTORY

Revision	Change descriptions
A	Document migration from legacy FlexQ SKW-MFG2006 Rev O
B	1. Revise section 4.4 sub-points 2. Remove section 4.5.5 and renumbering 3. Add section 4.5.22 4. Revise section 6.4.2, 6.4.2.13, 6.6.1, 6.6.10, 6.6.10.2, 6.6.10.3, 6.6.16, 6.7.3. 5. Remove section 6.7.4 sub-point 6. Revise section 7.1 Labels on the label design and color.
C	1. Revise document title in section 4.1 table, No.2 in section 4.2.1 table, Task in section 4.4 table, section 6.3, 6.6.11 2. Add International Standard in section 2, sub-point in section 6.6.10.12, 6.6.12 and renumbering, section 4.5.23, 4.5.24