

LAMPIRAN: STANDARD DAN KRITERIA PRESTASI DAN KESELAMATAN BAGI PERALATAN RADIOLOGI DIAGNOSTIK DAN KEMUDAHAN BERKAITAN

APPENDIX: PERFORMANCA AND SAFETY STANDARDS AND CRITERIA FOR DIAGNOSTIC RADIOLOGY EQUIPMENT AND ASSOCIATED FACILITIES

Jadual 1: Kebocoran Sinaran dan Sinaran Terserak
Table 1: Leakage and Scattered Radiation

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
1.	Kadar dedahan bagi setiap kawasan yang dihuni di luar bilik x-ray dan pada kedudukan yang biasa dihuni oleh operator di kawasan kawalan <i>Exposure rate at every occupied outside the x-ray room, and at the position normally occupied by the operator at the control area</i>	0.1mGy (10mR) seminggu <i>0.1mGy (10mR) per week</i>	Tahunan <i>Annually</i>
2.	Dedahan disebabkan kebocoran sinaran pada jarak 1m dari tiub x-ray dalam masa sejam pada setiap kadar yang ditetapkan oleh pengeluar <i>Exposure from the leakage radiation at 1m from the x-ray tube in an hour at every rating specified by the manufacturer</i>	0.1mGy (10mR)	Tahunan <i>Annually</i>

Jadual 2: Standard dan Kriteria Prestasi dan Keselamatan Bagi Peralatan X-Ray Am dan Kemudahan Berkaitan

Table 2: Performance and Safety Standards and Criteria for General X-Ray Equipment and Associated Facilities

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
1.	Generator X-Ray X-Ray Generator i) Kejituan bagi kVp <i>Accuracy of kVp</i> ii) Kejituan masa dedahan <i>Accuracy of exposure time</i> iii) Keboleholangan dedahan <i>Exposure reproducibility</i> iv) Kelinearan dedahan <i>Exposure linearity</i>	Sisihan maksima: 5% atau 5kV, yang mana lebih besar <i>Maximum deviation: 5% or 5kV whichever is greater</i> Sisihan maksima: 10% <i>Maximum deviation: 10%</i> Sisihan maksima: 10% <i>Maximum deviation : 10%</i> Sisihan maksima: 10% <i>Maximum deviation : 10%</i>	Separuh tahunan <i>Semi-annually</i>

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
2.	Penghadan Bim X-Ray X-Ray Beam Limitation <ul style="list-style-type: none"> i) Pengkolimatan bim <i>Beam collimation</i> ii) Penjajaran bim <i>Beam perpendicularity</i> 	Ketidakkajajaran maksima: 2% daripada jarak antara sumber dengan imej <i>Maximum misalignment: 2% of source-image distance (SID)</i> Kurang daripada 2° <i>Less than 2°</i>	Separuh tahunan <i>Semi-annually</i>
3.	Penapis Bim X-Ray X-Ray Beam Filtration	Rujuk Jadual 6 <i>Refer to Table 6</i>	Penerimaan <i>Acceptance</i>
4.	Kualiti Imej Image Quality <ul style="list-style-type: none"> i) Resolusi <i>Resolution</i> ii) Kontras <i>Contrast</i> 	Sila nyatakan resolusi dan kontras dan lampirkan filem ujian asal <i>Please specify the resolution and contrast and attach test films</i>	Separuh tahunan <i>Semi-annually</i>

Jadual 3: Standard dan Kriteria Prestasi dan Keselamatan Bagi Pengimbas Tomografi Berkomputer dan Kemudahan Berkaitan

Table 3: Performance and Safety Standards and Criteria for Computed Tomography Scanner and Associated Facilities

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
1.	Generator X-ray X-Ray Generator <ul style="list-style-type: none"> i) Kejituan kVp <i>Accuracy of kVp</i> ii) Kejituan arus tiub <i>Accuracy of tube current</i> iii) Kejituan masa dedahan <i>Accuracy of exposure time</i> iv) Kelinearan dedahan (mR/mAs) <i>Exposure linearity (mR/mAs)</i> 	Maximum deviation : $\pm 2kV$ <i>Sisihan maksima : $\pm 2kV$</i> Maximum deviation : $\pm 5\%$ <i>Sisihan maksima : $\pm 5\%$</i> Maximum deviation : $\pm 5\%$ <i>Sisihan maksima : $\pm 5\%$</i> Maximum deviation : $\pm 5\%$ <i>Sisihan maksima : $\pm 5\%$</i>	Separuh tahunan <i>Semi-annually</i>
2.	Radiation Dosimetry Dosimetri Sinaran <ul style="list-style-type: none"> i) Patient dosimetry (CTDI) <i>Dosimetri pesakit (CTDI)</i> ii) Imej peninjauan lokalisasi <i>Scout localization image</i> 	$\pm 20\%$ of nominal value $\pm 20\%$ daripada nilai nominal $\pm 20\%$ of nominal value $\pm 20\%$ daripada nilai nominal	Separuh tahunan <i>Semi-annually</i>

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
3.	<p>Lokalisasi Imbasan <i>Scan Localization</i></p> <p>i) Kejituan cahaya imbasan lokalisasi aksial <i>Axial scan localization light accuracy</i></p> <p>ii) Kejituan cahaya lokalisasi jajaran isocentre, sagital dan koronal <i>Isocenter alignment, sagittal and coronal localization light accuracy</i></p> <p>iii) Kejituan kecondongan gantri (atau meja) <i>Gantry (or table) tilt accuracy</i></p> <p>iv) Kedudukan dan indeks meja <i>Table index and position</i></p> <p>v) Lebar imbasan imej (profil sensitiviti) <i>Image scan width (sensitivity profile)</i></p> <p>vi) Profil dos sinaran <i>Radiation dose profile</i></p> <p>vii) Kejituan imbasan dipreskripsi dari imej peninjauan lokalisasi <i>Accuracy of scan prescription from scout localization image</i></p>	<p>$\pm 2\text{mm}$</p> <p>$\pm 5\text{mm}$</p> <p>$\pm 3^\circ$</p> <p>$\pm 0.5\text{mm} - 2.0\text{mm}$</p> <p>$\pm 1\text{mm}$ (lebar imbasan $\geq 5\text{mm}$), $\pm 0.5\text{mm}$ (lebar imbasan $< 5\text{mm}$) $\pm 1\text{mm}$ ($\geq 5\text{mm}$ prescribed scan width), $\pm 0.5\text{mm}$ ($< 5\text{mm}$ prescribed scan width)</p> <p>$\pm 1\text{mm}$</p> <p>$\pm 1\text{mm}$</p>	<p>Separuh tahunan <i>Semi-annually</i></p> <p>Bulanan <i>Monthly</i></p> <p>Separuh tahunan <i>Semi-annually</i></p> <p>Tahunan <i>Annually</i></p>
5.	<p>Paparan Imej <i>Image Display</i></p> <p>i) Paparan visual <i>Visual display</i></p> <p>ii) Paparan 'hard copy' <i>Hard copy display</i></p>	<ul style="list-style-type: none"> ▪ Tiada perbezaan signifikan antara Kontras dan luminans dan output 'hard copy' <i>Luminance and contrast not significantly different from hard copy output</i> ▪ Herotan geometrik tidak melebihi $\pm 1\text{mm}$ <i>Geometric distortion not exceed $\pm 1\text{mm}$</i> ▪ 'Patches' 5% dan 95% hendaklah kelihatan tanpa artifaks yang jelas <i>5% and 95% patches must be visible, no noticeable artifacts</i> ▪ Herotan geometri tidak melebihi $\pm 1\text{mm}$ <i>Geometric distortion not exceed $\pm 1\text{mm}$</i> ▪ Nilai densiti optik hendaklah pada julat yang ditetapkan <i>Optical density values must be within specified range</i> 	<p>Harian <i>Daily</i></p> <p>Harian <i>Daily</i></p> <p>Bulanan <i>Monthly</i></p>

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
6.	Kualiti Imej <i>Image Quality</i> <ul style="list-style-type: none"> i) Keseragaman nombor CT <i>CT number uniformity</i> ii) Imej artifaks (imej imbasan lokalisasi dan transaksial) <i>Image artifacts (transaxial and scan localization images)</i> iii) Hingar <i>Noise</i> iv) Resolusi kontras rendah <i>Low contrast resolution</i> v) Resolusi kontras tinggi <i>High contrast resolution</i> 	<ul style="list-style-type: none"> $\pm 5\text{HU}$ Tiada artifaks yang signifikan <i>No significant artifacts</i> Sisihan piawai bagi nombor CT berubah secara songsang dengan punca kuasa dua mAs <i>Standard deviation of CT numbers varies as reciprocal square root of mAs</i> 5mm 1mm holes (5lp/cm) 	<ul style="list-style-type: none"> Bulanan <i>Monthly</i> Separuh tahunan <i>Semi-annually</i> Bulanan <i>Monthly</i> Bulanan <i>Monthly</i>
7.	Kejituan Kuantitatif <i>Quantitative Accuracy</i> <ul style="list-style-type: none"> i) Kejituan bagi pengukuran jarak (imej transaksial dan imbasan lokalisasi) <i>Accuracy of distance measurements (transaxial and scan localization images)</i> ii) Kalibrasi nombor CT <i>CT number calibration</i> iii) Ketetapan nombor CT <i>CT number constancy</i> iv) Kebergantungan nombor CT terhadap ketebalan imbasan <i>CT number dependence on scan thickness</i> v) Kebergantungan nombor CT terhadap saiz phantom <i>CT number dependence on phantom size</i> vi) Kebergantungan nombor CT terhadap kedudukan phantom <i>CT number dependence on phantom position</i> vii) Kebergantungan nombor CT terhadap algoritma rekonstruksi <i>CT number dependence on reconstruction algorithm</i> 	<ul style="list-style-type: none"> $\pm 1\text{mm}$ ▪ Air Water: $0 \pm 1.5\text{HU}$ ▪ Udara Air: $-1000 \pm 3\text{HU}$ Nilai dan sisihan piawai bagi air secara relatifnya kekal tetap <i>Value and standard deviation for water remains relatively constant</i> $\pm 3\text{HU}$ $\pm 20\text{HU}$ $\pm 5\text{HU}$ $\pm 3\text{HU}$ 	<ul style="list-style-type: none"> Tahunan <i>Annually</i> Bulanan <i>Monthly</i> Daily <i>Harian</i> Separuh tahunan <i>Semi-annually</i> Tahunan <i>Annually</i> Tahunan <i>Annually</i>

Jadual 4: Standard dan Kriteria Prestasi dan Keselamatan Bagi Peralatan Fluoroskopi/Angiografi dan Kemudahan Berkaitan

Table 4: Performance and Safety Standards and Criteria for Fluoroscopy/Angiography Equipment and Associated Facilities

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
1.	<p>Generator X-ray <i>X-Ray Generator</i></p> <p>i) Kejituan kVp <i>Accuracy of kVp</i></p> <p>ii) Kejituan masa dedahan <i>Accuracy of exposure time</i></p> <p>iii) Pencatat masa fluoroskopi <i>Fluoroscopic timer</i></p> <p>iv) Keboleholulangan dedahan <i>Exposure reproducibility</i></p> <p>v) Kelinearan dedahan <i>Exposure linearity</i></p>	<p>Sisihan maksima: 5% atau 5 kV, yang mana lebih besar <i>Maximum deviation : 5% or 5kV, whichever is greater</i></p> <p>Sisihan maksima : 10% <i>Maximum deviation : 10%</i></p> <p>Mestilah dilengkapi dengan isyarat bunyi kepada pengendali fluoroskopi pada jeda masa tidak melebihi 5 minit dan paparan dapat di'set' kepada sifar untuk setiap pesakit <i>Must provide an audible signal to the fluoroscopist at intervals not exceeding 5 minutes and provision must be made for the display to be set to zero for each patient</i></p> <p>Sisihan maksima: 10% <i>Maximum deviation: 10%</i></p> <p>Sisihan maksima: 10% <i>Maximum deviation: 10%</i></p>	Separah tahunan <i>Semi-annually</i>
2.	<p>Penghadan Bim X-Ray <i>X-Ray Beam Limitation</i></p> <p>i) Pengkolimatan bim <i>Beam collimation</i></p>	<p>Ketidakkajaran maksima: 2% daripada jarak diantara sumber dengan imej <i>Maximum misalignment: 2% of source-image distance (SID)</i></p>	Separah tahunan <i>Semi-annually</i>
	<p>ii) Penjajaran bim <i>Beam perpendicularity</i></p>	<p>Kurang daripada 2° <i>Less than 2°</i></p>	
3.	<p>Penapis Bim X-Ray <i>X-Ray Beam Filtration</i></p>	<p>Rujuk Jadual 6 <i>Refer to Table 6</i></p>	Penerimaan <i>Acceptance</i>
4.	<p>Output Voltage Video – Bim dikalibrasi pada keupayaan 70 kVp dengan penapis tembaga 1mm, mengikut spesifikasi yang ditetapkan oleh pengeluar <i>Video Voltage output – calibrated beam at 70 kVp and 1mm copper filter, in accordance with manufacturers' specifications</i></p>	<ul style="list-style-type: none"> • V_o : antara 0.6V dan 1.0V walaupun setengah sistem hanya memberi nilai pada $0.3 V_{max}$ apabila diperbetulkan <i>V_o : between 0.6V and 1.0 V although some systems give only $0.3 V_{max}$ even when correctly adjusted</i> • Denyutan sync, V_s : antara 0.3V dan 0.4V <i>Sync pulse V_s : between 0.3V and 0.4V</i> 	Separah tahunan <i>Semi-annually</i>

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
		<ul style="list-style-type: none"> • Perbezaan antara 'blanking' dan paras hitam: antara 0.05V dan 1.0V <i>Difference between blanking and black level: between 0.05V and 1.0V</i> • Peralihan kecacatan dari paras hitam ke putih V_x: tidak melebihi 0.15 V_o. <i>The imperfect transition from black to white levels V_x: should not be > 0.15 V_o.</i> 	
6.	<p>Kualiti Imej (Penilaian Subjektif) <i>Image Quality (Subjective Assessment)</i></p> <p>i) Skala kelabu <i>Grey scale</i></p> <p>ii) Resolusi penghad <i>Limiting resolution</i></p> <p>iii) Objek penguji kontras rendah (pada kadar kerma udara dalam julat 0.3 – 1.0 $\mu\text{Gy/s}$). Keputusan ditentukan melalui graf <i>Low contrast test object (at air kerma rates in the range 0.3 1.0 $\mu\text{Gy/s}$). Results obtained graphically</i></p> <p>iv) Butir-butir minima yang kelihatan <i>Minimum visible details</i></p>	<p>Bintik hitam dan bintik putih dan kesemua daripada 10 'step wedge' hendaklah dapat dilihat <i>A black spot and white spot and all ten steps of the step wedge should be visible</i></p> <ul style="list-style-type: none"> ▪ medan 36cm: 0.9 – 1.0 pasang garis/mm <i>36 cm field: 0.9 – 1.0 line pairs/mm</i> ▪ medan 30cm: 1.12 pasang garis/mm <i>30cm field: 1.12 line pairs/mm</i> ▪ medan 23 cm: 1.2 pasang garis/mm <i>23cm field: 1.2 line pairs/mm</i> ▪ medan 15 cm: 1.6 pasang garis/mm <i>15cm field: 1.6 line pairs/mm</i> <ul style="list-style-type: none"> • medan 36cm: 4% <i>36cm field: 4%</i> • medan 30cm: 3.5% <i>30cm field: 3.5%</i> • medan 23 cm: 2.7% <i>23cm field: 2.7%</i> • medan 15 cm: 1.9% <i>15cm field: 1.9%</i> <p>Perbandingan grafik <i>Graphical comparison</i></p>	Separah tahunan <i>Semi-annually</i>
7.	<p>Jarak Minima Fokus Ke Permukaan Kulit <i>Minimum Focus to Skin Entrance Distance</i></p>	<p>i) Sokongan pesakit berada tetap di antara tiub x-ray dan pesakit <i>Patient support permanently between x-ray tube and patient</i></p> <ul style="list-style-type: none"> ▪ Tiub x-ray bawah-meja: 400mm antara titik fokus tiub x-ray dan sokongan pesakit <i>Undertable x-ray tube: 400mm between x-ray tube focal spot and patient support</i> ▪ Tiub x-ray atas-meja: 700mm antara titik fokus tiub x-ray dan sokongan pesakit <i>Overtable x-ray tube: 700mm between x-ray tube focal spot and patient support</i> 	Tahunan <i>Annually</i>

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
		<p>ii) Sokongan pesakit berada secara tetap atau tidak pada bim x-ray berguna <i>Patient support may or may not be permanently in the useful x-ray</i></p> <ul style="list-style-type: none"> ▪ Alat C-arm bergerak: 200mm antara titik fokus tiub x-ray dan kulit pesakit <i>Mobile C-arm: 200mm between x-ray tube focal spot and patient's skin</i> ▪ Radas fluoroskopi yang lain: 700 mm antara titik fokus tiub x-ray dan permukaan input bagi intensifier imej <i>Other fluoroscopic apparatus: 700 mm between x-ray tube focal spot and input surface of the image intensifier</i> <p>Dalam operasi fluoroskopi bergerak, jarak antara fokus tiub x-ray dan permukaan pesakit hendaklah sejauh mungkin secara praktikal dan sebaiknya kurang daripada 300mm <i>In operating a mobile fluoroscopic x-ray apparatus, the distance between the x-ray tube focus and the patient entrance surface should be as large as practicable and preferably not less than 300mm</i></p>	
8.	Kadar Dos Input Intensifier Imej <i>Image Intensifier Input Dose Rate</i>	Kadar dos maksima <i>Maximum dose rate</i> <ul style="list-style-type: none"> ▪ 120μGy/min bagi saiz medan 11cm hingga < 14cm <i>120μGy/min for field size of 11cm to < 14cm</i> ▪ 90μGy/min bagi saiz medan 14cm hingga < 23cm <i>90μGy/min for field size of 14cm to < 23cm</i> ▪ 60μGy/min bagi saiz medan \geq 23cm <i>60μGy/min for field size of \geq 23cm</i> 	Tahunan Annually
9.	Had Kadar Dos Ke Permukaan Kulit <i>Entrance Surface Dose Rate Limits</i>	<ul style="list-style-type: none"> ▪ Dengan AEC: < 100mGy seminit <i>With AEC: < 100mGy per minute</i> ▪ Tanpa AEC: < 50mGy seminit <i>Without AEC: < 50mGy seminit</i> 	

Jadual 5: Standard dan Kriteria Prestasi dan Keselamatan Bagi Peralatan Mamografi dan Kemudahan Berkaitan

Table 5: Performance and Safety Standards and Criteria for Mammography Equipment and Associated Facilities

Bil No	Parameter Parameters	Standard Optima Optimum Standard	Kekerapan Frequency
1.	Generator X-Ray <i>X-Ray Generator</i> i) Kejituan kVp <i>Accuracy of kVp</i> ii) Kebolehulangan <i>Reproducibility</i>	Sisihan maksima: $\pm 5\%$ daripada nilai nominal kVp <i>Maximum deviation: $\pm 5\%$ of nominal kVp</i> Variasi koefisien bagi kVp: < 0.02 <i>kVp coefficient of variation: < 0.02</i>	Separuh tahunan <i>Semi-annually</i>
2.	Penilaian Pengkolimatan <i>Collimation Assessment</i>	Ketidakajaran maksima: 2% daripada jarak antara sumber-imej <i>Maximum misalignment: 2% of source-image distance (SID)</i>	
3.	Kebocoran Sinaran <i>Radiation Leakage</i> i) 1 m daripada fokus <i>1 m from the focus</i> ii) 30 cm daripada fokus pada kedudukan sisi 'chest wall' pengkolimat <i>30 cm from focus on chest wall side of collimator</i>	$\leq 1\text{mGy/h}$ $\leq 10\mu\text{Gy}/100\text{mAs}$	Tahunan <i>Annually</i>
4.	Pengukuran Saiz Titik Fokus <i>Focal spot Size Measurement</i>	F_{perp} atau or $F_{\text{parallel}} \leq 2.0 \times F_{\text{nom}}$	Penerimaan <i>Acceptance</i>
5.	Pengukuran Kualiti Bim (HVL) <i>Beam Quality (HVL) Measurement</i>	Nilai HVL diukur $< \text{kVp}/100$ (dalam mm Al) atau nilai HVL diukur $< \text{kVp}/100 + 0.1$ (dalam mm Al) <i>Measured HVL $< \text{kVp}/100$ (in mm Al) or measured HVL $< \text{kVp}/100 + 0.1$ (in mm Al)</i>	Penerimaan <i>Acceptance</i>
6.	Prestasi Sistem Kawalan Dedahan Automatik (AEC) <i>Automatic Exposure Control (AEC) System Performance</i> i) Kebolehulangan <i>Reproducibility</i> ii) Keupayaan prestasi <i>Performance capability</i> iii) Fungsi kawalan densiti <i>Density control function</i>	Variasi koefisien mAs atau O.D < 0.5 <i>Coefficient of variation for mAs or O.D < 0.5</i> Julat O.D $< \pm 0.3$ daripada purata O.D <i>O.D range $< \pm 0.3$ of mean O.D</i> mAs dan O.D hendaklah meningkat dengan peningkatan 'setting' densiti <i>mAs and O.D. should increase as density setting is increased</i>	Separuh tahunan <i>Semi-annually</i>

Jadual 7: Keperluan Lapisan Separuh-Nilai (HVL)
 Table 7: Half-Value Layer Requirement (HVL)

Julat operasi voltan tiub <i>Tube voltage operating range</i>	Keupayaan operasi diukur <i>Measured operating potential</i>	Lapisan separuh-nilai (HVL) minima (mm Al) <i>Minimum HVL (mm Al)</i>
Di bawah 50 kVp <i>Below 50 kVp</i>	30	0.3
	40	0.4
	49	0.5
50 kVp hingga 70 kVp <i>50 kVp to 70 kVp</i>	50	1.2
	60	1.3
	70	1.5
70 kVp keatas <i>Above 70 kVp</i>	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

Jadual 8: Keadaan Sistem Pemprosesan
 Table 8: Processing Conditions

Bil No	Parameter-parameter <i>Parameters</i>	Standard Optima <i>Optimum Standard</i>	Kekerapan <i>Frequency</i>
1.	Keadaan bilik gelap <i>Condition of the darkroom</i>	Tiada kebocoran cahaya <i>No light leakage</i>	Tahunan <i>Annually</i>
2.	Keadaan kesemua kaset <i>Conditions of all the cassettes</i>	<ul style="list-style-type: none"> Tiada kebocoran cahaya <i>No light leakage</i> Filem dan skrin hendaklah bersentuhan dengan baik <i>Film and screen should be in good contact</i> 	Tahunan <i>Annually</i>
3.	Sensitometri <i>Sensitometry</i>	<ul style="list-style-type: none"> Indeks base + fog hendaklah kurang daripada 0.25 O.D. <i>Base + fog index should be less than 0.25 O.D.</i> Variasi indeks kelajuan hendaklah kurang daripada 10% <i>Variation of speed index should be less than 10%</i> Variasi bagi indeks kontras hendaklah kurang daripada 10% setiap hari <i>Variation of contrast index should be less than 10% daily</i> 	Harian <i>Daily</i>