

ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes C&B and ENV 002 Quality Assurance of Equipment Commonly Used in Chemical & Biological and Environmental Testing Laboratories

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1. Introduction

- 1.1 This document specifies the quality assurance activities for equipment commonly used in Chemical and Biological as well as Environmental Testing Laboratories. Other equipment may be added to the list as and when required.
- 1.2 This document is provided as guidelines to laboratory for its quality assurance programme. For equipment not listed in Table 1, the laboratory shall follow the recommendation of the equipment suppliers or manufacturers with documentations.
- 1.3 This document shall be studied in conjunction with ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories, SAC-SINGLAS 002 Requirements for the Application of ISO/IEC 17025 and other C&B and ENV Series Technical Notes published by SAC-SINGLAS. For undated references, the latest edition of the referenced document (including any amendments) applies.

2. Maintenance of Equipment

- 2.1 The laboratory shall institute a preventive maintenance programme to prevent failure of equipment and ensure that the equipment is operating with the reliability required for quality results. The activities include specification checks, calibration, cleaning, lubricating, reconditioning and adjusting by authorised and/or competent personnel on a regular basis. Proper records shall be kept for such activities.
- 2.2 The equipment shall be installed and housed in appropriate environmental conditions to eliminate or minimise the potential effects of accommodation on equipment performance. The effecting elements include corrosion, temperature, humidity, vibration, electrical power stability, dust and electromagnetic influences.

3. Calibration of Equipment

- 3.1 Table 1 in this document sets out the normal frequencies for calibration and performance check of general equipment used in the field of chemical & biological as well as environmental testing.
- 3.2 These frequencies of calibration are considered to be the minimum appropriate, provided that the other criteria specified below are met:
 - (a) that the equipment is in good working condition and of proven stability, and
 - (b) that the laboratory has both the equipment required, competent staff and expertise to perform adequate internal checks, and
 - (c) that if any suspicion or indication of overloading or mishandling arises, the equipment will be checked immediately and thereafter at fairly frequent intervals until it can be shown that stability has not been impaired.
- 3.3 Where the above criteria cannot be met or the relevant registered methods have specified more stringent requirements, more appropriate frequencies shall be adopted.

- 3.4 Where calibrations have been performed by the staff of the laboratory, full records of these measurements shall be maintained, including details of the numerical results, date of calibration and other relevant observations.
- 3.5 Where the accuracy of temperature measurement has a direct impact on the result of the analysis, equipment such as incubators, water baths, ovens and others shall be calibrated. For such equipment, the uniformity of temperature distribution shall be maintained initially and yearly thereafter. Daily records of temperature measurement shall be maintained to ensure the stability of the temperature when the equipment is in use for testing. Cross reference to internal calibration SAC-SINGLAS 002

TABLE 1: RECOMMENDED CALIBRATION AND PERFORMANCE CHECK OF EQUIPMENT COMMONLY USED IN CHEMICAL & BIOLOGICAL AND ENVIRONMENTAL TESTING LABORATORIES

S/N	Type of Instrument Or Equipment	Frequency of Check	Parameters To Be Checked	Certified Reference Materials or Reference Materials / Equipment	General procedures and / or Remarks
1.	Air Particulate Counter	Yearly	Particulate Distribution and Total Concentration	As per manufacturer's recommendation	As per manufacturer's recommendation or test method
2.	Anaerobic Glove Chamber (Incubator)	Daily when used	(a) Anaerobic condition	Anaerobic chemical indicators (eg. Methylene blue)	To be placed inside chamber to indicate anaerobic condition
			(b) Temperature	Calibrated thermometer	To be placed inside incubator of aerobic chamber
		daily when used	(c) Anaerobic condition	Anaerobic reference culture	
3.	Anaerobic Jar	When used	Anaerobic condition	Anaerobic chemical indicators (eg. Methylene Blue)	
			Anaerobic condition	Anaerobic reference culture	
4.	Atomic Absorption Spectrophotometer (Flame) Graphite Furnace AAS	When used	(a) Sensitivity	Standard solution of specific element	Aspirate standard solutions and determine the absorption. Compare sensitivity against previous results.

			(b) Detection limit	Standard solution of specific element to be determined giving a response of thrice the baseline variation at the highest expansion feasible.	 Aspirate blank and standard solution 7 to 10 consecutive times. The solution that gives a minimum of thrice the baseline standard deviation for every aspiration represents the detection limit concentration. Compare the detection limit against the previous results. (Refer ASTM D1976) (a) Use background corrector whenever possible. (b) Optimize parameters of instrument before use according to manufacturer's instructions. (c) Record sensitivity and detection limit in instrument log book.
		Quarterly	Sensitivity in frequently used Atomic Absorption lamps	Same as above for sensitivity	Same as above for sensitivity
5.	Automatic Distiller	Yearly	Temperature sensor	ASTM D 86	
			Recovery accuracy		
6.	Automatic Titrator		Functioning of		
		When used	(a) Response (end point)	Standard solutions	Response of detection system to be checked
		Half-yearly	(b) Burette		Accuracy of burettes to be checked

7.	Balance (All types)	When used	Level of balance and zero point (taring)		
		Monthly	Accuracy	Reference weights	One point check. Calibration procedures should be documented.
		Half-yearly Quarterly (for	Repeatability, Linearity, Accuracy	Reference weights	Calibration over full range. Documented calibration procedures. Determine measurement uncertainty.
	only)	only)			For repeatability of reading, ten weighings are made of mass having a value close to the maximum load of balance.
					Reference weights to be calibrated every three years.
					Note: A micro balance is defined as a balance that can measure up to 6 to 7 decimal places.
8.	Biological Safety Cabinet Monthly, quarterly or annually depending o the class of cabinet.	Monthly, quarterly or annually	Final filter & Exhaust filter integrity		Based on test methods requirements.
		the class of cabinet.	Air velocity and uniformity		
		Air ba conta Induc leaka	Air barrier containment, Induced air leakage,		

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			UV radiation		
			Light intensity		
			Noise level		
9.	Bomb Calorimeter	When used	Water Equivalent	Benzoic Acid Standard	Measurement in calories \pm 1 % (eg. petrochemicals \pm 50 cal/g)
		(Half-Yearly)	Water Equivalent	Certified Benzoic Acid	
10.	Chemical Fume Hood				

i) Ducted	Yearly	Air flow rates Face velocity rate 0.30 - 0.75 m/s, with a relatively higher face velocity of 0.50 - 0.75 m/s for more toxic materials. For Contant Volume (CV) system to be calibrated at full sash opening. For Variable Air Volume (VAV) and other systems, to follow manufacturer's recommendation	Calibrated anemometer or other appropriate flow instrument	Based on international or other national standards requirements for calibration of fumehood.
ii) Ductless	Before use	Filter life-span	Based on filter indicator	

		Yearly	Air flow rates Face velocity rate for full openings: 0.30 - 0.75 m/s, with a relatively higher face velocity of 0.50 - 0.75 m/s for more toxic materials.	Calibrated anemometer or other appropriate flow instrument	
11.	Carbon Dioxide Incubator	Daily	(a) Temperature	Calibrated thermometer	
			(b) Carbon dioxide content	Calibrated pyrite device or equivalent device	
		Half-yearly	Growth supporting of carbon dioxide	Carbon-dioxide dependent strain of <i>Neisseria</i> gonorrhoeae	
12.	Centrifuge	Yearly	Speed / temperature (if applicable)	Calibrated tachometer and thermometer (if applicable)	
13.	Conductivity Meter	Monthly	Conductivity	A relevant standard KCI solution	One point calibration. Adjust cell constant if necessary.
		Quarterly	Conductivity	Standard KCI solutions	Full range calibration
14.	Density Bottle	When used	Density	Double distilled water	
15.	Digital Density Meter	When temperature setting changed or weekly	Density	Double distilled water and air	Refer ASTM D4052 Frequency of check could be reduced if lab uses other test methods eg IP, ISO

16.	Disintegration Test (Tablet/Capsule)	Monthly	(a) Stroke distance	Calibrated ruler	Refer to the United States Pharmacopeia or British Pharmacopeia
			(b) Rate	Calibrated timer or watch	
			(c) Temperature	Calibrated thermometer	
17.	Dissolution Tester (Apparatus 1 and 2)	When use	Medium temperature	Calibrated thermometer	37 ± 0.5 °C
		Half yearly	Dissolution Performance Verification Testing (PVT)	USP Prednisone Tablets Reference Standards (current lot)	USP criteria for current lot
		Yearly	Mechanical Qualification (MQ)	MQ systems provided by instrument vendors	FDA DPA-LOP.002 ASTM E2503
18.	Dust monitor	Yearly	Accuracy	As per manufacturer's recommendation	As per manufacturer's recommendation
19.	Flash Point Testing Apparatus	5	·		
	(a) Tag Closed Tester	Monthly	Flash Point	Reference Materials	Refer to ASTM D 56
		Yearly	Flash Point	Certified Reference Materials: n-Decane: 50.9 ±2.3°C	Select the CRM which has a flash point close to the expected temperature range of the sample to be tested
	(b) Danaly Martana Olasad	Maathk	Flack Daint	n-Undecane: 67.1 ±2.3°C	Defer to ASTM D 02
	(b) Pensky-Martens Closed	iviontniy	Flash Point	Reference Materials	Kerer to ASTM D 93

	Tester	Yearly	Flash Point	Certified Reference Materials n-Decane: 52.8 ± 2.3 °C n-Undecane: 68.7 ± 3.0 °C n-Tetradecane: 109.3 ± 4.8 °C n-Hexadecane: 133.9 ± 5.9 °C	Select the CRM which has a flash point close to the expected temperature range of the sample to be tested
	(c) Tag Open-Cup Apparatus	Half -yearly	Flash Point	p-xylene / n-heptane Calibrated thermometer	Refer to ASTM D 1310
	(d) Cleveland Open-Cup	Monthly	Flash Point	Reference Materials	Refer to ASTM D 92
	Apparatus	Yearly	Flash Point	Certified Reference Materials n-Tetradecane: 115.5 ±8.0°C n-Hexadecane: 138.8 ±8.0°C	Select the CRM which has a flash point close to the expected temperature range of the sample to be tested
20.	Fluorescence Spectrophotometer	Monthly	Wavelength and/or photometric accuracy	1 mg/100 ml quinine sulphate in 0.25 M H ₂ SO ₄	Run excitation and emission spectra. Establish specification for 255nm, 355 nm excitation peaks and 455 nm emission peak heights
21.	Gas Chromatograph	Quarterly	System performance check accordingly to manufacturer's recommendation.	Relevant reference material	As per manufacturer's recommendation or test methods More frequent checks shall be performed depending on usage.

22.	Gas Chromatograph-Mass spectrometer	When Use	Leakage check, Isotope resolution Accuracy of masses	Perfluorotributylamine (PFTBA) or recommended solutions provided by manufacturers	Run the PFTBA standard to check for accuracy of the masses: detector gain is at the set criteria.
		Quarterly	(a) Resolution (b) Retention time repeatability	Between 2 compounds	Resolution, Retention time repeatability results should be within acceptance criteria set.
		Yearly	Gas flow rate		Check gas flow rate accuracy. The lab should set acceptance criteria or as recommended by the equipment manufacturer.
23.	Gamma spectrometry	When used	Detector background counts, source check background counts, energy calibration	A mixed standard containing Am-241, Cs-137, Ra-226, Co-60 or other gamma emitters or/and as provided by engineer / manufacturer	Refer to Standard Methods APHA 7030B or In-house method with reference to Journal of AOAC International, Vol 78,No.5, 1995
		When detector serviced	Background counts, energy calibration or/and as per engineer / manufacturer recommendation	A mixed standard containing Am-241, Cs- 137, Ra-226, Co-60 or other gamma emitters or/and as provided by engineer/manufacturer	As per manufacturer recommendation

24.	Gas-flow proportional counter	Daily or when used	Detector background count rate Alpha / beta check source count rate on each detector	Am-241, Pu-239, Th-230 or U-238 (alpha source) Sr-90 or Cs-137 (beta source)	Refer to Standard Methods APHA 7030B & 7020A
		When major parts of detectors replaced	Voltage plateau (Alpha or Beta) Pulse-height discriminator Counting efficiency Alpha or Beta	Alpha check source, Beta check source	Refer to Standard Methods APHA 7030B & 7020A
25.	Gas Monitors / Detectors	Yearly	Accuracy	As per test method	As per manufacturer's recommendation or test methods
26.	Hydrometer	Initial and subsequently every 3 years	Accuracy	Certified reference hydrometers or freshly prepared solutions of known specific gravity	Refer to ASTM E 126
27.	HPLC	Quarterly	System performance checks accordingly to manufacturer's recommendation.	Relevant reference material	As per manufacturer's recommendation or test methods More frequent checks shall be performed depending on usage.

28.	HPLC – Mass Spectrometry	Quarterly	System performance check accordingly to manufacturer's recommendation, e.g. (a) Count per second (b) Full Width Half Height (c) Mass accuracy (d) Resolution (e) Sensitivity	Manufacturer's specification	As per the manufacturer's recommendation
		Annually	Planned Maintenance Procedure	Manufacturer's specification	As per the manufacturer's recommendation
29.	Incubator	When in use	Temperature	Calibrated working thermometer	Maintain temperature to accuracy within a given range as stipulated in methods.
		Yearly	Temperature uniformity		Calibration by a accredited laboratory
30.	Inductively Coupled Plasma Spectrometer (ICP-OES)	When use	Sensitivity	Standard solution of specific element	As per manufacturer's recommendations

		Annually	Planned Maintenance Procedure	Manufacturer's specification	As per the manufacturer's recommendation
31.	Inductively Coupled Plasma – Mass Spectrometry	When Use	Sensitivity	Standard solution of specific element	As per manufacturer's recommendations
32.	Infrared Spectrophotometer / FTIR	Monthly or when in use	(a Infrared Spectrophotometer / FTIR12) Wavenumber accuracy	Polystyrene film peaks at 2851.5cm ⁻¹ , 1601.8cm ⁻¹ , 1028.3 cm ⁻¹	Scan total range Typical accuracy: within ± 5.0 cm ⁻¹ over 400 – 2,000cm ⁻¹ within ± 2.5 cm ⁻¹ over 2,000 – 4,000cm ⁻¹
			(b) Wavenumber repeatability	Polystyrene film	As above. Should be better than accuracy by approximately 20%.
			(c) Beam balance (if applicable)	Air	Scan total range. ± 2% T.
33.	Ion Analyzer	First use of the day	Potential (Voltage) range of electrode	Reference material depends on (ion selective) electrode used	As per manufacturer's recommendation
34.	Ion Chromatograph	Quarterly	System performance check accordingly to manufacturer's recommendation.	Relevant reference material	More frequent checks shall be performed depending on usage. As per manufacturer's recommendation or test methods

35.	Jet Fuel Thermal Oxidation Tester	Every 50 tests or at least 6-monthly,	(a) Thermocouple temperature	1. Pure tin and/or pure lead	Refer to ASTM D 3241
		New or yearly	(b) Differential pressure	2. Known density fluid	
		Yearly	(c) Metering pump (Gear Pumps only)	3. Flow rate: $9.0 \pm 1.0s$ for 20 drops	
			(d) Filter by-pass valve leakage test	4. The time to reach 100mm δP is not more than 60 s	
36.	Karl Fischer Titrator	First use of the day	Water content	Reference material	Refer to ASTM E1064 or ASTM D1744/D4377.
37.	Laminar Flow Clean Bench	Before use	Disinfection of bench	Use appropriate method, such as the use of Replicate Organism Direct Agar Contact (RODAC) plates or Swab plates.	
		Yearly	Air flow rates	Calibrated anemometer or other appropriate flow instrument	Refer to manufacturer's instruction manual

			Particle count based on High- Efficiency Particulate Air (HEPA, 99.9%) filters	Calibrated Particle Counter	Refer to manufacturer's instruction manual
38.	Liquid-borne Particle Counter	Quarterly	Sample Volume Accuracy	Water for Injection	The accuracy should be within ±5%
		Yearly or as recommended by manufacturer	Sensor Resolution	Monosized Particle Size Standard	Refer to manufacturer's instruction manual and the United States Pharmacopoeia or British Pharmacopoeia as appropriate
39.	Liquid scintillation counter	Daily or when used	Detector background count, Self-normalization and calibration	H-3, C-14 standards	Refer to Standard Methods APHA 7030B & 7020A or as per manufacturer recommendation
		When liquid scintillation cocktail changed	Alpha beta spill- over curve, counting efficiency or quench curve	Am-241 or other Alpha standard solution Cs-137 or other Beta standard solution	As per manufacturer recommendation
40.	Melting Point Apparatus	Monthly	Verification of thermometer	Reference materials	Take replicate melting points of reference materials.
41.	Microscope, Fluorescent	When used	Used time of UV bulb	Timer or watch	Record the used time of UV bulb each time of use. Bulb should be changed following manufacturer's recommendation.

42.	Microwave Digester	Monthly	Power Output	Water	Power (watts) = δ T (35 W / °C). Refer to ASTM 5513 Section 9, IEC Norms No. 705
					$\delta T = T_f - T_i$
					$W/^{\circ}C = [K \times C_{p} \times M]/t$
					W : watts
					K : 4.2 the factor for converting thermo-chemical calories/s to joules to watts
					C_p : 1.0 the heat capacity for water, cal g ⁻¹ degree ⁻¹
					M : mass of water, g (1 ml $H_2O = 1$ g)
					t = time, s
43.	Mixer	Yearly	Speed	Calibrated tachometer	
44.	Muffle Furnace	Yearly	Temperature Stability Accuracy Homogeneity		Calibration by accredited laboratory
45.	Oven, General	Yearly	Temperature Stability Accuracy Homogeneity		Calibration by accredited laboratory

46.	Air Sampling Pump	When used	Accuracy of indicator and Flow blockage	Calibrated flowmeter	Monitoring of temperature and pressure to be documented. Volume to be adjusted to appropriate temperature and pressure	
47.	pH Meter	Daily / When used	Accuracy and linearity	Standard buffer solutions	Standard buffer solutions used should be appropriate for the working range.	
48.	Pipettes (Mechanical and Elec	tronic)				
	(a) Reference	Yearly	Accuracy and repeatability		Calibration by accredited laboratory	
	(b) Working	Half-yearly	Accuracy and repeatability	Internal verification using calibrated pipette	Verification of Accuracy and repeatability	
49.	Polarimeter	Monthly	Specific rotation	200 mg of quinidine sulphate (dried for 3 hours) in 10 ml of 0.1N HCl	Do standard and blank readings Specific rotation = $100a$ = +275° to lc 287° where a = corrected reading I = length of polarimeter's tube in decimetres c= concentration as g/100 ml of solution	
50.	Pressure Gauge	Yearly	Accuracy	Calibrated dead weight tester		
51.	Pycnometer, Lipkin Bicapillary	Initial	Capacity	Distilled water		
52.	Refractometer	When used	Accuracy	Distilled water	Determine refractive index according to manufacturer's instructions.	

		Quarterly	Calibration	 1.Glycerol solution 2. n-octane 3. Monobromonaphthalene 	Determine refractive index of either glycerol solution or, n-octane, or monobromonaphthalene
53.	Saccharimeter	When used	Calibration and linearity	Standard sucrose solutions of 26g/100ml, 13g/100ml, and 10g/100ml	Calibrate with 26g/100ml and determine linearity with other standard solutions.
54.	Smoke Point Lamp	Quarterly	Smoking Point	ASTM knock test reference fuels	Refer ASTM D1322
55.	Steriliser				
	(a) Hot Air Oven	Daily	Temperature	Calibrated thermometer	
		Quarterly	(a) Temperature	Calibrated thermocouple	To validate thermometer readings, check the temperature at various locations by a calibrated thermocouple.
			(b) Sterility	Biological indicators	Spore Culture(s) required
	(b) Steamer	Daily	Recording chart		Check to determine if each cycle has been completed properly
		Bimonthly	Time-temperature relationships	Calibrated thermocouple	
	(c) Autoclave	Quarterly	(a) Temperature	Check using a calibrated thermometer. Temperature readout must show an average temperature of $121^{\circ}C \pm 1^{\circ}C$ for 15 minutes when a set-point of $121^{\circ}C$ and holding time of 15 minutes is used.	Laboratories must comply with statutory requirements requiring (i) examination of the autoclaves by an authorized examiner at least once every year and after any extensive repairs and (ii) examination of all fittings and attachments at least every 2 years.

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			(b) Pressure	Check using a calibrated pressure gauge. Pressure gauge/readout must show an average pressure of 101 kPa for 15 minutes when a set-point of 121°C and holding time of 15 minutes are used.	As all fittings and attachments must be examined at least every 2 years, companies may use the thermometer, pressure gauge and timer fitted to the autoclave as the calibrated sensor/timer.
			(c) Timer	Check using a calibrated timer. The autoclave must hold the temperature at an average temperature of $121^{\circ}C \pm 1^{\circ}C$ for 15 minutes when a holding time of 15 minutes is selected.	
			(d) Sterility	Calibrated thermocouple Biological indicators	Full load, calibrated thermocouple immersed in liquid, and BI placed in the innermost centre of the dry load
		When used	(a) Sterility	Check using biological indicators	For laboratories dealing with pathogenic microorganisms, biological indicators should be used to check for sterility whenever materials containing or potentially containing pathogenic microorganisms are being sterilised.
56.	Water Still	Weekly	(a) Cleanliness		Visual check to ensure no visible accumulation of scale, etc.

			(b) Conductivity	Calibrated conductivity meter	For systems with continuous on-line meters. Check accuracy of meter annually
57.	Thermocouple & Data Logger	Yearly	Temperature		Calibration by accredited laboratories
58.	Thermometer				
	(a) Reference	5 years	Temperature		Calibration by accredited laboratory Full calibration
		Annually	Temperature		Specific points check including melting point.
	(b) Working	Half-yearly depending on use	Temperature	Calibrated Reference thermometer	Specific points check
59.	Timer	Yearly	Accuracy	Calibrated stop-watch	
60.	Tintometer, Lovibond	Half-yearly	Colour plates Chlorine plates	Platinum-cobalt standard Potassium Permanganate standard	Refer to specified method
61.	Total Carbon Analyzer	When used	Carbon content	Certified reference materials	
62.	Total Sulphur Analyzer	When used	Sulphur content	Certified reference materials	
63.	Turbidimeter	When used	Turbidity	Turbidity standard solution	
		Quarterly	Turbidity	Full range of turbidity standard solutions	

64.	UV-Visible Spectrophotometer/ Colorimeter	Quarterly	(a) Wavelength accuracy and repeatability	Holmium filter and didymium filter	Check way Visible rang ±1.0 nm. R	Check wavelength over entire UV- Visible range. Maximum deviation ±1.0 nm. Run two spectra		
			b) Photometric accuracy and repeatability	60 ± 0.25 mg K ₂ Cr ₂ O ₇ /litre in 0.005M H ₂ SO ₄	Scan spect nm or chect wavelength	trum from 2 k absorbar ns:	210 nm to 450 nce at following	
					Wavelength (nm)	Absorbance (A)	Permitted Tolerance	
					235	0.748	0.740 - 0.756	
					257	0.865	0.856 - 0.874	
					313	0.292	0.289 - 0.295	
					350	0.640	0.634 - 0.646	
					Maximum of on all range	deviation ± es; run thre	1% of full scale e spectra.	
				For visible region				
				CuSO ₄ .5H ₂ O (20.0 g/litre) in 1% H ₂ SO ₄	Wavelength (nm)	Absorbance (A)	Permitted Tolerance	
					600	0.068	0.067 - 0.069	
					650	0.224	0.2195 – 0.2285	
					700	0.527	0.5165 – 0.5375	
					750	0.817	0.801 – 0.833	
					Maximum of on all range	deviation ± es; run thre	1% of full scale e spectra.	
65.	Viscometer	Half-yearly		Reference				
				materials				

66.	Viscosity bath	Yearly	Homogeneity and consistency of temperature		
67.	Water Bath (a) Precision water bath for Eijkman Test for confirming faecal coliform (e.g. <i>E. coli</i>)	Daily / When used	Temperature	Calibrated working thermometer with 0.1°C divisions immersed in water bath.	Maintain temperature to an accuracy of ±0.2°C or within a range as stipulated in methods.
		Yearly	Temperature	Traceable reference thermometer.	Calibration by an accredited laboratory.
	(b) Common Microbiological Water Bath	Daily / When used	Temperature	Calibrated working thermometer with 0.1°C divisions immersed in water bath.	Maintain bath to an accuracy of ±1°C of the requirement.
		Yearly	Temperature	Traceable reference thermometer.	Calibration by an accredited laboratory.