## STANDARD OPERATING PROCEDURES

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### CALIBRATION REQUIREMENTS for LABORATORY EQUIPMENT

#### PURPOSE

The purpose of this Standard Operational Procedure is to provide a standard calibration procedure and standard calibration sheets for the calibration of all types of laboratory equipment.

### 2. Responsibility

- Symbol indicates routine calibration performed by the departmental staff.
- 2 Symbol indicates twice annual calibration performed by metrology department
- **3** Symbol indicates annual or biannual calibration performed by an external contracted third party metrology firm.

### 3. Equipment

As defined on the calibration sheet and equipment specific SOPs

### 4. Frequency

Internal laboratory calibration ; Prior to **routine** use of equipment (e.g. daily balance calibration, system suitability test, pH meter etc.) •

Metrology department 2 calibration; Monthly (Analytical balances only)

Metrology department 2 calibration; Twice per year

Metrology department 2; and after equipment maintenance or relocation

Metrology department 2; and after repair of critical part replacement

External calibration **3**; Annually or biannually calibration by contracted Third Party according to equipment specific SOP

### 5. Procedure

- 5.1 Operate the equipment in accordance with the relevant Operating Instructions.
- 5.2 Perform the equipment calibration according to the equipment specific SOP
- 5.3 Fill out form "Calibration Record" Sheet, see Attachment 2.
- 5.4 Evaluate if "SUITABILITY Sticker" has been compromised, [Attachment 1].
- 5.5 In cases where the SUITABILITY of equipment has been compromised (e.g dissolution equipment) due to the re-calibration the technician will deface and cross-out the "SUITABILITY Sticker" and attach a note stating "Performance Verification Invalidated Due To Re-Calibration"
- 5.6 Attach "Calibration Sticker", to equipment [Attachment 1].
- 5.7 The performance verification of the equipment (only where necessary) shall be repeated prior to routine laboratory use.

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### CALIBRATION REQUIREMENTS for LABORATORY EQUIPMENT

#### 6. Re-calibration

- 6.1 If the calibration does not conform, repeat the procedure.
- 6.2 If the second calibration does not conform, clean and check equipment according to the manufacturer's instructions. Then, repeat the procedure.

#### 7. Limits

Calibration Instructions must be applied in accordance with equipment specific SOP

7.1 General limit of accuracy and sensitivity

Acceptance limits:

Minimum: 95%, maximum 105%.

- 7.2 If the manufacturer specifies stricter requirements, these specification may be used.
- 7.3 If, after the second calibration the equipment still does not conform, replace or repair the non-functional part or unit.

#### 8. Documentation

Document calibration results as per the attached "Calibration Record" Sheet. Refer to attached "Calibration Record" Sheets as guidance.

### 9. Labeling

- 9.1. White label (stuck on the apparatus after apparatus SUITABILITY test).
- 9.2. Green label (stuck on the apparatus after CALIBRATION of apparatus).

WHITE LABEL SUITABILITY TEST	GREEN LABEL CALIBRATION
ANALYST:	Metrology Dept.:
Date: Next Date:	Date: Next Date:

[End of Documen	t]
0234567	006

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### CALIBRATION REQUIREMENTS for LABORATORY EQUIPMENT

### STANDARD CALIBRATION RECORD

Equipment: Location		I. D. No. Installation Date		PLANT 
SOP Number		Out-of-Use Date		
Last Calibrated		Inventory No		
Scheduled For		Classification	CRITICAL □	
Next Calibrated		1	MAJOR □	MINOR 🗆
Calibration Expiry			System	Line 🔲
		•	-	
	TY	PE OF EQUIPME	NT	
Manufacturer			ACCURACY	
TYPE:			Max. Deviation	
MODEL:		TOLERANCE		
RANGE:		GRADUATION		
			Acceptance Limits	NLT 95 - NMT 105 %
	CALIBRA	TED AGAINST S	TANDARD	
TESTER ID				NAL STANDARDS
			YES 🗆 - NO 🗖 / Ce	ertificate 🗆 - No 🗅
WEIGHT ID				
WEIGHT ID				
		CALIBRATION		LIBRATION
REFERENCE	TEST BEFORE MEASURED	DEVIATION	AFTER CAI MEASURED	DEVIATION
REFERENCE VALUE				
VALUE	MEASURED	DEVIATION	MEASURED	DEVIATION
	MEASURED		MEASURED	
VALUE	MEASURED	DEVIATION	MEASURED	DEVIATION
VALUE	MEASURED	DEVIATION	MEASURED	DEVIATION
RESULTS Comments:	MEASURED  CALI	DEVIATION	MEASURED  NOT CA	DEVIATION
RESULTS Comments:	MEASURED  CALIBRATED	DEVIATION	MEASURED  NOT CA	DEVIATION
RESULTS Comments:  CALIBRATION DATES	MEASURED  CALIBRATED	DEVIATION  BRATED  METROLOGIST	MEASURED  NOT CA  IN-HOUSE EXTERNAL	DEVIATION
RESULTS Comments:	MEASURED  CALIBRATED	DEVIATION	MEASURED  NOT CA	DEVIATION
RESULTS Comments:  CALIBRATION DATES	MEASURED  CALIBRATED	DEVIATION  BRATED  METROLOGIST	MEASURED  NOT CA  IN-HOUSE EXTERNAL	DEVIATION

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