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SR 03:

JAMINAN MUTU PERALATAN YANG DIGUNAKAN OLEH LABORATORIUM PENGUJIAN KIMIA DAN PENGUJIAN BIOLOGI

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SR-03
Persyaratan Tambahan untuk Akreditasi Laboratorium Pengujian Kimia dan Biologi

(Jaminan Mutu Peralatan yang Digunakan dalam Laboratorium Pengujian Kimia dan Biologi)

1 Pendahuluan

Dokumen ini memberikan rekomendasi kegiatan jaminan mutu untuk peralatan yang pada umumnya digunakan dalam laboratorium pengujian kimia dan biologi. Dokumen ini diterbitkan untuk menjelaskan beberapa persyaratan teknis khusus seperti dipersyaratkan dalam SNI 19-17025-2000 ”Persyaratan Umum Kompetensi Laboratorium Pengujian dan Laboratorium Kalibrasi”.

2 Pemeliharaan Peralatan

2.1 Laboratorium harus memiliki program pemeliharaan untuk mencegah kegagalan peralatan dan menjamin bahwa peralatan bekerja sesuai dengan reliabilitas yang diperlukan untuk mutu hasil pengujian yang dikehendaki.

2.2 Peralatan harus dipasang dan ditempatkan di lokasi dengan kondisi lingkungan yang memadai untuk meminimalkan pengaruh potensial dari akomodasi terhadap kinerja peralatan. Elemen yang berpengaruh tersebut termasuk korosi, temperatur, kelembaban, vibrasi, kestabilan daya listrik, debu dan pengaruh elektromagnetik.

3 Kalibrasi Peralatan

3.1 Tabel 1 dokumen ini memberikan rekomendasi frekuensi normal dari kalibrasi atau pengecekan kinerja peralatan yang pada umumnya digunakan dalam bidang pengujian kimia atau biologi.

3.2 Frekuensi kalibrasi yang direkomendasikan adalah cukup memadai, bila kriteria yang tersebut di bawah ini dapat dipenuhi:

(a) bahwa peralatan tersebut mempunyai kualitas yang baik dan kestabilan yang telah dibuktikan dengan rekaman yang memadai.

(b) bahwa laboratorium memiliki peralatan yang diperlukan dan staf yang kompeten serta keahlian untuk melaksanakan pengecekan internal yang memadai.

(c) bahwa bila terdapat kecurigaan atau indikasi kelebihan beban atau kesalahan penanganan, peralatan harus diperiksa dengan segera dan setelah itu diperiksa dalam interval yang cukup sampai dapat ditunjukkan bahwa stabilitas peralatan tidak terganggu.

3.3 Bila kriteria di atas tidak dapat dipenuhi atau metoda yang relevan menetapkan persyaratan yang lebih ketat, laboratorium harus mengadopsi frekuensi kalibrasi yang lebih sering.

3.4 Bila kalibrasi telah dilakukan oleh staf laboratorium, rekaman lengkap pengukuran tersebut harus dipelihara, termasuk rincian hasil numerik, tanggal kalibrasi dan pengamatan lain yang relevan.

3.5 Bila akurasi pengukuran temperatur mempunyai pengaruh yang signifikan terhadap hasil analisis, alat ukur temperatur untuk peralatan seperti inkubator, waterbath dan oven harus dikalibrasi. Untuk peralatan tersebut distribusi temperatur harus ditentukan pada awal pemakaian dan dua tahun sekali. Rekaman harian pengukuran temperatur pada saat peralatan digunakan untuk menguji harus dipelihara.

TABEL 1 :

REKOMENDASI KALIBRASI DAN PENGECEKAN KINERJA DARI PERALATAN YANG UMUM DIGUNAKAN DI LABORATORIUM PENGUJIAN KIMIA DAN BIOLOGI

NO	TYPE OF INSTRUMENT OR EQUIPMENT	FREQUENCY OF CHECK	PARAMETERS TO BE CHECKED	STANDARD OR REFERENCE MATERIALS / EQUIPMENT	GENERAL PROCEDURES AND/OR REMARKS
1.	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 anaerobic chamber.
		Half- yearly depending on use	Anaerobic condition	Anaerobic reference culture	
2.	Anaerobic Jar	When used	Anaerobic condition	Anaerobic chemical indicators (eg. Methylene blue)	
		Half- yearly depending on use	Anaerobic condition	Anaerobic reference culture	
3.	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 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 response of thrice the previous results. (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
4.	Automatic Titrator		Functioning of		
		Half-yearly	(a) Burette		Accuracy of burettes be checked.
		When used	(b) Response (end point)	Standard solutions	Response of detection system be checked.
5.	Automatic Distiller	Yearly	Temperature sensor Recovery accuracy		

NO	TYPE OF INSTRUMENT OR EQUIPMENT	FREQUENCY OF CHECK	PARAMETERS TO BE CHECKED	STANDARD OR REFERENCE MATERIALS / EQUIPMENT	GENERAL PROCEDURES AND/OR REMARKS
6.	Balance (All types)	When used	Level of balance, zero point, cleanliness		Clean after use
		Monthly	Accuracy	Reference weights	One point check. Calibration procedures should be documented.
		Half-yearly	Repeatability, linearity, accuracy	Reference weights	Calibration over full range. Repeatability of readings, ten weighings are made of a mass having a value close to the maximum load of the balance. Reference weights to be calibrated every three years.
7.	Balance, Micro	Quarterly	Repeatability, linearity, accuracy	Reference weights	
8.	Bomb Calorimeter	When used	Water-equivalent	Benzoic Acid Standard	Measurement in calories, ±1% (eg. petrochemicals, ±50 cal/g)
		Half-yearly	Water-equivalent	Certified Benzoic Acid	
9.	Carbon Dioxide Incubator	Daily	(a) Temperature (b) Carbon dioxide content	Calibrated thermometer Calibrated pyrite device	
		Half-yearly	Growth	Carbon Dioxide dependent strain of *Neisseria gonorrhoea*	
10.	Centrifuge	Yearly	Speed	Calibrated tachometer	
11.	Conductivity Meter	Monthly	Conductivity	A relevant standard KCl solution	One point calibration. Adjust cell constant if necessary.
		Quarterly	Conductivity	Standard KCl solutions	Full range calibration
12.	Density Bottle	When used	Density	Double distilled water	
13.	Digital Density Meter	When temperature setting changed or weekly	Density	Double distilled water and air	Frequency of check could be reduced if lab uses other test methods eg. IP or ISO
14.	Disintegration Apparatus (Tablet/Capsule)	Monthly	(a) Stroke distance	Calibrated ruler	Refer to the Indonesian Pharmacopeia, United States Pharmacopeia or British Pharmacopeia
			(b) Rate	Calibrated timer or watch	
			(c) Temperature	Calibrated thermometer	
15.	Dissolution Apparatus Quarterly (Tablet/Capsule)	Quarterly	(a) Rotation Speed (b) Temperature (c) Distance	Calibrated tachometer Calibrated thermometer Calibrated ruler	Speed specified within ± 4% 37°±0.5°C 25 ±2 mm
		Yearly or as recommended by manufacturer	(a) Apparatus Suitability Test (b) Level check	Dissolution Calibrator	Refer to the Indonesian Pharmacopeia, United States Pharmacopeia or British Pharmacopeia
16.	Flash Point Testing				Dimensional check of apparatus should be carried out according to test method.
	(a) Tag Closed Tester	Monthly	Flash point	Secondary Working Standards	

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		Yearly	Flash point	Certified Reference Materials n-Decane :50.9 +/-2.3 °C n-unDecane :67.1+/-2. 3 ° C	Select the CRM which has a flash point close to the expected temperature range of the sample to be tested
	(b) Pensky-MartensClosed Tester	Monthly	Flash point	Secondary Working Standards	
		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	xylene/n-heptane, calibrated thermometer	
	(d) Cleveland Open-Cup Apparatus	Monthly	Flash point	Secondary Working Standards	
		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
17.	Fluorescence Spectrophotometer	Monthly	Wavelength and/ or photometric accuracy	1 mg/100 ml quinine sulphate in 0.25 M H2S04	Run excitation and emission spectra. Establish specification for 255 nm, 355 nm excitation peaks and 455 nm emission peak heights.
18.	Gas Chromatograph	Quarterly	System performance including : Resolution, sensitivity, reproducibility, retention time and noise level	Relevant reference material	More frequent checks shall be performed depending on usage.

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19	Hydrometer	Initial and subsequently every 3 years	Accuracy	Certified reference hydrometer or freshly prepared solutions of known specific gravity	
20.	Incubator	Daily	Temperature	Calibrated thermometer	Maintain temperature to an accuracy of ±2°C or within a given range as stipulated in methods.
		Fortnightly	Temperature	Reference thermometer with 0.1 °C divisions	As above
21.	Infrared Spectrophotometer	Monthly depending on use	(a) Wave number accuracy	Polystyrene film peaks at Scan total range.2851.5 cm^{-1},1601.8 cm-1 1028.3 cm-1	Typical accuracy: ±3.0 - 5.0 cm-1over 4,000 -2,000 cm-1 ±1.5 -2.5 cm-1over 2,000 -400 cm-1
			(b) Wave number reproducibility	Polystyrene film	As above, should be better than accuracy by approximately 20 %
			(c) Beam balance	Air	Scan total range + 2%T
22.	Ion analyzer	When used	Voltage range of electrode	Reference material depends on ion selective electrode	Use calibration chart at fixed temperature for each ion (e.g) F^-, Cl^-, NO_3^-
23	Jet Fuel Thermal Oxidation Tester	Every 50 tests or at least 6-monthly	(a) Thermocouple	1. Pure tin and/or pure lead	
		Initial or yearly	(b) Differential Pressure Cell	2. Known density fluid	
			(c) Metering Pump (gear pumps only)	3. Flow rate : 9.0+/- 1.0 s for 20 drops	
			(d) Filter by-pass valve leakage test	4. The time to reach 100 mm δP is not more than 60 seconds	
24.	Karl Fischer Titrator	When used	Moisture content	Laboratory reference material	
25	Inductively Coupled Plasma Spectrometer	Monthly	Drift correction	Reference materials	Check against old calibration values and re-calibrate
		When used	Sensitivity	Standard solutions of specific element	Aspirate standard solutions and determine the absorption. Compare sensitivity against previous results
		When used	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 represent the detection limit concentration. Compare the detection limit against the previous results (a) use background corrector whenever possible

NO	TYPE OF INSTRUMENT OR EQUIPMENT	FREQUENCY OF CHECK	PARAMETERS TO BE CHECKED	STANDARD OR REFERENCE MATERIALS / EQUIPMENT	GENERAL PROCEDURES AND/OR REMARKS
					(b) optimize parameters of instrument before use according to manufacturer's instructions (c) © Record sensitivity and detection limit in instrument log book
26	Liquid Chromatograph/Ion Chromatograph	Quarterly depending on use	System performance including resolution, sensitivity, reproducibility, retention time and noise level	Relevant reference material	More frequent checks shall be performed depending on usage
27	Liquid Borne Particle Counter	Quarterly	Sample volume accuracy	Water for injection	The accuracy should be within $\pm$ 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
28	Melting Point Apparatus	monthly	Calibration of thermometer	Standard materials	Take replicate melting point of standard materials
29	Microscope, Fluorescent	When used	Used time of UV bulb	Calibrated time or watch	Record the used time of UV bulb each time of use. Bulb should be changed when time reaches 200 hours
30	Microwave Digestor	monthly	Power output	water	Power (watts) = (35 $W/^0C$). where $\delta T = T_f - T_i$ $W/^0C = [K \times C_p \times M]/t$ W : watts K: 4.2 the factor for converting thermo clinical calories 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 T : times, s = 1 g)
31	Mixer	Yearly	Speed	Calibrated tachometer	
32	Muffle Furnace	Yearly	Temperature	Calibrated thermometer	
33	Oven, general	Quarterly	Temperature	Calibrated thermometer	
34	pH Meter	Daily/when used	Accuracy and linearity	Commercially prepared buffers or other equivalent standard buffers	Bracket pH value expected as closely as possible with buffer
35	Polarimeter	Monthly	Specific rotation	200 mg of quinide sulphate (dried for 3 hours) in 10 ml of 0.1 N HCl	Do standard and blank readings Specific rotation = 100 / (l.c) = 275^0 C to 287^0C Where: a: corrected reading l: length of polarimeter's tube in decimeters c: concentration as g/100 ml of solution

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36	Pressure Gauge	Yearly	Accuracy	Calibrated Dead Weight Tester	
37	Pycnometer, Lipkin Bicapillary	Initial and subsequently every 3 years	Capacity	Distilled water	
38	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 monobromonaphtalene
39	Saccharimeter	When used	Calibration and linearity	Standard sucroce solutions of 26g/ 100 ml, 13g/100 ml and 10g/100ml	Calibrate with 26g/100 ml and determine linearity with other standard solutions
40.	Smoke Point Lamp	Quarterly	Smoking point		
41	Sterilizer				
	(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	Bimonthly	Time-temperature relationship	Calibrated thermocouple	
		Daily	Recording chart		Check to determine if each cycle has been completed properly
	(c) autoclave	When used	(a) temperature	Calibrated thermometer	
			(b) pressure	Calibrated pressure gauge	
		Quarterly	(a) temperature	Calibrated thermocouple	
			(b) pressure	Reference pressure gauge	
		Daily	(a) sterility	Biological indicators	Daily for pathogenic microorganism
		Monthly			Monthly for others
42	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
		Monthly	pH	Calibrated pH meter	
43	Thermocouple	Yearly	Temperature		
44	Thermometer				
	(a) reference	(a) 5 years	Temperature		Full calibration
		(b) annually			Specific points check including melting point
	(b) working	Half-yearly depending on use	Temperature	Reference thermometer	Specific points check
45	Timer	Yearly	Accuracy	Calibrated stop-watch	
46	Tintometer, Lovibond	Half-yearly	Colour plates	Platinum-cobalt standard	
			Chlorine plate	Potassium Permanganate standard	Refer to specified method

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47	Total Carbon Analyzer	When used	Carbon content	Certified reference materials	
48	Total Organic Carbon Analyzer	When used	Organic carbon content	Relevant reference materials	Check accuracy for results
49	Total Sulfur Analyzer	As recommended by manufacturer	Sulfur content	Certified reference materials	QC check is required in between calibration
50	Turbidimeter	When used Quarterly	Turbidity Turbidity	Reference turbidity standard Full range of reference turbidity standards	
51	UV-Visible Spectrophotometer / Colorimeter	Quarterly	(a) wavelength accuracy and reproducibility	Holmium filter and/or didinium filter	Check wavelength over entire UV-Visible range. Maximum deviation $\pm$ 1.00 nm. Run two spectra
			(b) Photometric accuracy and reproducibility	60 $\pm$ 0.25 mg $K_2Cr_2O_7$/litre in 0.005 M H_2SO_4	Scan spectrum from 210 nm to 450 nm or check absorbance at following wavelength: Wavelength Absorbance, A Permitted Tolerance 235 nm 0.748 0.740 – 0.756 257 nm 0.865 0.856 – 0.874 313 nm 0.292 0.289 – 0.295 350 nm 0.640 0.634 – 0.646 maximum deviation $\pm$ 1% of full scale on all ranges; run the spectra
			(c) photometric accuracy and reproducibility	For visible region $CuSO_4.5H_2O$ (20.0 g/litre) in 1% H_2SO_4	Wavelength Absorbance A Permitted Tolerance 600 nm 0.688 0.067 – 0.069 650 nm 0.224 0.2195– 0.2285 700 nm 0.527 0.5165 - 0.5375 750 nm 0.817 0.801 – 0.833
52	Viscometer (a) reference (b) working	 3 years Half-yearly		 Certified standard oil Reference standard oil	
53	Viscosity Bath	Yearly	Homogeneity and consistency of temperature		

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54	Water Bath (a) precision water bath for Eijkman Test for confirming faecal coliform (e.g. E.coli)	Daily (when used)	Temperature	Calibrated thermometer with 0.1^0C divisions contained in water bath	Do not use water bath if reading deviates more than $\pm$ 0.2^0C from required temperature
		Whenever water bath thermometer has been replaced and whenever water bath has been out of operation for a long time	Accuracy of water bath thermometer	Reference thermometer	Record water bath thermometer correction factor and attach to water bath
	(b) common microbiological water bath	As above	As above	As above	Maintains baths to an accuracy of $\pm$ 1^0C of the requirement. Record water bath thermometer correction factor and attach to water bath. For media-holding water bath, place an additional thermometer in a water bottle that is in the bath.