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Pengarah
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Semua Pemegang Lesen (Kelas C, Kelas A&C dan Kelas H)
Di bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304)
Bagi Maksud Perubatan

YBhg. Datuk/ Dato'/ Datin/ Tuan/ Puan,

PINDAAN MANUAL PELAKSANAAN PROGRAM PENJAMINAN MUTU (QUALITY ASSURANCE PROGRAM-QAP) DALAM PERKHIDMATAN RADIOLOGI DI BAWAH AKTA PERLESENAN TENAGA ATOM 1984 (AKTA 304) BAGI MAKSUD PERUBATAN

Dengan hormatnya merujuk perkara di atas.

2. Untuk makluman YBhg. Datuk/ Dato'/ Datin/ Tuan/ Puan, terdapat beberapa penambahbaikan telah dibuat dalam dokumen "Manual Pelaksanaan Program Jaminan Kualiti (QAP) dalam Perkhidmatan Radiologi di Bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304) bagi Maksud Perubatan" yang telah diedarkan sebelumnya melalui surat bertarikh 18 Januari 2019. Pindaan pada manual QAP adalah hasil maklum balas daripada perlaksaan manual serta hasil perbincangan dan persetujuan ahli mesyuarat Jawatankuasa Induk Pelaksanaan Program Jaminan Kualiti (QAP) Dalam Perkhidmatan Radiologi Peringkat Kebangsaan Bil. 1/2023 yang telah diadakan pada 12 Julai 2023 yang lepas. Sila rujuk **Lampiran 1.**

3. Sehubungan itu, sukacita bersama-sama ini dilampirkan "Manual Pelaksanaan Program Jaminan Kualiti (QAP) dalam Perkhidmatan Radiologi di Bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304) bagi Maksud Perubatan (Versi Pindaan September 2023) yang telah dibuat pindaan.

..2/-

4. YBhg. Datuk/ Dato'/ Datin/ Tuan/ Puan diminta untuk melaksanakan Program Jaminan Kualiti (QAP) mengikut Versi Pindaan September 2023 tersebut sebelum pindaan ini dikuatkuasakan kelak.

5. Sekiranya terdapat sebarang pertanyaan lanjut berhubung perkara ini, sila hubungi Bahagian Kawalselia Radiasi Perubatan, KKM di talian 03-8892 4727 atau faks 03-8892 4746.

Kerjasama YBhg. Datuk/ Dato'/ Datin/ Tuan/ Puan amatlah dihargai.

Sekian, terima kasih.

"MALAYSIA MADANI"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DATUK DR. MUHAMMAD RADZI ABU HASSAN)

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		Pindaan pada Indikator 4.1 (Jadual 1(2)): *Standard* bagi Peratus Penolakan Filem atau Imej Radiografi Am telah bertukar dari < 2.5% kepada < 5%
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MANUAL PELAKSANAAN PROGRAM JAMINAN KUALITI (QAP) DALAM PERKHIDMATAN RADIOLOGI

Disediakan oleh:
Kumpulan Kerja Pelaksanaan Program Jaminan Kualiti Dalam Perkhidmatan Radiologi Di Bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304)
Kementerian Kesihatan Malaysia
Pindaan: September 2023

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1. PENGENALAN

Pelaksanaan Program Jaminan Kualiti (*Quality Assurance Programme - QAP*) bertujuan untuk memastikan pesakit, keluarga dan komuniti mendapat faedah daripada perkhidmatan yang disediakan pada tahap yang optima dengan sumber yang sedia ada. Selain itu, QAP juga dapat meningkatkan kualiti, kecekapan dan keberkesanan perkhidmatan kesihatan serta memudahkan penilaian kualiti perkhidmatan supaya lebih terancang dan sistematik. QAP dianggap sebagai satu *tool* untuk memantau tahap kualiti perkhidmatan merangkumi aspek penjagaan, pengurusan pesakit, penggunaan sumber dan kepuasan pelanggan untuk mencapai kualiti yang ditetapkan.

Dalam konteks penggunaan radiasi perubatan bagi tujuan pengimejan, pelaksanaan QAP merupakan langkah seiringan di antara kepatuhan tahap keselamatan dan perlindungan radiasi dengan kualiti perkhidmatan. Dengan lain perkataan, tahap kualiti perkhidmatan radiologi yang disediakan akan mempengaruhi kepatuhan keselamatan dan perlindungan radiasi serta keperluan perundangan berkaitan. Maka dengan sebab itu, berdasarkan "Peraturan 53(1) dalam Peraturan-peraturan Perlesenan Tenaga Atom (Perlindungan Sinaran Keselamatan Asas) 2010", QAP menjadi salah satu keperluan mandatori bagi pematuhan keselamatan dan perlindungan radiasi iaitu:

"53(1). *Pemegang lesen atau orang bertanggungjawab hendaklah mewujudkan suatu program jaminan kualiti yang komprehensif bagi dedahan perubatan dengan penglibatan pakar berkelayakan yang sesuai dalam bidang yang berkaitan sebagaimana yang dinyatakan oleh pihak berkuasa yang berkenaan."*

Program QAP dalam perkhidmatan radiologi di Kementerian Kesihatan Malaysia (KKM) telah mula diperkenalkan pada tahun 1985. Jawatankuasa Pemandu (*Steering Committee*) telah ditubuhkan bagi menyelaras pelaksaaan program tersebut yang mana turut melibatkan perkhidmatan farmasi dan patologi. Pelaksanaan QAP bagi perkhidmatan radiologi telah menetapkan beberapa elemen seperti berikut:

- Kawalan kualiti peralatan penyinaran dan kemudahan berkaitan;
- Indikator analisa kadar penolakan filem iaitu *"film reject rate analysis";*
- Pendidikan Perubatan Secara Berterusan (*Continuous Medical Education* - CME) bagi personel.

Pelaksanaan QAP dalam perkhidmatan hospital KKM telah mula dilaksanakan pada tahun 1987 membabitkan sebanyak 14 hospital negeri dan 2 hospital daerah. Pada tahun 1989, pelaksanaan QAP ini seterusnya diperluaskan kepada hospital-hospital daerah di seluruh negara. Pengumpulan data-data indikator penolakan filem daripada hospital negeri telah mula dilaksanakan sejak Julai 1987 manakala bagi hospital daerah pula, ianya dimulakan sejak Julai 1989. Analisa daripada indikator-indikator tersebut mendapati terdapat pelbagai faktor yang menjadi punca penolakan. Di antara punca-punca penolakan adalah disebabkan oleh faktor manusia (*human factor*) dan prestasi peralatan. Hasil penemuan tersebut boleh menjadi asas kepada penambahbaikan terhadap sebarang punca-punca berkaitan.

Pada tahun 1999, KKM telah menjadikan QAP sebagai keperluan mandatori kepada fasiliti perubatan kerajaan dan swasta melalui pengeluaran pekeliling surat Ketua Pengarah Kesihatan (KPK) iaitu "Pekeliling Mengenai Keperluan Tambahan Perlesenan Di Bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304) Bagi Perkhidmatan Radiologi Diagnostik Yang Diberikan Oleh Institusi-institusi Perubatan Swasta". Susulan itu, KKM turut mengeluarkan pekeliling "Pekeliling Keperluan Tambahan Perlesenan Di Bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304)" kepada Timbalan Ketua Pengarah Kesihatan (Perubatan), Timbalan Ketua Pengarah Kesihatan (Kesihatan Awam) dan Pengarah Perancangan dan Pembangunan yang mewajibkan fasiliti perubatan kerajaan mematuhi Akta 304 termasuk pelaksanaan QAP. Program QAP ini juga turut diperluaskan dalam perkhidmatan klinik kesihatan di bawah penyelarasan Bahagian Pembangunan Kesihatan Keluarga, KKM.

Indikator analisa kadar penolakan filem ini masih digunapakai dalam pelaksanaan QAP perkhidmatan radiologi diagnostik sehingga kini. Malahan beberapa fasiliti perubatan telah mengamalkan kadar peratusan penolakan daripada 10% kepada 5% memandangkan terdapat peningkatan tahap kualiti perkhidmatan. Namun begitu, sejajar dengan perkembangan teknologi dan amalan perubatan terkini, penggunaan peranti pengimejan secara konvensional telah digantikan dengan peranti pengimejan digital dari semasa ke semasa. Oleh itu, indikator analisa kadar penolakan filem sediada perlu dikaji semula berdasarkan penggunaan pemprosesan imej secara digital. Di samping itu, pelaksanaan QAP perlu diperluaskan kepada radas penyinaran selain radiografi am seperti tomografi berkomputer (*CT Scanner*), fluoroskopi dan radiologi intervensional (*interventional radiology*).

Sehubungan itu, dokumen "Manual Pelaksanaan Program Jaminan Kualiti (QAP) dalam Perkhidmatan Radiologi" ini diwujudkan sebagai panduan kepada fasiliti perubatan untuk melaksanakan QAP dalam perkhidmatan radiologi mengambilkira beberapa modaliti selain daripada radiografi am dan peranti digital. Pengeluaran manual ini diharap dapat membantu fasiliti perubatan terbabit mencapai objektif pelaksanaan QAP dalam perkhidmatan radiologi secara menyeluruh dan berkesan.

Adalah diharapkan komuniti perubatan yang terlibat dalam memberikan perkhidmatan radiologi di negara ini tidak menganggap keperluan ini hanya bertujuan untuk memenuhi keperluan perlesenan dan perundangan semata-mata malahan yang lebih penting daripada itu ianya merupakan sebagai salah satu program peningkatan kualiti secara berterusan di kalangan personel. Usaha ini diharap dapat mencapai objektif pelaksanaan QAP secara menyeluruh dan berkesan serta membudayakan keselamatan radiasi "radiation *safety culture"* sepertimana disarankan oleh *International Atomic Energy Agency* (IAEA) dan *World Health Organization* (WHO) serta memenuhi kepentingan dasar dan polisi KKM.

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2. OBJEKTIF PELAKSANAAN QAP

Objektif pelaksanaan QAP dalam perkhidmatan radiologi adalah:

i. Mempertingkatkan kualiti perkhidmatan radiologi;
ii. Memastikan penggunaan sinaran mengion yang optimum untuk menghasilkan imej yang berkualiti;
iii. Memastikan penggunaan sumber secara efektif;
iv. Memenuhi dan mematuhi keperluan regulatori dan perundangan berkaitan di bawah Akta Perlesenan Tenaga Atom 1984.

3. SKOP PELAKSANAAN QAP

Skop pelaksanaan QAP bagi semua fasiliti perubatan yang mempunyai radas penyinaran merangkumi perkara-perkara berikut:

3.1 Justifikasi Pemeriksaan Pesakit

i. Dedahan radiasi perubatan hendaklah dijustifikasikan dengan mempertimbangkan faedah diagnostik atau terapeutik yang dihasilkan oleh dedahan itu mengambil kira faedah dan risiko dedahan.
ii. Perlu memastikan maklumat sejarah klinikal pesakit, soalan-soalan berkaitan klinikal/ diagnosis, kesesuaian pemeriksaan disertakan dan tiada kontra indikasi untuk menjalankan pemeriksaan berkenaan.
iii. Sebagai langkah alternatif, teknik yang tidak melibatkan sinaran mengion mungkin boleh memberikan maklumat yang diperlukan. Langkah di atas juga adalah bagi mengelakkan pemeriksaan kes berulangan yang sama/ tidak diperlukan.

3.2 Perancangan Prosedur

i. Perancangan prosedur perlu dilakukan untuk memastikan pesakit menerima dedahan radiasi perubatan yang bersesuaian dan bertepatan dengan jenis penyakit bagi mengelakkan dedahan tidak perlu (*unnecessary exposure*).
ii. Ini juga merangkumi memastikan identiti pesakit, jenis pemeriksaan dan prosedur persediaan pesakit adalah betul.

3.3 Prosedur Pemeriksaan

i. Memastikan prinsip perlindungan sinaran perlu diamalkan setiap masa.
ii. Pemeriksaan perlu dilaksanakan mengikut konsep pengoptimuman iaitu "*As Low As Reasonably Achievable* (ALARA)". Penggunaan konsep ini memastikan dedahan radiasi kepada pesakit adalah serendah munasabah bagi menghasilkan imej berkualiti diagnostik.
iii. Faktor dedahan radiasi perubatan dedahan yang ditetapkan perlu mencapai objektif klinikal iaitu penghasilan imej yang berkualiti.
iv. Tindakan perlu ditentukan berdasarkan aras rujukan diagnostik (*Diagnostic Reference Level* - DRL) yang ditetapkan bagi mengelakkan kejadian *accidental medical exposure* kepada pesakit terlibat.

v. Bagi dedahan yang jatuh dengan banyaknya di bawah aras rujukan diagnostik, tindakan pembetulan perlu mengambilkira kualiti penghasilan imej samada boleh memberikan maklumat diagnosis yang berguna (*useful diagnostic information*). Bagi dedahan radiasi perubatan yang melebihi aras rujukan diagnostik, penyiasatan untuk penambahbaikan perlu dijalankan bagi memastikan perlindungan optimum terhadap pesakit dan mengekalkan aras amalan yang baik.

vi. Data-data dosimetri klinikal setiap radas penyinaran perlu ditentukan dan didokumenkan untuk memastikan pematuhan terhadap keperluan di atas.

3.4 Latihan dan Pengalaman

i. Semua personel yang terlibat seperti pakar radiologi, ahli fizik perubatan, juru X-ray dan lain-lain personel adalah berkelayakan dan mempunyai pengalaman yang sesuai.

ii. Semua personel yang terlibat juga perlu menghadiri latihan CME pada setiap tahun bagi meningkatkan pengetahuan dan pengalaman.

3.5 Laporan

i. Laporan radiologi yang disediakan adalah disarankan merangkumi data pesakit dan pemeriksaan, perbandingan imej dan laporan terdahulu (yang berkaitan), penemuan dan keputusan pemeriksaan dan nasihat lanjutan (jika berkaitan).

3.6 Audit

i. Aktiviti audit adalah penting dalam pelaksanaan QAP bagi mengenalpasti kelemahan/ ketidakpatuhan.

ii. Sebarang ketidakpatuhan berlaku akan diambil tindakan pencegahan dan penambahbaikan bagi mempertingkatkan kualiti perkhidmatan.

3.7 Pemantauan Pelaksanaan Program

i. Pelaksanaan QAP yang berkesan dapat ditentukan melalui faktor-faktor seperti keberhasilan klinikal (*clinical outcome)* dan dos dedahan radiasi perubatan.

ii. Pencapaian pelaksanaan program dapat diukur melalui indikator-indikator seperti di Jadual 1.

4. PELAKSANAAN QAP DI BAWAH AKTA 304

Pelaksanaan QAP hendaklah merangkumi elemen-elemen yang diwajibkan seperti berikut:

4.1 INDIKATOR

Indikator QAP sediada iaitu analisa kadar penolakan filem masih digunapakai dalam perkhidmatan radiologi sehingga kini. Kadar peratusan penolakan radiografi am dikurangkan dari 10% kepada 2.5% bagi meningkatkan tahap kualiti perkhidmatan. Bagi memperluaskan pelaksanaan QAP, indikator-indikator baru melibatkan radiografi digital, radiografi berkomputer, fluoroskopi, tomografi berkomputer dan mammografi diwujudkan. Maklumat lanjut mengenai indikator adalah seperti di Jadual 1.

Jadual 1: Senarai Indikator bagi Pelaksanaan QAP ***(List of Indicators for the QAP Implementation)***

Bil.	Modaliti	Indikator	Standard	Rujukan
1.	Radiografi Am *General Radiography*	Peratus Penolakan Radiografi Am *Percentage of Radiographs Rejected*	≤ 5%	Lampiran 1 Lampiran 1A *Appendix 1* *Appendix 1A*
2.	Radiografi Digital *Digital Radiography*	Peratus Penolakan Filem atau Imej Radiografi Am *Percentage of Radiographs Rejected/ Retake*	≤ 5%	Lampiran 2 Lampiran 2A *Appendix 2* *Appendix 2A*
3.	Fluoroskopi *Fluoroscopy*	Peratus Prosedur Fluoroskopi Intervensi yang mana Dos Pesakit Melebihi Aras Rujukan Diagnostik Malaysia (*Malaysian Diagnostic Reference Level* - DRL) *Percentage of Fluoroscopic Procedures Where Patient Dose Exceed the Malaysian Diagnostic Reference Level (DRL)*	≤20%	Lampiran 3 Lampiran 3A Lampiran 3B *Appendix 3* *Appendix 3A* *Appendix 3B*
4.	Tomografi Berkomputer *Computed Tomography*	Peratus Pemeriksaan CT Otak Biasa yang mana *Dose Length Product* (DLP) Melebihi Aras Rujukan Diagnostik (*Diagnostic Reference Level* - DRL) *Percentage of Plain CT Brain Examination Where Dose Length Product (DLP) Exceed Malaysian Diagnostic Reference Level (DRL)*	≤ 10% yang melebihi nilai DRL. (Nilai DLP bagi pemeriksaan CT Otak ialah 1050 mGy.cm.) *≤10% exceed DRL values (The DLP value for CT Brain examination is 1050 mGy.cm).*	Lampiran 4 Lampiran 4A Lampiran 4B *Appendix 4* *Appendix 4A* *Appendix 4B*

5.	Mammografi *Mammography*	Peratus Penolakan Filem atau Imej Mammografi *Percentage of Rejected Mammography Films or Images*	< 3 %	Lampiran 5 Lampiran 5A Lampiran 5B Lampiran 5C Lampiran 5D *Appendix 5* *Appendix 5A* *Appendix 5B* *Appendix 5C* *Appendix 5D*

4.2 KAWALAN KUALITI (*QC*) RADAS PENYINARAN DAN KEMUDAHAN BERKAITAN

Semua radas penyinaran dan kemudahan berkaitan perlu menjalani ujian kawalan kualiti (*Quality Control - QC*) bagi memastikan pematuhan terhadap standard prestasi dan keselamatan sinaran yang ditetapkan. Pelaksanaan *QC* bagi radas penyinaran dan kemudahan berkaitan adalah termasuk ujian penerimaan (*acceptance test*) dan pentauliahan *(commissioning*). Ujian penerimaan dan pentauliahan perlu dijalankan bersama pembekal setelah peralatan dipasang. Selain memastikan bahawa prestasi peralatan memenuhi spesifikasi yang ditetapkan, ujian pentauliahan perlu dilakukan bagi mendapatkan data rujukan asas (*baseline data*).

Ujian *QC* bagi radas penyinaran dan kemudahan berkaitan hendaklah dilaksanakan secara berkala bagi mematuhi keperluan piawaian prestasi dan keselamatan sinaran seperti di **Lampiran 6**. Sijil pengujian kawalan kualiti berserta laporan ujian yang telah disahkan oleh juruperunding fizik perubatan hendaklah dikemukakan setiap tahun bagi memenuhi keperluan pihak berkuasa KKM. Pengujian ini termasuk melibatkan kerja-kerja selepas pembaikan atau pertukaran sebarang komponen peralatan yang boleh menjejaskan fungsi dan prestasi peralatan serta kemudahan berkaitan. Di samping itu, peralatan pengukuran sinaran hendaklah dipastikan ditentukur secara berkala.

Kerja-kerja pembaikan perlu dijalankan sekiranya prestasi radas penyinaran dan kemudahan berkaitan tidak mematuhi spesifikasi atau/ dan piawaian yang ditetapkan. Ujian *QC* hendaklah dijalankan dan laporan berkaitan disahkan oleh juruperunding fizik perubatan yang diiktiraf oleh pihak berkuasa KKM.

4.3 AUDIT RADIOGRAF

Semua fasiliti perubatan yang mempunyai perkhidmatan radiologi perlu menjalankan audit radiograf. Kriteria dan standard pengauditan tersebut adalah seperti di Jadual 2.

Jadual 2: Senarai Audit Radiograf bagi Pelaksanaan QAP
(List of Audit Radiographs for QAP Implementation)

<table>
<tr><th>Bil</th><th>Modaliti</th><th>Audit Radiograf</th><th>Standard</th></tr>
<tr><td>i.</td><td>Radiografi Am
General Radiography</td><td>Audit Kualiti Radiograf
Audit on the Quality of Radiographs</td><td>Markah keseluruhan perlu sekurang-kurangnya 80% dengan pecahan berikut mengikut kategori.

Bagi setiap radiograf, 80% adalah skor lulus.
<table>
<tr><th>Jenis Premis</th><th>Jenis Pemeriksaan</th><th>Minimum Markah Lulus Untuk Setiap Radiograf</th><th>Bilangan Minimum Radiograf untuk lulus</th><th>Rujukan</th></tr>
<tr><td rowspan="2">Klinik Pengamal Perubatan Swasta</td><td>Dada Dewasa</td><td>12 dari 15 Kriteria</td><td rowspan="2">8 dari 10 Radiograf</td><td rowspan="2">Lampiran 7
Lampiran 7A
Lampiran 7B
Lampiran 7C</td></tr>
<tr><td>Ekstrimiti/ Lumbar-Dewasa</td><td>8 dari 10 Kriteria</td></tr>
<tr><td rowspan="2">Klinik Kesihatan</td><td>Dada Dewasa</td><td>12 dari 15 Kriteria</td><td>8 dari 10 Radiograf</td><td rowspan="2">Lampiran 7
Lampiran 7A
Lampiran 7B
Lampiran 7C</td></tr>
<tr><td>Ekstrimiti/ Lumbar-Dewasa</td><td>8 dari 10 Kriteria</td><td>8 dari 10 Radiograf</td></tr>
<tr><td rowspan="4">Semua Hospital/ Institusi Perubatan</td><td>Dada Dewasa</td><td>12 dari 15 Kriteria</td><td>12 dari 15 Radiograf</td><td rowspan="4">Lampiran 7
Lampiran 7A
Lampiran 7B
Lampiran 7C
Lampiran 7D
Lampiran 7E</td></tr>
<tr><td>Ekstrimiti/ Lumbar-Dewasa</td><td>8 dari 10 Kriteria</td><td>12 dari 15 Radiograf</td></tr>
<tr><td>Dada Neonate</td><td>16 dari 20 Kriteria</td><td rowspan="2">8 dari 10 Radiograf</td></tr>
<tr><td>Abdomen Neonate</td><td>8 dari 10 Kriteria</td></tr>
</table>
</td></tr>
</table>

The total score should be a minimum of 80% with the following breakdown according to categories.

For each radiograph, 80% is the passing score.

Type of Premises	Type of Exami-nations	Minimum Passing Criteria for Each Radiograph	Minimum Numbers of Radiographs to Pass	*Reference*
Private Medical Practition-er (GP's) / Clinics	Adult Chest	12 out of 15	8 out of 10	*Appendix 7 Appendix 7A Appendix 7B Appendix 7C*
	Extremity / Lumbar	8 out of 10		
Health Clinics	Adult Chest	12 out of 15	8 out of 10	*Appendix 7 Appendix 7A Appendix 7B Appendix 7C*
	Adult Extremity / Lumbar	8 out of 10	8 out of 10	
All Hospital /Medical Institution	Adult Chest	12 out of 15	12 out of 15	*Appendix 6 Appendix 6A Appendix 6B Appendix 6C Appendix 6D Appendix 6E*
	Adult Extremity / Lumbar	8 out of 10	12 out of 15	
	Neonatal Chest	16 out of 20	8 out of 10	
	Neonatal Abdomen	8 out of 10		

ii. Mammografi
Mammography

Kategori PGMI / klasifikasi imej mammogram
PGMI categorization / classification of mammogram images

Kriteria	Standard	Rujukan
Kategori imej yang berstatus P, G, M	>97%	Lampiran 7 Lampiran 7A
Kategori imej yang berstatus P dan G	>50% (75% dipertimbangkan)	
Kategori imej yang berstatus I (Inadequate)	< 3%	

Setiap kes mesti memenuhi standard di atas.

Criteria	*Standard*	*Reference*
Images with P, G, M categories	>97%	*Appendix 7 Appendix 7A*
Images with P and G categories	>75%	
Images with I (Inadequate)	< 3%	

Each case shall satisfy the above standards

4.4 PENDIDIKAN PERUBATAN SECARA BERTERUSAN (*CONTINUOUS MEDICAL EDUCATION*)

Semua personel hendaklah menghadiri program pendidikan perubatan secara berterusan (*Continuous Medical Education* - CME) yang diiktiraf oleh pihak berkuasa KKM di bawah Akta 304 setiap tahun untuk meningkatkan pengetahuan dan kompetensi. Tempoh latihan minimum adalah 4 jam terkumpul setahun dan mengandungi mana-mana topik berkaitan seperti berikut:

i. Perundangan dan Peraturan Berkaitan Akta 304
ii. Kesedaran Keselamatan Sinaran
iii. Pengurusan Program Penjaminan Kualiti
iv. Peralatan X-ray dan Kemudahan-Kemudahan Berkaitan
v. Amalan-Amalan Klinikal dan Hubung Kait Radiologi
vi. Kehendak-Kehendak dan Kriteria Kualiti Imej
vii. Interpretasi Imej-Imej Klinikal
viii. Perkembangan Terkini Berkaitan Modaliti dan Perlindungan Sinaran

Bukti kehadiran kursus seperti sijil/ senarai kehadiran yang disahkan oleh penganjur/ ketua jabatan hendaklah direkod dan dikemukakan kepada pihak berkuasa KKM. Maklumat terperinci mengenai CME adalah seperti di **Lampiran 8.**

5. PENGURUSAN REKOD

Rekod-rekod berkaitan dengan indikator-indikator, ujian QC, audit radiograf, CME dan lain-lain yang berkaitan hendaklah diurus dan disimpan mengikut tempoh yang ditetapkan oleh pihak berkuasa iaitu tujuh tahun.

6. PEMANTAUAN PELAKSANAAN QAP

Pelaksanaan QAP akan dipantau oleh pihak berkuasa KKM bagi memastikan ianya dilaksanakan secara berkesan. Carta alir pemantauan pelaksanaan QAP adalah seperti di **Lampiran 9**. Laporan penilaian audit dan indikator QAP hendaklah dihantar kepada JKN sebelum atau pada 31 Januari setiap tahun bagi memenuhi keperluan semasa pihak berkuasa KKM.

7. DEFINISI

Dalam manual ini, melainkan jika konteksnya mengkehendaki makna yang lain:

Ahli Fizik Perubatan	Seorang yang telah menjalani latihan yang sesuai dalam penggunaan prinsip-prinsip fizik dalam pengimejan dan/ atau radiasi terapi dan didaftarkan sebagai seorang ahli fizik perubatan yang diluluskan oleh pihak berkuasa yang berkenaan.
Aras Rujukan Diagnostik (DRL)	Satu bentuk tahap penyiasatan dos sinaran pesakit atau aktiviti yang diberikan (jumlah bahan radioaktif) untuk prosedur spesifik digunakan dalam pengimejan perubatan, untuk menunjukkan sama ada, dalam keadaan rutin, dos pesakit atau aktiviti yang diberikan adalah luar biasa tinggi atau rendah untuk prosedur spesifik tersebut.
Data Rujukan Asas *(baseline data)*	Satu nilai yang diperolehi semasa ujian pentauliahan yang digunakan sebagai rujukan untuk perbandingan dengan nilai keputusan ujian prestasi rutin yang dilakukan secara berkala.
Fasiliti Perubatan	Premis yang menyediakan perkhidmatan perubatan dan kesihatan merangkumi klinik serta hospital kerajaan dan swasta.
Fizik Perubatan	Bidang pengkhususan yang melibatkan penggunaan dan pemakaian fizik dalam perubatan.
Indikator	Sesuatu perkara yang telah dirancang, dipersetujui dan dilaksanakan untuk mengenalpasti tahap kualiti bagi perkhidmatan yang diberi.
Juru X-ray Diagnostik	Seorang yang melakukan prosedur sinaran mengion dan sinaran tak mengion bagi tujuan perubatan, untuk mana-mana bahagian tubuh badan manusia, bagi tujuan diagnostik. Juru X-ray diagnostik hendaklah mempunyai kelayakan yang diiktiraf dalam radiografi atau pengimejan perubatan atau lain-lain bidang yang berkaitan yang diluluskan oleh pihak berkuasa yang berkenaan.
Kawalan Kualiti (QC)	Proses kawal selia di mana prestasi kualiti sebenar diukur, berbanding dengan piawaian/ standard yang sedia ada, dan

	tindakan yang perlu untuk menyimpan atau mendapatkan semula pematuhan dengan piawaian/ standard.
Pakar Radiologi	Seorang pengamal perubatan berdaftar yang telah menamatkan program latihan yang diluluskan oleh pihak berkuasa berkenaan dalam penggunaan modaliti pengimejan yang menggunakan sinaran mengion dan sinaran tak mengion untuk tujuan pemeriksaan, diagnosis dan rawatan.
Pihak Berkuasa KKM	Ketua Pengarah Kesihatan seperti yang dinyatakan dalam Seksyen 2 di bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304).
Program Jaminan Kualiti	Segala yang dirancang dan tindakan sistematik yang perlu untuk memberikan keyakinan bahawa produk atau perkhidmatan yang diberikan memenuhi keperluan tahap kualiti yang ditetapkan.
Radiologi	Satu cabang perubatan yang melibatkan penggunaan sinaran mengion dan sinaran tak mengion untuk tujuan pemeriksaan diagnosis dan rawatan.
Sinaran Mengion	Sinaran elektromagnet atau sinaran zarah yang boleh menyebabkan pengionan dalam perjalanannya melalui jirim.
Ujian Penerimaan *(acceptance test)*	Pemeriksaan bagi tujuan mengenalpasti sesuatu radas yang dipasang/ dibeli adalah boleh diterima. Pemeriksaan ini boleh merangkumi ujian-ujian yang dijalankan selepas pemasangan sesuatu radas untuk mengenalpasti ianya dihasil dan dipasang mengikut spesifikasi teknikal yang dipersetujui; nilai keputusan ujian-ujian ini menjadi nilai rujukan kepada ujian berkala yang akan dijalankan pada masa hadapan bagi menilai prestasi radas.
Ujian Pentauliahan *(commissioning test)*	Satu set ujian yang dijalankan oleh wakil pembeli untuk memastikan bahawa peralatan tersebut telah bersedia untuk kegunaan klinikal dan untuk mewujudkan data rujukan asas bagi membandingkan keputusan ujian prestasi rutin yang berikutnya.

8. SINGKATAN

ALARA	As Low As Reasonably Achievable
AEC	Automatic Exposure Control
COV	Coefficient of Variation
CME	Continuous Medical Education
CR	Computed Radiography
CT	Computed Tomography
CTDI	Computed Tomography Dose Index
DICOM	Digital Imaging and Communications in Medicine
DLP	Dose Length Product
DR	Digital Radiography
DRL	Diagnostic Reference Level
FFDM	Full Field Digital Mammography
FID	Focus Image Distance
GSDF	Grayscale Display Function
HVL	Half Value Layer
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
JKN	Jabatan Kesihatan Negeri
KKM	Kementerian Kesihatan Malaysia
OD	Optical Density
PGMI	Perfect, Good, Moderate, Inadequate
QAP	Quality Assurance Programme
QC	Quality Control
SMPTE	The Society of Motion Picture and Television Engineers
WHO	World Health Organization

9. RUJUKAN

1. Akta Perlesenan Tenaga Atom 1984 (Akta 304)
2. *Family Health Development Division, Ministry of Health Malaysia. 2008. Quality Assurance Programme Manual*
3. Garis Panduan *Malaysian Diagnostic Reference Levels in Medical Imaging (Radiology)*. Rujukan (9) dlm.KKM 153(13/206)Jld.7
4. *Institute of Physics and Engineering in Medicine, 2010. Report 91: Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems*
5. Kementerian Kesihatan Malaysia 1999 : Surat Pekeliling KPK mengenai Keperluan Tambahan Perlesenan Di Bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304) Bagi Perkhidmatan Radiologi Diagnostik Yang Diberikan Oleh Institusi-Institusi Perubatan Swasta. Rujukan (5) dlm.KKM 153(13/172)Bhg.2
6. Kementerian Kesihatan Malaysia. 2001 : Surat Pekeliling Kepada Pengarah (Perancangan & Pembangunan) Mengenai Keperluan Tambahan Perlesenan Di Bawah Akta 304 Bagi Perkhidmatan Radiologi Diagnostik Yang Diberikan Oleh Institusi Perubatan Di Bawah Kementerian Kesihatan Malaysia. Rujukan (27) dlm.KKM 153(13/172)Bhg.2
7. Kementerian Kesihatan Malaysia. 2001 : Surat Pekeliling Kepada TKPK (Perubatan) dan TKPK (Kesihatan Awam) Mengenai Keperluan Tambahan Perlesenan Di Bawah Akta 304 Bagi Perkhidmatan Radiologi Diagnostik Yang Diberikan Oleh Institusi Perubatan Swasta. Rujukan (27) dlm.KKM 153(13/172)Bhg.2
8. *Medical Development Division, Ministry of Health Malaysia. 1999. Quality Manual: National Indicator Approach*
9. *Ministry of Health Malaysia. Quality Assurance-A Problem Solving Approach. (1999)*
10. Peraturan-Peraturan Perlesenan Tenaga Atom (Perlindungan Sinaran Keselamatan Asas) 2010
11. *Report Medical Radiation Exposure Study in Malaysia, Ministry of Health*

PERCENTAGE OF RADIOGRAPHS REJECTED

Programme	:	Radiology
Area of Concern	:	Performance Quality and Radiation Safety of Radiology Services
Indicator	:	Percentage of Radiographs Rejected
Definition of Term	:	Reject radiographs: Any radiograph acquired during radiographic examinations/ radiological procedures that has no diagnostic value and has to be discarded. This refers to radiographs of patients that are assessed by the radiographer or the requesting clinician/ radiologist, to be clinically unacceptable and need to be repeated by the radiographers.
Inclusion Criteria	:	1. Radiographs rejected by radiographers 2. Radiographs rejected by radiologists and clinicians
Exclusion Criteria		1. Radiographs discarded due to testing purposes 2. Radiographs used for quality assurance procedures
Rationale	:	It is a measure of human factor, equipment and miscellaneous faults 1. To keep the radiation dose to patient as low as reasonably achievable (ALARA) 2. Adequate quality control in performing radiological examinations 3. Avoid unnecessary cost to the facility and exposure to the patient 4. To reduce patient's waiting time
Type of Indicator	:	Rate-based indicator
Numerator	:	Total number of radiographs or images rejected or retakes
Denominator	:	Total number of radiographs used or images taken
Calculation of Rate	:	(Numerator ÷ Denominator) x 100%
Standard	:	≤5%
Methodology	:	1. Data collection i.Record in Lampiran 1A Form ii.Each data should be recorded monthly 2. Data analysis Analyse the cause of reject and take remedial action monthly 3. Results have to be recorded in the designated form
Form	:	Lampiran 1A Form: Report of Percentage of Rejected Images
Submission	:	Lampiran 1A: Report shall be sent to JKN before or on January 31 every year to meet the current requirements by the KKM appropriate authority

EXPLANATION TYPE OF ERROR (RADIOGRAPHS REJECTED)

TYPE OF ERROR		EXPLANATION TYPE OF ERROR
HUMAN FAULTS	Over Exposure	1. Radiographs that demonstrate high density (too dark). The bony trabecular pattern and structure of soft tissue in the area of interest are not well visualised. 2. Radiographs that over penetrated – radiographs demonstrate high density. Bony cortical outline of thin and thick structure cannot be seen in the single radiograph.
	Under Exposure	1. Radiographs that demonstrates low density (too light). The bony trabecular pattern and structure of soft tissue in the area of interest are not well visualised. 2. Radiographs that under penetrated – radiographs demonstrate low density. Bony cortical outline of thin and thick structure cannot be seen in the single radiograph
	Double Exposure	There are more than one images in the radiograph. Double exposure results when the receptor/radiographic cassette is exposed more than 1 times, and the images appear superimposed onto each other.
	Wrong Technique	1. Wrong positioning – patient incorrectly position/place, image not true lateral / not true AP 2. Wrong alignment of x ray tube 3. Wrong angulation of x-ray tube 4. Wrong source image distance (SID) 5. Wrong centering point 6. Wrong Region of interest (ROI)
	Wrong Patient/ Exam	1. Wrong patient /wrong patient identification 2. Wrong exam/ wrong request by doctor/clinician (wrong body part/wrong view) 3. Wrong part of examination done
	No Primary/ Wrong Marker	1. No primary marker 2. Wrong marker 3. Marker outside collimation 4. Marker superimposed with Region Of Interest and etc
	Collimation Error	Collimation too small/too big or incorrect which leads to examination part requested to be cut off.
	Patient Movement	1. Image blurring due to patient movement/condition (Uncooperative, restless, Short of breath, rapid breathing (tachypnoea), on ventilator and etc. 2. Anatomical part requested has been cut off because patient move before or during exposure

	Patient Related Artifact	1. Radio opaque material attached/on the patient that include in the radiograph such as underwired bra, key in the pocket, jewellery, coin, belt, hair clip and etc. 2. Artifact due patient clothing, patient hair and etc
EQUIPMENT	Equipment Fault (X-Ray Tube/ Grid/ Bucky)	1. Light Beam Diaphragm fault causing collimation error/ cone cut 2. Alignment problem 3. Electronic failure 4. Collimation knob problem 5. Bucky/ Grid error (grid cut-off) 6. AEC malfunction/problem 7. Electrical fault, and etc.
	Cassette/ Screen Fault	1. Artifact due to cassette /screen 2. Poor screen and film contact 3. Cassette unable to close properly 4. Light leaking from cassette (film fog) and etc.
PROCESSING	Darkroom Fault	1. Light leakage that caused film fogged 2. Faulty safe lighting and etc.
	Film Artifact	1. Electric static artifact 2. Handling fault artifact - finger mark 3. Chemical spot artefact and etc.
	Fogged Film	Fogged film (due to exposed to heat, exposed to light, chemical fogging, exposed to background radiation, film out of date, diachronic fog (brown discoloration) and etc.
	Processor Fault	1. Film stuck in the processor 2. Roller mark 3. Film too dark or too light due to processing fault (chemical concentration to high/over diluted/too long developing time/ too short developing time) and etc.
OTHERS	Miscellaneous.	1. Radiographs rejected due to other than those type of errors mentioned above such 2. Rejected by doctor/clinician due to insufficient diagnostic preference such as ryles tube insertion/ implant monitoring (Orthopedic cases / pediatric cases) and etc.

REPORT OF PERCENTAGE OF RADIOGRAPHS REJECTED

FACILITY : _____

MACHINE MODEL / YEAR OF MACHINE : _____

YEAR OF INSTALLATION : _____

STANDARD : ≤5%

	TYPE OF ERROR	MONTHS												TOTAL	PERCENTAGE (%)
		Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.		
HUMAN FAULTS	1. Over Exposure/ High Index														
	2. Under Exposure/ Low Index														
	3. Double Exposure														
	4. Wrong Technique														
	5. Wrong Patient/ Exam														
	6. No Primary/ Wrong Marker														
	7. Collimation Error														
	8. Patient Movement														
	9. Patient Related Artifact														
EQUIPMENT	10. Equipment Fault (X-ray Tube/ Grid/ Bucky)														
	11. Cassette/ Screen Fault														
PROCESSING	12. Darkroom Fault														
	13. Film Artifact														
	14. Fogged Film														
	15. Processor Fault														

TYPE OF ERROR		MONTHS												TOTAL	PERCENTAGE (%)
		Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.		
OTHERS	16. Miscellaneous. Please specify:.....														
Total number of error															
Total number of radiograph rejected (A)															
Total number of radiograph used (B)															
Percentage (%) (A+B) x 100%															

COMMENT : .....

.....

CORRECTIVE ACTION : .....

.....

Reported by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Supervisor*:
Date:

***Supervisor**: Radiologist, Ketua Juru X-ray atau Orang Yang Bertanggungjawab

PERCENTAGE OF RETAKES FOR DIGITAL RADIOGRAPHY

Programme	:	Radiology
Area of Concern	:	Performance Quality and Radiation Safety of Radiology Services
Indicator	:	Percentage of Retakes for Digital Radiography
Definition of Term	:	1. Non-diagnostic Image: Any digital image acquired during radiographic examinations/ radiological procedures that has no diagnostic value and must be repeated by the radiographers 2. Retake: Repeat exposure to the patient due to earlier non-diagnostic image or rejected by the radiologists and clinicians.
Inclusion Criteria	:	All images that need to be repeated
Exclusion Criteria	:	Exposures done for testing purposes
Rationale	:	It is a measure of human factor, equipment and miscellaneous faults 5. To keep the radiation dose to patient as low as reasonably achievable (ALARA) 6. Adequate quality control in performing radiological examinations 7. Avoid unnecessary cost to the facility and exposure to the patient 8. To reduce patient's waiting time
Type of Indicator	:	Rate-based indicator
Numerator	:	Total number of repeat exposure
Denominator	:	Total number of images
Calculation of Rate	:	(Numerator ÷ Denominator) x 100%
Standard	:	≤5%
Methodology	:	1. Data collection i. Record in Lampiran 2A Form ii. Each data should be recorded monthly 2. Data analysis Analyse the cause of reject and take remedial action monthly 3. Results have to be recorded in the designated form
Form	:	Lampiran 2A Form: Report of Percentage of Retakes for Digital Radiography
Submission	:	Lampiran 2A: Report shall be sent to JKN before or on January 31 every year to meet the current requirements by the KKM appropriate authority

EXPLANATION TYPE OF ERROR (RETAKES FOR DIGITL RADIOGRAPHS)

TYPE OF ERROR		EXPLANATION / EXAMPLE OF ERROR
HUMAN FAULTS	Over Exposure/ High Index	1. Images that demonstrate high density (too dark). The bony trabecular pattern and structure of soft tissue in the area of interest are not well visualised. 2. Images that over penetrated – images demonstrate high density. Bony cortical outline of thin and thick structure cannot be seen in the single radiograph
	Under Exposure/ Low Index	1. Images that demonstrates low density (too light). The bony trabecular pattern and structure of soft tissue in the area of interest are not well visualised. 2. Images that under penetrated – radiograph demonstrates low density. Bony cortical outline of thin and thick structure cannot be seen in the single radiograph
	Double Exposure	1. There is more than one image. 2. Double exposure results when the receptor/radiographic cassette/imaging plate is exposed more than 1 times, and the images appear superimposed onto each other.
	Wrong Technique	1. Wrong positioning – patient incorrectly position/place, image not true lateral / not true AP 2. Wrong alignment of x-ray tube 3. Wrong angulation of x-ray tube 4. Wrong source image distance (SID) 5. Wrong centering point 6. Wrong Region of interest (ROI) and etc.
	Wrong Patient/ Exam	1. Wrong patient /wrong patient identification 2. Wrong exam/ wrong request by doctor/clinician (wrong body part/wrong view) 3. Wrong order (IT Hospital) 4. Wrong part of examination done
	No Primary/ Wrong Marker	1. No primary marker 2. Wrong marker 3. Marker outside collimation 4. Marker superimposed with Region of Interest (ROI)
	Collimation Error	Collimation too small/too big or incorrect which leads to examination part requested to be cut off.
	Patient Movement	1. Image blurring due to patient movement/condition (uncooperative, restless, short of breath, rapid breathing (tachypnoea), on ventilator and etc

		2. Anatomical part requested has been cut off because patient move before or during exposure
	Patient Related Artifact	1. Radio opaque material attached/on the patient that include in the radiograph such as underwired bra, key in the pocket, jewelry, coin, belt, hair clip and etc. 2. ArtIfact due to patient clothing, patient hair and etc
EQUIPMENT	Equipment Fault (X-Ray Tube/ Grid/ Bucky)	1. Light Beam Diaphragm fault causing collimation error/ cone cut 2. Alignment problem 3. Electronic failure 4. Collimation knob problem 5. Bucky/ Grid error (grid cut-off) 6. AEC malfunction/problem 7. Electrical fault 8. Network error and etc.
	Detector/Imaging Plate	1. Mechanical damage & electronic disfunction 2. Dirty IP plate/detector 3. Ghosting image due to improper erasing grey scale of detector problem 4. Detector faulty and etc.
	Image Artifact	1. Line cause from dirt collected in CR reader 2. Damage laser beam head in CR reader appears as multiple linear white line and etc.
	Processing Fault	1. Network error 2. Mechanical issues/problem from CR Reader 3. IP plate stuck inside reader 4. Improper scanning / error during image reading 5. Sudden shutdown (electrical failure) and etc.
OTHERS	Miscellaneous.	Rejected by doctor/clinician due to insufficient diagnostic preference such as ryles tube insertion/ implant monitoring (Orthopedic cases/ pediatric cases) and etc.

REPORT OF PERCENTAGE OF REJECTED DIGITAL RADIOGRAPHY

FACILITY : _____
MACHINE MODEL / YEAR OF MACHINE : _____
YEAR OF INSTALLATION : _____
STANDARD : ≤5%

TYPE OF ERROR		MONTHS												TOTAL	PERCENTAGE (%)
		Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.		
HUMAN FAULTS	1. Over Exposure/ High Index														
	2. Under Exposure/ Low Index														
	3. Double Exposure														
	4. Wrong Technique														
	5. Wrong Patient/ Exam														
	6. No Primary/ Wrong Marker														
	7. Collimation Error														
	8. Patient Movement														
	9. Patient Related Artifact														
EQUIPMENT	10. Equipment Fault (X-ray Tube/ Grid/ Bucky)														
	11. Detector/ Imaging Plate														
	12. Image Artifact														
	13. Processor Fault														
OTHERS	14. Miscellaneous. Please specify:.....														
Total number of error															

TYPE OF ERROR	MONTHS												TOTAL	PERCENTAGE (%)
	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.		
Total number of retakes exposure (A)														
Total number of images (B)														
Percentage (%) (A÷B) x 100%														

COMMENT : .....

.....

CORRECTIVE ACTION : .....

.....

Reported by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Supervisor*:
Date:

***Supervisor**: Radiologist, Ketua Juru X-ray atau Orang Yang Bertanggungjawab

PERCENTAGE OF FLUOROSCOPIC INTERVENTIONAL PROCEDURES WHERE PATIENT DOSE EXCEED THE MALAYSIAN DIAGNOSTIC REFERENCE LEVEL (DRL)

Programme	:	Radiology
Area of Concern	:	Performance Quality and Radiation Safety of Radiology Services
Indicator	:	Percentage of fluoroscopic procedures where patient dose exceed the Malaysian Diagnostic Reference Level (DRL)
Definition of Term	:	Diagnostic Reference Level (DRLs) is defined as: *A form of investigation level of patient dose or administered activity (amount of radioactive material) for a specified procedure used in medical imaging, to indicate whether, in routine conditions, the patient dose or administered activity is unusually high or low for that procedure* (from International Commission on Radiological Protection, ICRP)
Inclusion Criteria	:	All fluoroscopic procedures listed in Guidelines on Malaysian DRLs in Medical Imaging (Radiology)
Exclusion Criteria	:	1. Fluoroscopic procedures that are not listed in Guidelines on Malaysian DRLs in Medical Imaging (Radiology) 2. Fluoroscopic procedures on patients below 16 years old (no Malaysian DRLs value) 3. Examinations done with fluoroscopy equipment that does not have KAP meter
Type of Indicator	:	Rate -based indicator
Numerator	:	Total number of selected fluoroscopic procedures where patient dose exceed the Malaysian Diagnostic Reference Level (DRL)
Denominator	:	Total number of fluoroscopic procedures done as listed in Guidelines on Malaysian DRLs performed
Calculation of Rate	:	(Numerator ÷ Denominator) x 100%
Standard	:	≤20%
Methodology	:	1. Data of the selected fluoroscopic procedures shall be collected monthly 2. KAP and fluoroscopic procedures shall be obtained from available recording dose information method 3. Recorded in Lampiran 3A Form. 4. Data from Lampiran 3A Form shall be transferred to Lampiran 3B Form for monthly analysis

Form	:	Lampiran 3A Form	:	Percentage of Fluoroscopic Procedures Where Patient Dose Exceed the Malaysian Diagnostic Reference Level (DRL)
		Lampiran 3B Form	:	Annual Analysis Report for Percentage of Fluoroscopic Procedures Where Patient Dose Exceed the Malaysian Diagnostic Reference Level
Submission	:	Lampiran 3A and 3B: Report shall be sent to JKN before or on January 31 every year to meet the current requirements by the KKM appropriate authority.		

PERCENTAGE OF FLUOROSCOPIC PROCEDURES WHERE PATIENT DOSE EXCEED THE MALAYSIAN DIAGNOSTIC REFERENCE LEVEL (DRL)

FACILITY : _____
DEPARTMENT : _____
MONTH/YEAR : _____
UNIT : _____
MACHINE MODEL : _____

NO.	Examination date	Examination No. / Accession No.	*Examination Type	KAP value (mGy.m²)	Exceed DRL	
					Yes	No
				Total		

Malaysian standard DRL value :
Angiography (Diagnostic)
Cardiac: 5.44 mGy.m²
Non-Cardiac: 5.22 mGy.m²

Conventional Studies
GI Lower: 0.68 mGy.m²
GI Upper: 0.9 mGy.m²
MCU : 1.41 mGy.m²
ERCP : 0.83 mGy.m²

Interventional Studies
Cerebral: 8.70 mGy.m²
ESWL: 0.81 mGy.m²
PTCA: 15.70 mGy.m²
Vascular: 5.87 mGy.m²
Others**: 2.01 mGy.m²

*Note: Fill in with the correct procedure provided: Cardiac / Non-Cardiac / ERCP / GI Lower / GI Upper / MCU / Cerebral / ESWL / PTCA / Vascular / Others
** Others include Nephrostomy, Percutaneous Transhepatic Biliary Drainage (PTBD), Sinogram, Anal Fistulogram, Ascending Urethrogram, Lower Limb Angiography, Cystography and Renal Embolization

ANNUAL ANALYSIS REPORT FOR PERCENTAGE OF FLUOROSCOPIC PROCEDURES WHERE PATIENT DOSE EXCEED THE MALAYSIAN DIAGNOSTIC REFERENCE LEVEL

FACILITY: _____

DEPARTMENT: _____

MACHINE MODEL: _____

YEAR: _____

MONTH	Total Number of Fluoroscopic Procedures Done/ Performed (as Listed in Guideline on Malaysian DRLs Performed)	Total Number of Fluoroscopic Procedures where Patient Dose Exceed the Malaysian Diagnostic Reference Level (DRL)	% of KAP Value that exceed DRLs
Jan.			
Feb.			
Mar.			
Apr.			
May			
June			
July			
Aug.			
Sept.			
Oct.			
Nov.			
Dec.			
TOTAL			
	(D)	(N)	

% of KAP for fluoroscopic procedure that exceed DRL = (N/D x 100%)

SHORTFALL IN QUALITY

Causes : _____

Corrective Action: _____

_____

Reported by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Person In-Charge:
Position:
Date:

PERCENTAGE OF PLAIN CT BRAIN EXAMINATION WHERE DOSE LENGTH PRODUCT (DLP) EXCEED DIAGNOSTIC REFERENCE LEVEL (DRL)

Programme : Radiology

Area of Concern : Performance Quality and Radiation Safety of Radiology Services

Indicator : Percentage of plain CT brain examination where dose length product (DLP) exceed Diagnostic Reference Level (DRL)

Definition of Term : Diagnostic Reference Level (DRLs) is defined as:

A form of investigation level of patient dose or administered activity (amount of radioactive material) for a specified procedure used in medical imaging, to indicate whether, in routine conditions, the patient dose or administered activity is unusually high or low for that procedure (from International Commission on Radiological Protection, ICRP)

The Dose Length Product (DLP) is the product of the $CTDI_{vol}$ and the scan length for a group of scans. This number can be summed over the entire exam to give an estimate of the total dose. The value is expressed in milliGray x centimeters (mGy.cm).

DLP (dose length product) = $CTDI_{vol}$ x scan length

CT dose index (CTDI) is a standardized measure of radiation dose output of a CT scanner which allows the user to compare radiation output of different CT scanners. For helical scanners in current use, the parameter $CTDI_{vol}$ is the most relevant one.

$CTDI_{vol}$ is obtained by dividing $CTDI_w$ by pitch factor.

Inclusion Criteria : Adult Plain CT brain

Exclusion Criteria :
1. Adult Plain CT brain which include the spine
2. CT brain examination on patients below 16 years old (no Malaysian) DRLs value)

Rationale :
1. CT examination is the highest contributor to medical exposure
2. CT Brain is the most commonly done examination
3. DLP software is currently available in most CT Scanner. DLP can be
4. calculated manually ($CTDI_{vol}$ x scan length)
5. To monitor DLP value with benchmarking to standard Malaysian DRLs value
6. To increase awareness of radiation dose in CT Brain

Type of Indicator : Rate-based indicator

Numerator	:	Total number of Adult Plain CT Brain Examination for which the DLP value exceed the Malaysian DRL values
Denominator	:	Total Number of Adult Plain CT Brain Examinations Collected
Calculation of Rate	:	(Numerator ÷ Denominator) x 100%
Acceptable Deviation	:	NA
Standard	:	≤0% exceed Malaysian DRL values (The Malaysian standard for CT Brain examination is 1050 mGy.cm)
Methodology	:	1. Data of up to 5 consecutive adult plain CT brain examinations shall be collected daily including DLP value 2. Record data as required in Lampiran 4A Form and Lampiran 4B Form
Form	:	Lampiran 4A Form : Report of Monthly Percentage of Adult Plain CT Brain Examination That Exceed DRL Lampiran 4B Form : Report of Yearly Percentage of Adult Plain CT Brain Examination That Exceed DRL
Submission	:	Lampiran 4A and 4B: Report shall be sent to JKN before or on January 31 every year to meet the current requirements by the KKM appropriate authority

LAMPIRAN 4A

REPORT OF MONTHLY PERCENTAGE OF ADULT PLAIN CT BRAIN EXAMINATION WHERE DOSE LENGTH PRODUCT (DLP) EXCEED DIAGNOSTIC REFERENCE LEVEL (DRL)

Facility: _____ Month/Year: _____

Department: _____

Machine Model: _____

Year of Installation: _____

No.	Examination date	CT Scan No./ Accession No.	Age and Gender Distribution		QAP Indicator			DRL Exceeded	
			Male/Female	Age (Years)	~~Scan Length (cm)~~	$CTDI_{vol}$	DLP (mGy.cm)	Y	N

Note: Malaysian DRL value for brain is 1050mGy.cm

Number of Adult Plain CT Brain examinations that exceed the DRL value in a month | |

Reported by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Radiologist:
Date:

ANNUAL ANALYSIS REPORT OF ADULT PLAIN CT BRAIN EXAMINATION WHERE DLP EXCEED DIAGNOSTIC REFERENCE LEVEL (DRL)

Facility : _____

Department : _____

Machine Model : _____

Year : _____

MONTH	Total No. of Adult Plain CT Brain Examination	No. of Adult Plain CT Brain Exam That Exceed the DRL Value	% of DLP value that exceed DRL
Jan.			
Feb.			
Mar.			
Apr.			
May			
June			
July			
Aug.			
Sept.			
Oct.			
Nov.			
Dec.			
TOTAL			
	(D)	(N)	
% of DLP for Adult Plain CT Brain exam that exceed DRL: (N/D x 100%)			

SHORTFALL IN QUALITY

Causes : _____

Corrective Action: _____

Reported by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Radiologist:
Date:

PERCENTAGE OF REJECTED MAMMOGRAPHY FILMS OR IMAGES

Programme	:	Radiology
Area of Concern	:	Performance Quality and Radiation Safety of Radiology Services
Indicator	:	Percentage of Mammogram Films or Images Rejected/ Retake
Definition of Term	:	Mammogram Films: Films processed using conventional (non-digital) system. Mammogram Image: Images acquired using digital (DR/CR) system. Rejected mammogram films or images: Any mammogram films/ images acquired during a mammography examination/ procedure that has no diagnostic value and has to be discarded. This refers to mammogram films or images of patients that are assessed by the radiographer or the requesting radiologist/ clinician to be clinically unacceptable and needs to be repeated.
Inclusion Criteria	:	1. Mammogram films or images rejected by the radiographers. 2. Mammogram films or images rejected by the radiologists and clinicians.
Exclusion Criteria	:	1. Any mammogram films or images discarded due to testing processes. 2. Any mammogram films or images discarded due to quality assurance procedures.
Rationale	:	The purpose of this indicators to determine the factors that contributed to the number of repeated mammography films or images and to institute remedial measures. It is a measure of human factor, equipment and miscellaneous faults to : i. keep the radiation dose to patient as low as reasonably achievable (ALARA) ii. maintain quality control in performing mammography examinations iii. avoid unnecessary cost to the facility iv. reduce patient's waiting time
Type of Indicator	:	Rate-based indicator
Numerator	:	Total number of mammogram films or images rejected
Denominator	:	Total number of mammogram films or images used or exposure made
Calculation of Rate	:	(Numerator ÷ Denominator) x 100%
Standard	:	≤3%

Methodology : Procedure for Film or Image Reject Analysis

1. Data collection

   i. Collect, sort and count all rejected mammogram films or retake images according to the categories listed.
   ii. All data should be recorded.

2. Data analysis

   i. Determine the percentage of rejected films or images out of the total number of films or exposure made during the audit period, according to the formula:

$$\frac{\text{Number of films or images rejected (A)}}{\text{Total number of films or exposure made (B)}} \times 100\%$$

   ii. All data should be recorded monthly in the Lampiran 5A/5B Form.
   iii. Record and analyse the reasons for the reject and institute remedial action monthly.
   iv. All monthly data should be recorded at year end into the Lampiran 5C/5D Form.

Note: If reject images cannot be digitally stored it is recommended that a log be kept during reject analysis period.

Form : Lampiran 5A Form: Report of Reject Analysis : Percentage of Mammogram Films Rejected Monthly (Conventional)
Lampiran 5B Form: Report of Retake Analysis : Percentage of Mammogram Retake Images Monthly (FFDM/CR)
Lampiran 5C Form: Report of Reject Analysis : Percentage of Mammogram Films Rejected Yearly (Conventional)
Lampiran 5D Form: Report of Retake Analysis : Percentage of Mammogram Retake Images Yearly (FFDM/CR)

Submission : Lampiran 5C/5D: Report shall be sent to JKN before or on January 31 every year to meet the current requirements by the KKM appropriate authority

REPORT OF REJECT ANALYSIS
PERCENTAGE OF MAMMOGRAM FILMS REJECTED MONTLY (CONVENTIONAL)

FACILITY : _____
MACHINE MODEL : _____
YEAR OF INSTALLATION : _____
IMAGE PROCESSOR TYPE/MODEL : _____
STANDARD : **< 3%**

	Reason For Retake	Projection Repeated						Sub Totals	% of Repeats
		Left CC	Right CC	Left MLO	Right MLO	Left Other	Right Other		
HUMAN FAULTS	1. Incorrect Patient ID								
	2. Wrong Patient								
	3. Marker								
	4. Positioning Technique								
	5. Exposure Faults								
	6. Patient Motion								
	7. Patient Related Artifact								
EQUIP MENT	8. Mechanical Fault								
	9. Aborted AEC								
PROSES SING	10. Film Artifacts								
	11. Cassette/ Film								
	12. Darkroom Processing								
OTHERS	13. Other Reasons. Please specify:.....								
	Total number of error								
	Total number of images rejected (A)								
	Total number of images used (B)								
	Percentage of images rejected (A÷B) x 100%								

Remarks: _____

Corrective Action: _____

Data Analyzed by:

.....
Name:
Position:
Date:

Verified by:

.....
Name:
Position: Senior Radiographer/ Radiologist
Date:

REPORT OF RETAKE ANALYSIS
PERCENTAGE OF MAMMOGRAM IMAGES RETAKE MONTHLY (FFDM/ CR)

FACILITY : _____

MACHINE MODEL / YEAR OF MACHINE : _____

YEAR OF INSTALLATION : _____

CASSETTE READER TYPE/MODEL : _____

LASER PRINTER TYPE/MODEL : _____

STANDARD : < 3%

	Reason For Retake	Projection Repeated						Sub Totals	% of Repeats
		Left CC	Right CC	Left MLO	Right MLO	Left Other	Right Other		
HUMAN FAULTS	1. Incorrect Patient ID								
	2. Wrong Patient								
	3. Marker								
	4. Positioning Technique								
	5. Exposure Faults								
	6. Patient Motion								
	7. Patient Related Artifact								
EQUIPMENT	8. CR Image Reader Fault								
	9. Mechanical Fault								
	10. Blank Image								
	11. Aborted AEC								
	12. Software Failure								
	13. Detector / Imaging Plate								
	14. Artifacts								
OTHERS	15. Other Reasons. Please specify:.....								
	Total number of error								
	Total number of images rejected (A)								
	Total number of images used (B)								
	Percentage of images rejected (A÷B) x 100%								

Remarks: _____

Corrective Action: _____

Data Analyzed by:

.....
Name:
Position:
Date:

Verified by:

.....
Name:
Position: Senior Radiographer/ Radiologist
Date:

REPORT OF REJECT/ RETAKE ANALYSIS: PERCENTAGE OF MAMMOGRAM FILMS REJECTED YEARLY (CONVENTIONAL)

FACILITY : _____
MACHINE MODEL : _____
LASER PRINTER TYPE/MODEL : _____

	REASON FOR RETAKE	MONTHS												TOTAL	PERCENTAGE
		Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.		
HUMAN FAULTS	1. Incorrect Patient ID														
	2. Wrong Patient														
	3. Marker														
	4. Positioning Technique														
	5. Exposure Faults														
	6. Patient Motion														
	7. Patient Related Artifact														
EQUIPMENT	8. Mechanical Fault														
	9. Aborted AEC														
PROCESSING	10. Film Artifacts														
	11. Cassette/ Film														
	12. Darkroom Processing														
OTHERS	13. Other Reasons. Please specify:.....														
	Total number of error														
	Total number of films rejected (A)														
	Total number of films used (B														
	Percentage of films rejected (A÷B) x 100%														

REMARKS : _____
CORRECTIVE ACTION : _____

Data Analyzed by:

.....
Name:
Position: Senior Radiographer
Date:

Verified by:

.....
Name:
Position: Radiologist
Date:

REPORT OF RETAKE ANALYSIS: PERCENTAGE OF MAMMOGRAM IMAGES RETAKE YEARLY (FFDM/CR)

FACILITY : _____

MACHINE MODEL : _____

CASSETTE READER TYPE/MODEL : _____

LASER PRINTER TYPE/MODEL : _____

	REASON FOR RETAKE	MONTHS												TOTAL	PERCENTAGE
		Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.		
HUMAN FAULTS	1. Incorrect Patient ID														
	2. Wrong Patient														
	3. Marker														
	4. Positioning Technique														
	5. Exposure Faults														
	6. Patient Motion														
	7. Patient Related Artifact														
EQUIPMENT	8. CR Image Reader Fault														
	9. Mechanical Fault														
	10. Blank Image														
	11. Aborted AEC														
	12. Software Failure														
	13. Detector / Imaging Plate														
	14. Artifacts														
OTHERS	15. Other Reasons. Please specify:.....														
	Total number of error														
	Total number of films rejected (A)														
	Total number of films used (B														
	Percentage of films rejected (A÷B) x 100%														

REMARKS : _____

CORRECTIVE ACTION : _____

Data Analyzed by:

.....
Name:
Position: Senior Radiographer
Date:

Verified by:

.....
Name:
Position: Radiologist
Date:

PERFORMANCE AND SAFETY STANDARDS FOR QUALITY CONTROL OF EQUIPMENT AND ASSOCIATED FACILITIES USED IN RADIOLOGY

Table 1.a	:	Performance and Safety Standards for Associated Facilities	L19
Table 1.b	:	Performance and Safety Standards for Digital System Associated Facilities	L22
Table 2	:	Performance and Safety Standards for General/ Mobile X-ray Equipment	L24
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Table 2.b	:	Additional Performance and Safety Standards of Digital Radiography (DR) System	L31
Table 3	:	Performance and Safety Standards for Fluoroscopy Systems	L34
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Table 5.a	:	Performance and Safety Standards for Screen Films and Computed Radiography Mammography System	L46
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Note:

1. All test in Table 1.a and Table 1.b shall be carried out by radiographer/ physicist
2. All test in Table 2 – Table 6 shall be carried out by qualified personnel who are registered and approved under the class H license, MOH

The following Standard or Levels may be used as a general guideline to be read together in relation to Table 1 – Table 6:

- **Acceptable Level**: Level at which the performance of that parameter is within stipulated requirements.
- **Remedial Level**: Level at which the performance of that parameter is not within the stipulated requirements where corrective action shall be taken within a prescribed time period.
- **Suspension Level**: Level at which the performance of that parameter is not within stipulated requirements where the equipment shall be removed from clinical use immediately until appropriate corrective action is taken.
- **Baseline**: The value of a parameter (unless specified otherwise), which is determined at the time of commissioning (for new equipment) or as determined for the first time of the QC. This is to determine whether there are any changes in the performance of equipment over time.
- **Commissioning**: A set of tests carried out by the purchaser's representative to ensure that the equipment is ready for clinical use and to establish baseline values against which the results of subsequent routine performance tests can be compared

Table 1.a: Performance and Safety Standards for Associated Facilities

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
1.	**Darkroom and Processor Monitoring**				
	i. Condition of the darkroom	Shall have no light leakage	NA	NA	Annually
		Base + fog index ≤0.25 OD	> 0.25 OD and < 0.3 OD	> 0.3 OD	Daily
		Baseline for the Speed Index	± 0.15 Baseline at the same step	± 0.3 Baseline at the same step	Daily
		Baseline for the Contrast Index	± 0.15 Baseline at the same 2 steps	± 0.3 Baseline at the same step	Daily
	ii. Sensitometry (Single Emulsion)	Base + fog index ≤0.2 OD	> 0.2 OD and < 0.3 OD	> 0.3 OD	Daily
		Baseline for the Speed Index	± 0.1 Baseline at the same step	± 0.2 Baseline at the same step	Daily
		Baseline for the Contrast Index	± 0.1 Baseline at the same 2 steps	± 0.2 Baseline at the same 2 steps	Daily
	iii. Developer Temperature				
	a) General X-ray	According to manufacturer's recommendation	± 2 ^{0}C	> 2 ^{0}C	Daily
	b) Intra oral and OPG	NA	As recommended by manufacturer	< 18 ^{0}C > 40 ^{0}C	Annually
	iii. Replenishment Rate	Set baseline value	Baseline ±10%	NA	Quarterly

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
2.	**Cassette & Intensifying Screen**				
	i. Relative speed of intensifying screen - general X-ray	• Baseline value; • Difference between new cassette ±10%	NA	> 10%	Semi-annually
	ii. Light leakage cassettes test	Shall have no light leakage	NA	Light leakage observed	Annually
	iii. Screen film contact test - general film	Film and screen shall be in good contact	NA	NA	Semi-annually
	iv. Screen film contact test - mammography film	Film and screen shall be in good contact	NA	NA	Semi-annually
3.	**X-ray Film Illuminator**				
	i. General X-ray	≥1500 cd/m^2	Variation < 1500 cd/m^2	NA	Semi-annually
	ii. Mammography	≥3500 cd/m^2	Variation < 3500 cd/m^2	NA	Semi-annually
4.	**Protective Devices**				
	(Lead Aprons/Thyroid Shield/Half Apron)	• < 15 mm^2 over the critical area for apron; • < 11 mm^2 for thyroid shield	NA	• > 15 mm^2 over the critical area for apron; • > 11 mm^2 for thyroid shield	Annually
5.	**Safe Light**				
	i. Pre-Exposed (Film 1.0 OD)	2 minutes	< 2 minutes	< 1.5 minutes	Semi-annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	ii. Unexposed	Time taken to fog X-ray film > 45 s	NA	< 45 s	Semi-annually

Note: All tests shall be carried out during commissioning and after replacement of major components.

Table 1.b: Performance and Safety Standards for Digital System Associated Facilities

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
1.	**Image Display**				
	i. Image display monitor condition	The 5% and 95% details superimposed on the 0% and 100% squares, respectively should be visible.			Weekly, Annually
	ii. Greyscale	NA	• Ratio white (100%) to black (0%) < 250 lux • Black base-line ± 25% • White base-line ± 20%	NA	Quarterly, Annually
	iii. Resolution	Both low contrast and high contrast resolution pattern should be visible. The resolution at center and peripheral should be consistent and similar to baseline.			Quarterly, Annually
	iv. DICOM Greyscale calibration	Remedial level: GSDF ±10%			Annually
	v. Uniformity	NA	> 30%	NA	Annually
	vi. Variation between monitor	NA	White (100%) to black (0%) ratio deviates > 30% of the mean value of the monitors tested.	NA	Annually
2.	**Laser Film Printer**				
	i. Self-calibration	NA	Manufacturer's specification	NA	Weekly
	ii. Hardcopy device optical density consistency (image from printer)	NA	Baselines ± 0.20 OD	NA	Quarterly, Annually
	iii. Hardcopy device image quality (image	1. The 5% and 95% details superimposed on the 0% and 100% squares, respectively should be			Quarterly

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	from printer)	visible. 2. Both low contrast and high contrast resolution pattern should be visible. The resolution at center and peripheral should be consistent and similar to baseline.			
	iv. Hardcopy device image quality (image from workstation used for printing)	The print out image should be similar to the monitor display.			Quarterly

Note : All tests shall be carried out during commissioning and after replacement of major component.

Table 2: Performance and Safety Standards for General / Mobile X-ray Equipment

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
1.	**Unit Assembly**	All mechanical movement and locks are functioning properly	NA	Mechanical fault which affects functionality and safety	Annually
2.	**X-ray Generator Performance**				Annually
	Accuracy of kVp				
	a. Tube Potential < 100 kV	Max. deviation ≤ ±5 kV	> ±5 kV	> ±10 kV	
	b. Tube Potential ≥100 kV	Max. deviation ≤ ±5%	> ±5%	> ±10%	
	Accuracy of Exposure Timer				
	a. For time < 0.1 sec	Max. deviation ≤ ±20%	> ±20%	> ±30%	
	b. For time ≥0.1 sec	Max. deviation ≤ ±10%	> ±10%	> ±20%	
	i. Repeatability of Radiation Output	COV ≤5%	COV > 5%	COV > 10%	
	ii. Coefficient of Linearity	≤10%	> 10%	> 20%	
3.	**X-ray Beam Limitation**				Annually
	i. X-ray Beam/ Light Field Alignment	Max. misalignment ≤ 1% of FID on any one side	Max. misalignment > 1% of FID on any one side	Max. misalignment > 3% of FID on any one side	
	ii. Beam Perpendicular	≤1.5°	≤3°	> 3°	
	iii. X-ray Beam/ Light Field Centering (at 1 meter of FID)	Max. deviation ≤ 1 cm	Max. deviation > 1 cm	Max. deviation > 2 cm	
	iv. Collimation light field illumination	Illuminance ≥ 160 lux	Illuminance < 160lux	No collimation light seen	

No.	Physical Parameters		Performance Level			Frequency
			Acceptable Level	Remedial Level	Suspension Level	
4.	**X-ray Beam Filtration (HVL Measurement)**					Annually
	Tube Voltage Range (kVp)	Operating Potential (kVp)	Minimum HVL in mm Al			
	50 to 70	50	1.2	< 1.2	NA	
		60	1.3	< 1.3	NA	
		70	1.5	< 1.5	NA	
	> 70	71	2.1	< 2.1	NA	
		80	2.3	< 2.3	NA	
		90	2.5	< 2.5	NA	
		100	2.7	< 2.7	NA	
		110	3.0	< 3.0	NA	
		120	3.2	< 3.2	NA	
		130	3.5	< 3.5	NA	
		140	3.8	< 3.8	NA	
		150	4.1	< 4.1	NA	
	ii. Coefficient of Linearity		≤10%	> 10%	> 20%	
5.	**Image Quality (for film screen radiography only)**					Annually
	i. Resolution Limit		5 lp/mm	< 5 lp/mm	NA	
	ii. Contrast		Baseline Group	≤2 groups from baseline	NA	

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
6.	**AEC System Performance**				Annually
	6.1 Film Screen Radiography				
	i. Repeatability				
	a. Film Density	≤±0.2 OD of mean	> ±0.2 OD of mean	> ±0.3 OD of mean	
	b. Post-exposure mAs	≤±20% of mean mAs	> ±20% of mean mAs	> ±30% of mean mAs	
	ii. Detector Matching	≤±0.3 OD of mean	> ±0.3 OD of mean	> ±0.5 OD of mean	
	iii. Consistency of Film Density with change in kVp	≤±0.3 OD of mean	> ±0.3 OD of mean	> ±0.5 OD of mean	
	iv. Consistency of film density with change in phantom thickness	≤±0.3 OD of mean	> ±0.3 OD of mean	> ±0.5 OD of mean	
	6.2 CR and DR Radiography System				
	i. Repeatability	≤±20% of mean pixel value	> ±20% of mean pixel value	> ±30% of mean pixel value	
	ii. Detector Matching	≤±20% of mean pixel value	> ±20% of mean pixel value	> ±30% of mean pixel value	
	iii. Consistency of Pixel Value or DDI with change in kVp	≤±20% of mean pixel value	> ±20% of mean pixel value	> ±30% of mean pixel value	
	iv. Consistency of Pixel Value or DDI with change in phantom thickness	≤±20% of mean pixel value	> ±20% of mean pixel value	> ±30% of mean pixel value	
	Focal Spot Size Measurement	F_{perp} or $F_{parallel}$ ≤2.0 x F_{nom}	NA	NA	During commissioning and after replacement of major component
	KAP Calibration for Clinical Radiation Exposure Monitors (for system with KAP meter)	Deviation ≤ 20% of reference value	Deviation > 20% of reference value	Deviation > 30% of reference value	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
9.	**Leakage Radiation** Exposure from the leakage radiation at 1 meter from the X-ray tube in an hour at every rating specified by the manufacturer	≤ 0.1 mGy (≤ 10 mR)	≤ 1 mGy (≤ 100 mR)	> 1 mGy (> 100 mR)	Annually
10.	**Scattered Radiation** Exposure in one week at every occupied area outside the X-ray room and at the position normally occupied by the operator at the control area	≤ 0.1 mGy (≤10 mR)	NA	> 0.1 mGy (> 10 mR)	Annually

Note : All tests shall be carried out during commissioning and after replacement of major component

Table 2.a: Additional Performance and Safety Standards for Computed Radiography (CR) System

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
1.	**Visual Check of Uniformity & Condition of Cassettes and Image Plates**	Clean and undamaged image plate	NA	Artefacts likely to affect clinical image quality	Semi-annually Annually
2.	**Matching of CR Image Plates**	DAK_{DDI} varies by ≤±20% of between image plates	NA	> ±20%	Annually
3.	**Dark Noise**				Annually
	Agfa	SAL < 100 IgM < 0.28	> ±50% of baseline value at commissioning	NA	
	Fujifilm	PV < 280 PV_{SD} < 4			
	Carestream/Kodak	EI_{GP} < 80 PV_{GP} < 80 PV_{SD} < 4 EI_{HR} < 380 PV_{HR} < 80 PV_{SD} < 4			
	Konica	S ≥5000 $PV_{Average}$ < 10.0 PV_{SD} < 1.0			
4.	**Detector Dose Indicator (DDI) Accuracy**	DDI ≤±20%	NA	DDI > ±20%	Annually
5.	**Differences Between CR Readers**	DAK_{DDI} varies by ≤±20% of between readers	NA	NA	Annually
6.	**DDI Repeatability**	CoV of DAK_{DDI} ≤±10%	CoV of DAK_{DDI} > ±10%	CoV of DAK_{DDI} > ±20%	Annually
7.	**DDI Reproducibility**	Mean DAK_{DDI} ≤±20% of baseline value	Mean DAK_{DDI} > ±20% of baseline value	Mean DAK_{DDI} > ±50% of baseline value	Monthly Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
8.	**Signal Transfer Property (STP)**	i. Simple STP relationship (linear or logarithmic) ii. Regression coefficient for graph of mean PV versus DAK: $R^2 \geq 0.98$	Regression coefficient for graph of mean PV versus DAK: $R^2 < 0.98$	Regression coefficient for graph of mean PV versus DAK: $R^2 < 0.95$	Annually
9.	**Variation of Noise with Detector Air Kerma (DAK)**	Correlation (R^2) of linear fit of system noise vs. Log(DAK) $R^2 \geq 0.95$	Correlation $R^2 < 0.95$	Correlation $R^2 < 0.95$	
10.	**Measured Uniformity**	i. No artefacts ii. Mean STP corrected ROI values within mean ≤□10%.	i. No obvious artefacts ii. Mean STP corrected ROI values > □10%	i. Obvious artefacts likely to affect clinical image quality ii. Mean STP corrected ROI values > □20%	Annually
11.	**Signal-to-Noise Ratio (SNR)**	≤±15% of baseline value	> ±15% of baseline value	> ±30% of baseline value	Annually
12.	**Erasure Cycle Efficiency**				Annually
	i. Visual assessment	No visible ghost image	Visible ghost image	Obvious visible ghost image likely to affect clinical image quality	

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	ii. Quantitative assessment (If ROI analysis tool available)	Lag ≤1%	NA	Lag > 1.0%	
13.	**Threshold Contrast Detail Detectability (TCDD)**	Baseline IQF ≤10%	Deviation of fitted curve from baseline > 10%	Deviation of fitted curve from baseline > 30%	Annually
14.	**Limiting High Contrast Spatial Resolution**	≥0.70 / 2Δ*p* for scan and sub-scan measurements	-25% change from baseline value (45° image)	NA	Annually
15.	**Blurring**	No obvious blurring in image	Obvious blurring at the centre of the image	Local decision based on perceived effect on clinical image	Annually
16.	**Laser Beam Function**	i. Edge continuous across whole image ii. Uniform 'stair' characteristics across whole image	Occasional jitter	Edge not the full length of the image	Annually
17.	**Scaling Error: Measurement Calibration and Aspect Ratio**				Annually
	i. Measurement Calibration	Error ≤4%	Error > 4%	Local decision based on perceived effect on clinical image	
	ii. Aspect Ratio	within 1 ± 0.04	< 0.96 or > 1.04	Local decision based on perceived effect on clinical image	

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
18.	**Moiré Patterns and Anti-Scatter Grids**	Not visible	Appearance of Moiré patterns or any grid lines	NA	Annually

Note :

1. All tests shall be carried out during commissioning and after replacement of major components.

2. Test for purpose of commissioning and after replacement of major components should not be limited to the above physical PARAMETERS.

Table 2.b: Additional Performance and Safety Standards of Digital Radiography (DR) System

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
1.	Dark Noise	i. Compare to manufacturer's specification or the baseline value obtained during commissioning ii. 50% of baseline value obtained at commissioning	> ±50% of baseline value	NA	Annually
2.	Detector Dose Indicator (DDI) Accuracy	DDI ≤±20%	NA	DDI > ±20%	
3.	Differences between Detectors	DAK_{DDI} varies by ≤±20% of between detectors	NA	NA	Annually
4.	DDI Repeatability	CoV of DAK_{DDI} ≤±10%	CoV of DAK_{DDI} > ±10%	CoV of DAK_{DDI} > ±20%	Annually
5.	DDI Reproducibility	Mean DAK_{DDI} ≤±20% of baseline value	Mean DAK_{DDI} > ±20% of baseline value	Mean DAK_{DDI} > ±50% of baseline value	Monthly Annually
6.	Signal Transfer Property (STP)	Linear fit of mean PV versus DAK: R^2 ≥0.98	R^2 < 0.98	R^2 < 0.95	Annually
7.	Variation of Noise with Detector Air Kerma (DAK)	Correlation (R^2) of linear fit of system noise vs. DAK R^2 ≥0.98	Correlation R^2 < 0.98	Correlation R^2 < 0.95	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
8.	Measured Uniformity	i. No artefacts ii. Mean STP corrected ROI values within mean □10%	i. No obvious artefact ii. Mean STP corrected ROI values > □10%	i. Obvious artefacts likely to affect clinical image quality ii. Mean STP corrected ROI values > □20%	Annually
9.	Uncorrected Defective Detector Elements	i. No uncorrected pixels. ii. Deviation from mean PV in 1 cm^2 ROI ≤ 20% if uncorrected pixels observed	Uncorrected pixels detected	Uncorrected pixels likely affect clinical image quality	Annually
10.	Signal-To-Noise Ratio (SNR)	≤±15% of baseline value	> ±15% of baseline value	> ±30% of baseline value	Annually
11.	Limiting High Contrast Spatial Resolution	≥0.70/2Δ*p* at 45°	-25% change from baseline value	NA	Annually
12.	Square Wave Contrast Transfer Function (SWCTF)	≤±10% or ≤±0.05% of baseline value (whichever is larger)	> ±10% or > ±0.05% of baseline value (whichever is larger)	NA	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
13.	Scaling Errors				Annually
	i. Measurement of Software Distance Indicators Accuracy	Error ≤4%	Error > 4%	Local decision based on perceived effect on clinical image	
	ii. Aspect Ratio	within 1 ±0.04	< 0.96 or > 1.04	Local decision based on perceived effect on clinical image	
14.	Blurring/ Line Defects	i. No blurred areas ii. No adjacent defective lines	i. New blurred areas ii. 2 defective lines together or separated by one line	Local decision based on perceived effect on clinical image	Annually
15.	Stitching Artefacts	Stitching gap ≤0.4 mm	2 defective lines together or separated by one line	Local decision based on perceived effect on clinical image	Annually
16.	Image Retention	i. No residual signal detected ii. Lag ≤0.5% (if residual signal detected)	Lag > 0.5%	Lag ≥1.0%	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
17.	Threshold Contrast Detail Detectability (TCDD)	Baseline IQF ≤ 10%	Deviation > 10% from baseline	Deviation > 30% from baseline	Annually

Note :

1. All tests shall be carried out during commissioning and after replacement of major components.

2. Test for purpose of commissioning and after replacement of major components should not be limited to the above physical PARAMETERS.

Table 3: Performance and Safety Standards for Fluoroscopy Systems

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	**Remedial Level**	**Suspension Level**	
1.	**Unit Assembly**	All mechanical movement and locks are functioning properly	NA	Mechanical fault which affects functionality and safety	Annually
2.	**Minimum Focus to Skin Entrance Distance**				Annually
	i. Permanent or fixed				
	a. Under table X-ray tube	≥40 cm between X-ray tube focal spot & patient support	NA	NA	
	b. Over table X-ray tube	≥70 cm between X-ray tube focal spot & patient support	NA	NA	
	ii. May or may not be permanent				
	a. Mobile C-arm	≥20 cm between X-ray tube focal spot and patient's skin	NA	NA	
	b. Other unit	≥70 cm between X-ray tube focal spot and input surface of the image receptor	NA	NA	
3.	**X-ray Generator Performance and Radiation Output**				Annually
	Accuracy of kVp				
	a. Tube Potential < 100 kV	Max. deviation ≤ ±5 kV	Max. deviation > ±5 kV	Max. deviation > ±10 kV	
	b. Tube Potential ≥100 kV	Max. deviation ≤ ±5%	Max. deviation > ±5%	Max. deviation > ±10%	

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	ii. Accuracy of Exposure Timer				
	a. For time < 0.1 sec	Max. deviation ≤ ±20%	Max. deviation > ±20%	Max. deviation > ±30%	
	b. For time ≥ 0.1 sec	Max. deviation ≤ ±10%	Max. deviation > ±10%	Max. deviation > ±20%	
	iii. Fluoroscopic alarm timer indicator	Audible warning when exceeding 5 minutes	> 5 minutes	NA	
	iv. Repeatability of radiation output (Radiographic or fluoroscopic mode)	CoV ≤5%	CoV > 5%	CoV > 10%	
	v. Coefficient of linearity (Output variation with mA or mAs)	≤10%	> 10%	> 20%	
4.	**X-ray Beam Limitation**				Annually
	i. Alignment of the centre of X-ray tube to the image receptor	≤2% of FID	> 2% of FID	> 3% of FID	
	ii. Coincidence of radiation field size to image field size	i. The sum of the excess length and the excess width shall be < 4% of FID. ii. Radiation field shall be restricted to image receptor size when the collimator is fully opened.	i. ≥ 4% of FID ii. Radiation area > 1.1x image receptor	i.> 5% of FID ii.Radiation area > 1.25x image receptor	

No.	Physical Parameters		Performance Level			Frequency
			Acceptable Level	Remedial Level	Suspension Level	
5.	**X-ray Beam Filtration (HVL Measurement)**					Annually
	Tube Voltage Range (kVp)	Operating Potential (kVp)	Minimum HVL in mm Al			
	50 to 70	50	1.2	< 1.2	NA	
		60	1.3	< 1.3	NA	
		70	1.5	< 1.5	NA	
	> 70	71	2.1	< 2.1	NA	
		80	2.3	< 2.3	NA	
		90	2.5	< 2.5	NA	
		100	2.7	< 2.7	NA	
		110	3.0	< 3.0	NA	
		120	3.2	< 3.2	NA	
		130	3.5	< 3.5	NA	
		140	3.8	< 3.8	NA	
		150	4.1	< 4.1	NA	
6.	**Image Receptor Input Dose Rate**					Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	Maximum Dose Rate for field size:				
	i. 11 cm to < 14 cm	≤120 µGy/min	> 120 µGy/min	> 180 µGy/min	
	ii. 14 cm to < 23 cm	≤90 µGy/min	> 90 µGy/min	> 135 µGy/min	
	iii. ≥23 cm	≤60 µGy/min	> 60 µGy/min	> 90 µGy/min	
7.	**Typical Patient Entrance Surface Dose** (Simulating the standard adult patient thickness of 20cm)				Annually
	i.Typical Patient Entrance Surface Dose				
	a. With ABC	≤25 mGy/min (2.5 R/min)	NA	≥25 mGy/min (2.5 R/min)	
	b. Without ABC	≤12 mGy/min (1.2 R/min)	NA	≥12 mGy/min (1.2 R/min)	Annually
	ii.Patient Entrance Dose Per Frame				
	a. Normal Digital Fluoroscopic Acquisition Mode	≤2 mGy/frame	NA	> 2 mGy/frame	Annually
	b. For Cardiac Mode	≤0.2 mGy/frame	NA	> 0.2 mGy/frame	
8.	**Entrance Surface Dose Rate Limit**				Annually
	i. With ABC	≤100 mGy/min (10 R/min)	NA	> 100 mGy/min (10 R/min)	
	ii. Without ABC	≤50 mGy/min (5 R/min)	NA	> 50 mGy/min (5 R/min)	
	iii. High Dose Rate System	≤200 mGy/min (20 R/min)	NA	> 200 mGy/min (20 R/min)	
9.	**Primary Protective Barrier** (Not applicable for c-arm type fluoroscopy)	≤20 µGy/hr (2 mR/hr) at 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor per 10 µGy/min of entrance dose rate	NA	> 20 µGy/hr (2 mR/hr) at 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor per 10 µGy/min of entrance dose rate	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
10.	**Image Quality**				Annually
	i. Grey scale test	A black spot and a white spot and all 10 steps of the step wedge shall be visible	NA	No visibility of black spot, white spot and < 10 steps of the step wedge	
	ii. Limiting spatial resolution	Baseline or	Baseline reduced by up to 2 groups or	Baseline reduced by up to 3 groups or	
	Field Size	**Spatial resolution**			
	> 40 cm	> 0.6 lp/mm (No. of groups: > 3)	≤0.6 lp/mm	< 0.4 lp/mm	
	36 - 40 cm	> 0.7 lp/mm (No. of groups: > 4)	≤0.7 lp/mm	< 0.5 lp/mm	
	30 - 35 cm	> 0.8 lp/mm (No. of groups: > 5)	≤0.8 lp/mm	< 0.56 lp/mm	
	25 - 29 cm	> 0.9 lp/mm (No. of groups: > 6)	≤0.9 lp/mm	< 0.63 lp/mm	
	20 - 24 cm	> 1.0 lp/mm (No. of groups: > 7)	≤1.0 lp/mm	< 0.71 lp/mm	
	< 19 cm	> 1.25 lp/mm (No. of groups: > 9)	≤1.25 lp/mm	< 0.9 lp/mm	

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	iii. Low Contrast Resolution	Baseline	Baseline reduced by up to 2 discs or	Baseline reduced by up to 3 discs or	
	Field Size	**Low Contrast Resolution**			
	> 40 cm	≤4.2% (Group 9)	> 4.2%		
	36 - 40 cm	≤3.9% (Group 10)	> 3.9%	≥6.6%	
	30 - 35 cm	≤3.3% (Group 11)	> 3.3%	≥5.5%	
	19 - 25 cm	≤2.7% (Group 12)	> 2.7%	≥4.5%	
	< 19 cm	≤2.3% (Group 13)	> 2.3%	≥3.9%	
	iv. Threshold Contrast Detail Detectability	Baseline IQF ≤10%	Deviation of fitted curve from baseline > 30%		
11.	**Focal Spot Size Measurement**	F_{perp} or $F_{parallel}$ ≤ 2.0 x F_{nom}	NA	NA	During commissioning and after replacement of major component
12.	**KAP Calibration for Clinical Radiation Exposure Monitors** (for system with KAP meter)	Deviation ≤20% of reference value	Deviation > 20% of reference value	Deviation > 30% of reference value	Annually
13.	**Leakage Radiation** Exposure from the leakage radiation at 1 meter from the X-ray tube in one hour at every rating specified by the manufacturer	≤0.1 mGy (≤10 mR)	≤1 mGy (≤100 mR)	> 1 mGy (> 100 mR)	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
14.	**Scattered Radiation** Exposure in one week at every occupied area outside the X-ray room and at the position normally occupied by the operator at the control area	≤0.1 mGy (≤10 mR)	NA	> 0.1 mGy (> 10 mR)	Annually

Note : All tests shall be carried out during commissioning and after replacement of major components

Table 4: Performance and Safety Standards for Computed Tomography (CT) Scanner

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
1.	**Unit Assembly**	All mechanical movement and locks are functioning properly	NA	Mechanical fault which affects functionality and safety	Annually
2.	**X-ray Generator Performance**				Annually
	i. Accuracy of kVp				
	a. Tube Potential < 100 kV	Max. deviation ≤±5 kV	> ±5 kV	> ±10 kV	
	b. Tube Potential ≥100 kV	Max. deviation ≤±5%	> ±5%	> ±10%	
	ii. Coefficient of Linearity	≤10%	> 10%	> 20%	
3.	**Radiation Dosimetry**				Annually
	Patient Dosimetry (CTDI)	≤±20% of baseline or manufacturer reference value	> ±20% of baseline or manufacturer reference value	> ±40% of baseline or manufacturer reference value	
4.	**Scan Localisation**				Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	i. Axial Scan Localisation Light Accuracy	Max. deviation ≤±2 mm	> ±2 mm	> ±5 mm	
	ii. Isocenter Alignment: Sagittal and Coronal Localisation Light Accuracy	Max. deviation ≤±5 mm	> ±5 mm	NA	
	iii. Gantry Tilt Accuracy	Max. deviation ≤±3° of intended	> ±3°	NA	
	iv. Table Travel Accuracy	Max. deviation ≤±2.0 mm	> ±2.0 mm	NA	
	v. Gantry Movement Accuracy	Max. deviation ≤±2.0 mm	> ±2.0 mm	NA	
	vi. Accuracy of Scan Prescription from Scout Localisation Image	Max. deviation ≤±1.0 mm	> ±1.0 mm	NA	
5.	**Image Scan Width** (Sensitivity Profile)				Annually
	i. For ≥ 5 mm prescribed scan width	Max. deviation ≤±1.0 mm	> ±1.0 mm	NA	
	ii. For < 5 mm prescribed scan width	Max. deviation ≤±0.5 mm	> ±0.5 mm	NA	
6.	**Radiation Dose Profile** (Irradiated Beam Thickness)	Max. deviation ≤±1.0 mm or within manufacturer's specifications for multi-slice CT	> ±1.0 mm or outside of manufacturer's specifications for multi-slice CT	NA	Annually
7.	**Image Display (Review Monitor at Control Panel)**				Monthly Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	Visual Display of SMPTE Pattern	i. Geometric distortion ≤ ±1.0 mm; ii. 5% and 95% patches must be visible; iii. No noticeable artifacts	NA	NA	
8.	**Image Quality**				Monthly Annually
	i. CT Number Uniformity				
	a. Head Phantom	≤±5 HU	> ±5 HU	NA	
	b. Body Phantom	≤±20 HU	> ±20 HU	NA	
	ii. Image Noise (Standard deviation of CT numbers varies as reciprocal square root of mAs)	R^2 ≥0.97	R^2 < 0.97	NA	
	iii. Image Artefacts (transaxial scan localisation images)	No disturbing artefacts should be visible	Any disturbing artefacts visible	NA	
	iv. Low Contrast Resolution	≤5 mm for 0.3% of nominal target contrast	> 5 mm for 0.3% of nominal target contrast	NA	
	v. High Contrast Resolution	≤5 lp/cm	> 5 lp/cm	NA	

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
9.	**Quantitative Accuracy**				
	i. Accuracy of Distance Measurements ii. (transaxial scan localisation images)	Max. deviation ≤±1 mm	Max. deviation > ±1 mm	NA	Annually
	iii. CT Number Value				Annually
	a. Water	0 ± 5 HU	Outside range of 0 ± 5 HU	NA	
	b. Air	-1000 ± 10 HU	Outside range of -1000 ± 10 HU	NA	
	iv. CT Number Constancy	Value and standard deviation for water remains relatively constant	NA	NA	Monthly Annually
	v. CT Number (water) dependence on:				Semi-annually, Annually
	a. Scan Thickness	0 ± 5 HU	Outside range of 0 ± 5 HU	NA	
	b. Reconstruction Algorithm	0 ± 5 HU	Outside range of 0 ± 5 HU	NA	
	c. kV	0 ± 5 HU	Outside range of 0 ± 5 HU	NA	
	d. Phantom Size	Max. deviation ± 10 HU	Max. deviation > ± 10 HU	NA	

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	e. Phantom Position	Max. deviation ± 10 HU	Max. deviation > ± 10 HU	NA	
	vi. CT Number Linearity	CT number shall change linearly with linear attenuation coefficient of different material with $R^2 > 0.97$	NA	NA	Annually
10.	**Leakage Radiation** Exposure from the leakage radiation at 1 meter from the X-ray tube in an hour at every rating specified by the manufacturer	≤0.1 mGy (≤10 mR)	≤1 mGy (≤100 mR)	> 1 mGy (> 100 mR)	Annually
11.	**Scattered Radiation** Exposure in one week at every occupied area outside the X-ray room and at the position normally occupied by the operator at the control area	≤0.1 mGy (≤10 mR)	NA	> 0.1 mGy (> 10 mR)	Annually

Note : All tests shall be carried out during commissioning and after replacement of major components.

Table 5.a: Performance and Safety Standards for Screen Films and Computed Radiography Mammography System

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
1.	**Unit Assembly**	All mechanical movement and locks are functioning properly	NA	Mechanical fault which affects functionality and safety	Annually
2.	**X-Ray Generator Performance**				
	i. Accuracy of kVp	Accuracy ≤± 5%	> 5%	> 2 kV	Annually
	ii. Repeatability of radiation output	kVp repeatability COV ≤2%	> 2%	> 5%	Annually
	iii. Specific output	< 120μGy/mAs at 50 cm 28 kV Mo/Mo	> 120μGy/mAs at 50 cm 28 kV Mo/Mo	NA	Annually
	iv. Radiation output consistency	COV ≤ 5%	COV > 5%	NA	Annually
3.	Collimation Assessment				
	i. Deviation between x-ray field and light field	≤ 2% of FID	> 2%	NA	Annually
	ii. Difference between x-ray field and image receptor at chest wall	≤ 1% of FID	> 1%	NA	Annually
	iii. Alignment of chest wall edges of compression paddle and image receptor	≤ 1% of FID	> 1%	NA	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
4.	**Compression Force and Thickness Accuracy**				
	i. Compression force (CF)	130 N ≥CF ≤200N	CF < 130 N or CF > 200 N	NA	Annually
	ii. Difference between measured compression force and indicated compression force	≤±20 N	> ±20 N	NA	Annually
	iii. Difference between measured thickness and indicated thickness	≤ 5 mm	> 5 mm	NA	Annually
5.	**Focal Spot Size Measurement**	F_{perp} or $F_{parallel}$ ≤ 2.0 x F_{nom}	NA	NA	Commissio-ning/Tube Change
6.	**X-Ray Beam Filtration (HVL Measurement)**	Half Value Layer (in mm Al)			
	Mo/Mo	(kVp/100) + 0.03 < Measured HVL < (kVp/100) + 0.12	NA	NA	Annually
	Mo/Rh	(kVp/100) + 0.03 < Measured HVL < (kVp/100) + 0.19	NA	NA	Annually
	Rh/Rh	(kVp/100) + 0.03 < Measured HVL < (kVp/100) + 0.22	NA	NA	Annually
	W/Rh	(kVp/100) + 0.03 < Measured HVL < (kVp/100) + 0.30	NA	NA	Annually
	W/Ag	Manufacturer's criteria	NA	NA	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
7.	**AEC System Performance**				
	i. Repeatability	COV for either mAs or OD ≤ 0.05	COV > 0.05	NA	Annually
	ii. Consistency in film density	OD range ≤ 0.3 of mean OD *(Use SAL or S or EI value for CR system instead of OD)*	OD range > 0.3 of mean OD	NA	Annually
	iii. Density control function	mAs and OD should increase as density setting is increased as manufacturer's specification	mAs does not increase as density setting increases	NA	Annually
	iv. AEC variation with detector position	SF: Variation in mAs ≤10%	SF: Variation in mAs > 10%	NA	Annually
	v. Consistency of OD with baseline value	$OD = OD_{target} \pm 0.2$	$OD = OD_{target} > 0.2$	NA	Annually
8.	**Breast Entrance Exposure and Mean Glandular Dose (MGD)** (for 4.5 cm effective breast thickness)	MGD ≤2.5 mGy	MGD > 2.5 mGy	NA	Annually
9.	Image Quality Evaluation **(Mammographic Accreditation Phantom)**				
	i. Optical density at centre of phantom image (Note that the OD_{target} should be	$OD \leq OD_{target} \pm 0.20$	$OD > OD_{target} \pm 0.20$	NA	Monthly

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	should be between 1.5 and 1.9 OD)				
	ii. mAs changes for given density control setting	≤ ±15%	> ±15%	NA	Monthly
	iii. Optical density difference due to the 4 mm acrylic disc (OD difference should be at least 0.40)	± 0.05	< 0.35 OD or > 0.45 OD	NA	Monthly
	iv. Image evaluation	Should be able to image at least i. 4 of 0.75 nylon fibres; ii. 3 of the 0.32 simulated micro-calcification; iii. 3 of the 0.75mm tumour-like mass	NA	NA	Monthly
	v. Artifact evaluation (Artifact detection)	No significant artifacts visible	Significant artifacts visible	NA	Monthly
10.	**Radiation Leakage**				
	Exposure from the leakage radiation at 1 meter from the x-ray tube in an hour at every rating specified by the manufacturer	≤1 mGy (≤100mR)	NA	>1 mGy (>100 mR)	Annually
11.	**Scattered Radiation**				
	Exposure in one week at every occupied area outside the x-ray room and at the position normally occupied by the operator at the control area	≤0.1 mGy (≤10 mR)	NA	> 0.1 mGy (>10 mR)	Annually

Table 5.b: Performance and Safety Standards for Full Field Digital Mammography System

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
1.	**Unit Assembly**	All mechanical movement and locks are functioning properly	NA	Mechanical fault which affects functionality and safety	Annually
2.	**X-Ray Generator Performance**				
	i. Accuracy of kVp	Accuracy ≤±5%	> 5%	> 2 kV	Annually
	ii. Repeatability of radiation output	kVp repeatability COV ≤2%	> 2%	> 5%	Annually
	iii. Specific output	< 120μGy/mAs at 50 cm 28 kV Mo/Mo	> 120μGy/mAs at 50 cm 28 kV Mo/Mo	NA	Annually
	iv. Radiation output consistency	COV ≤ 5%	COV > 5%	NA	Annually
3.	**Collimation Assessment**				
	i. Deviation between x-ray field and light field	≤ 2% of FID	> 2%	NA	Annually
	ii. Difference between x-ray field and image receptor at chest wall	≤ 1% of FID	> 1%	NA	Annually
	iii. Alignment of chest wall edges of compression paddle and image receptor	≤ 1% of FID	> 1%	NA	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	iv. Size of imaged field for FFDM	≤ 5%	> 5%	NA	Annually
4.	**Compression Force and Thickness Accuracy**				
	i. Compression force (CF)	130 N ≥CF ≤200 N	CF < 130 N or CF > 200 N	NA	Annually
	ii. Difference between measured compression force and indicated compression force	≤±20 N	> ±20 N	NA	Annually
	iii. Difference between measured thickness and indicated thickness	≤ 5 mm	> 5 mm	NA	Annually
5.	**Focal Spot Size Measurement**	F_{perp} or $F_{parallel}$ ≤ 2.0 x F_{nom}	NA	NA	Commissio-ning/Tube Change
6.	**X-Ray Beam Filtration (HVL Measurement)**	Half Value Layer (in mm Al)			
	Mo/Mo	(kVp/100) + 0.03 < Measured HVL < (kVp/100) +0.12	NA	NA	Annually
	Mo/Rh	(kVp/100) + 0.03 < Measured HVL < (kVp/100) +0.19	NA	NA	Annually
	Rh/Rh	(kVp/100) + 0.03 < Measured HVL < (kVp/100) +0.22	NA	NA	Annually
	W/Rh	(kVp/100) + 0.03 < Measured HVL < (kVp/100) +0.30	NA	NA	Annually
	W/Ag	Manufacturer's criteria	NA	NA	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
7.	**AEC System Performance**				
	i. Repeatability	Maximum deviation in mAs from mean ≤ 5%	Maximum deviation in mAs from mean > 5%	Maximum deviation in mAs from mean ≥10%	Annually
	ii. Grey scale with change in kVp and phantom thickness (Using the same target and filter material combination)	Variation MPV or EI in range ± 10% mean (MPV or EI)	Variation MPV or EI exceed ± 10% mean (MPV or EI)	NA	Annually
	iii. Density control function	Constant change in mAs per step	AEC density control step outside manufacturer's specification	NA	Annually
	iv. AEC variation with detector position	Variation in mAs ≤10%	Variation in mAs > 10%	NA	Annually
	v. Consistency in Gray scale level with fixed in kVp and phantom thickness (Using the same target and filter material combination)	Variation MPV or EI = ± 5 % of mean MPV or mean EI	Variation PV or EI exceed ± 5 % of mean MPV or mean EI	NA	Annually
	vi. Contrast to Noise Ratio (CNR)	Change from baseline CNR for any thickness ≤ 10%	Change from baseline CNR for any thickness > 10%.	NA	Annually
8.	**Breast Entrance Exposure and Mean Glandular Dose (MGD)** (for 4.5 cm effective breast thickness)	MGD ≤2.5 mGy	MGD > 2.5 mGy	NA	Annually

No.	Physical Parameters		Performance Level			Frequency
			Acceptable Level	**Remedial Level**	**Suspension Level**	
	Dose versus thickness					
	Thickness of PMMA (cm)	Thickness of equivalent breast (cm)	NA	For mean glandular dose to equivalent breast (mGy)	NA	Annually
	2.0	2.1		> 1.0		
	3.0	3.2		> 1.5		
	4.0	4.5		> 2.0		
	4.5	5.3		> 2.5		
	5.0	6.0		> 3.0		
	6.0	7.5		> 4.5		
	7.0	9.0		> 6.5		
9.	Image Quality Evaluation (Mammographic Accreditation Phantom)					
	i. mAs changes for given density control setting (If applicable)		≤ ±15%	> ±15%	NA	Monthly
	ii. Image evaluation		• 5 of 0.75 nylon fibres; • 4 of the 0.32 simulated micro-calcification; • 4 of the 0.75mm tumour-like mass	NA	NA	Monthly

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
		or Equivalent specify by manufacturer			
	iii. Artifact evaluation (Artifact detection)	No significant artifacts visible	Significant artifacts visible	NA	Monthly
10.	**Detector Performance**				
	i. Uniformity	COV ≤10%	COV > 10%	NA	Semi-annually
	ii. Artifacts	No significant artifacts that may affect clinical image quality	Any significant artifacts that may affect clinical image quality	NA	Semi-annually
	iii. Detector response, noise level and signal to noise ratio measurement	Meet all following criteria:	Meet all following criteria:	NA	Semi-annually
		i. Reference air kerma ≤ 20% from baseline value;	i. Reference air kerma > 20% from baseline value;		
		ii.Standard deviation ≤ 10% from baseline; and	ii.Standard deviation > 10% from baseline; and		
		iii. SNR change ≤ 10%	iii. SNR change > 10%		
	iv. Spatial resolution / Modulation Transfer Function (MTF)	i. < 10% change in SWCTF (f);	i. > 10% change in SWCTF(f);	NA	Semi-annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
		ii. Limiting resolution > 75% of baseline	ii. Limiting resolution < 75% of baseline		
	v. Geometric distortion	No distortion	Any distortion	NA	Semi-annually
	vi. Detector ghosting	Ghost image SDNR ≤2.0	Ghost image SDNR > 2.0	NA	Semi-annually
11.	**Image Display (Workstation Monitor)**	SMPTE test pattern. i. Grey-scale areas from 0-100% in 10% steps & both 0% with 5% inner area and 100% with 95% inner square. Both should be visible. ii. Horizontal and vertical bars sized range from 2-6 pixels/bar.	NA	NA	Semi-annually
	i. Illuminance	Illuminance ≤10 lux	Illuminance >10 lux	NA	Semi-annually
	ii. Luminance response	NA	NA	NA	Semi-annually
	iii. Luminance uniformity	Maximum variation ≤30%	Maximum variation > 30%	NA	Annually
	iv. Resolution	No loss in resolution	Any loss in resolution	NA	Annually
	v. Geometric distortion	No distortion	Any distortion	NA	Annually
	vi. Artifacts	No artifacts	Any artifacts	NA	Annually
	vii. Overall imaging performance	Subtle details visible	Subtle details not visible	NA	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
12.	**Image Display (Printer)**				
	i. Optical density response	OD variation from DICOM standard ≤ 10%	OD variation from DICOM standard > 10%	NA	Semi-annually
	ii. Contrast visibility	Small contrast steps clearly visible OD outside baseline ± 10%	Small contrast steps not clearly visible OD outside baseline ± 10%	NA	Semi-annually
	iii. Density uniformity	Max variation ≤ 10%	Max variation >10%	NA	Semi-annually
	iv. Artifacts	No artifacts	Any artifacts	NA	Semi-annually
	v. Geometric distortion	No distortion	Any distortion	NA	Semi-annually
	vi. Resolution	No loss in resolution	Any loss in resolution	NA	Semi-annually
13.	**Radiation Leakage**				
	Exposure from the leakage radiation at 1 meter from the x-ray tube in an hour at every rating specified by the manufacturer	≤1 mGy (≤00mR)	NA	>1 mGy (>100 mR)	Annually
14.	**Scattered Radiation**				
	Exposure in one week at every occupied area outside the x-ray room and at the position normally occupied by the operator at the control area	≤0.1 mGy (≤0 mR)	NA	> 0.1 mGy (>10 mR)	Annually

Note : All tests shall be carried out during commissioning and after replacement of major components.

Table 6: Performance and Safety Standards for Bone Mineral Densitometry (BMD) System with Dual Energy X-ray Absorptiometry (DXA)

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
1.	Unit Assembly Evaluation i. Emergency Stop Switch Test ii. X-ray Beam Enable Key Switch Test iii. Table Functionality	All mechanical movements and switches are functioning properly	NA	Mechanical fault which affect functionality and safety	Annually
2.	Accuracy of Laser Light Positioning	≤±5mm	>±5mm	NA	Annually
.	Bone Mineral Density (BMD) Reproducibility	≤±1.5% or manufacturer specification	>±1.5% or manufacturer specification	> ±3%	Annually
4.	Accuracy of Scan Line Spacing and Step Spacing (for pencil beam)	≤±2%	NA	> ± 2%	Annually
5.	Patient Entrance Surface Dose	≤200 μGy	>200 μGy	>500 μGy	Annually
6.	Radiation Leakage				
	Exposure from the leakage radiation at 1 meter from the x-ray tube in an hour at every rating specified by the manufacturer	≤1 mGy (≤100mR)	NA	>1 mGy (>100 mR)	Annually
7.	Scattered Radiation				
	i. Scattered Radiation at the position where the operator occupied at workstation	≤0.1 mGy (≤10mR)	NA	>0.1mGy (>10mR)	Annually

No.	Physical Parameters	Performance Level			Frequency
		Acceptable Level	Remedial Level	Suspension Level	
	ii. Exposure in one week at every occupied area outside the X-ray room	≤0.1 mGy (≤10mR)	NA	>0.1 mGy (>10 mR)	

Note : All tests shall be carried out during commissioning and after replacement of major components.

AUDIT ON THE QUALITY OF RADIOGRAPH

Programme : Radiology

Area of Concern : Performance Quality and Radiation Safety of Radiology Services

Rationale :

1. The audits on the quality of radiographs are to ensure that the images produced by the facility concerned achieve diagnostic quality for clinical interpretation and in accordance with the ALARA principle

2. For the purpose of Licensing / Registration requirement

Definition of Term :

1. Radiograph
   Images are processed conventionally.
2. Digital
   Radiographic images are digitally processed via :

   a) Computed Radiography (CR)
   b) Digital Radiography (DDR).

3. Neonate
   It refers to an infant in the first 28 days of life after birth.

Target : All medical facilities providing conventional and digital radiography

Exclusion Criteria : All neonatal radiographs with internal line

Audit Frequency : The process of sampling and radiographic evaluation shall be conducted annually.

Criteria for Assessment :

1. **Image Annotation**

   Patient identification, examination date, clinic/ hospital name and anatomical markers * must be clearly recorded on the radiograph. Ensure that the image annotation does not cover the region of interest.

   *The use of primary anatomical markers are mandatory

2. **Patient Positioning**

   It should cover the region of interest.

3. **X - ray Beam Collimation**

   X-ray is collimated to the region of interest.

: 4. **Image Quality Assessment**

i. The exposure of patient at the minimum level required in order to achieve the intended diagnostic objective.
ii. Visualization of vital anatomical structures.

Scope of Audit : **Types Of Examinations**

1. Chest
2. Extremities
3. Lumbar
4. Neonatal Chest (if applicable)
5. Neonatal Abdomen (if applicable)

Number of Radiographs / Images Audited :

Type of Examination	Type of Premises		
	Private Medical Practitioner (GP's) / Clinics	Health Clinics	All Hospital /Medical Institutions
Adult Chest	10	10	15
Adult Extremity / Lumbar		10	15
Neonatal Chest / Abdomen	-	-	10
Total	**10**	**20**	**40**

Methodology : 1. **Data Collection**

i. Selection of radiographs shall be from either conventional or digital processing.
ii. Radiographs are randomly selected. Audit will be conducted in accordance with the pre-determined criterias.
iii. For neonatal and paediatric radiograph, shall only be applicable to facilities providing this service.
iv. Submission of radiographs shall be in hard copy or digital format.

Auditing of Radiographs and Digital Images

i. The audit is performed by Radiologist and/ or Radiographer
ii. The Radiographers must have at least 3 years experience.

3. **Report and Result of the Audit**

i. Auditor shall prepare the report. Report shall be verified by a radiologist.
ii. The audit assessment report shall be sent to JKN before or on January 31 every year to meet the current requirements by the KKM appropriate authority.

Scoring Method : It shall be evaluated through a scoring system as follows

1 - Criteria fulfilled
0. - Criteria not fulfilled

Standard Percentage : The passing score for each radiograph is 80%.

No.	Type of Premises	Type of Examinations	Minimum Passing Criteria for Each Radiograph	Minimum Numbers of Radiographs to Pass
1.	Private Medical Practitioner (GP's) / Clinics	Adult Chest	12 out of 15	8 out of 10
		Extremity/ Lumbar	8 out of 10	
2.	Health Clinics	Adult Chest	12 out of 15	8 out of 10
		Adult Extremity / Lumbar	8 out of 10	8 out of 10
3.	All Hospital /Medical Institutions	Adult Chest	12 out of 15	12 out of 15
		Adult Extremity / Lumbar	8 out of 10	12 out of 15
		Neonatal Chest	16 out of 20	8 out of 10
		Neonatal Abdomen	8 out of 10	

Form :

1. Lampiran 7A: Image Quality Assessment : Chest Radiograph for Adult
2. Lampiran 7B Image Quality Assessment: Extremities Radiograph for Adult
3. Lampiran 7C Image Quality Assessment : Lumbar Radiograph for Adult
4. Lampiran 7D Image Quality Assessment : Chest Radiograph for Neonatal
5. Lampiran 7E Image Quality Assessment : Abdominal Radiograph for Neonatal

AUDIT FORM A
IMAGE QUALITY ASSESSMENT : CHEST RADIOGRAPH FOR ADULT

FACILITY : _____

TYPE OF MACHINE / YEAR OF MACHINE : _____

TYPE OF IMAGE PROCESSOR
(Choose one only. Pick the main processor used) : **Conventional Processor** ☐ **CR System** ☐ **DR System** ☐

MARKING FOR EACH CATEGORY:
(All criteria have to be fulfilled)
a) **1 : YES**
b) **0 : NO**

NUM.	CRITERIA	RADIOGRAPH/IMAGE														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
PART 1.0 - IMAGE ANNOTATION																
1.1	**Patient identification**															
1.2	**Date of Examination**															
1.3	**Name of Clinic/Hospital**															
1.4	**Primary anatomical marker**															
PART 2.0 - PATIENT POSITIONING																
2.1	**Symmetrical positioning of thorax** *Stemoclavicular joints should be equidistant.*															
2.2	**Medial border of the scapulae to be outside of the lung fields**															
PART 3.0 - IMAGE COLLIMATION																
3.1	**Collimation of image** a) *The upper border of the illuminated fields should be slightly above the shoulders bilaterally to include both apices without superimposition of the chin and the lower border down to the level of T12/ L2 to include the diaphragm .*															
	b) *The lateral border to include the rib cage and part of shoulder joints.*															
PART 4.0 - IMAGE QUALITY ASSESSEMENT																

AUDIT FORM A
IMAGE QUALITY ASSESSMENT : CHEST RADIOGRAPH FOR ADULT

NUM	CRITERIA	RADIOGRAPH/IMAGE														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
4.1	**Contrast and exposure are adequate** *a) Able to visualize retro cardiac area.*															
	b) Linear and recticular details seen out to the lung periphery.															
	a) Able to visualize vertebral body T1 to T4.															
4.2	**The lungs are well inflated** *Able to visualize either six ribs anteriorly or ten ribs posteriorly.*															
4.3	**Sharp visualization of normal chest anatomy** *Visually sharp :* *a) Trachea and proximal bronchi*															
	b) Borders of the heart and aorta															
	a) Diaphragm and costo-phrenic angles															
TOTAL MARKS / 15 *For each radiograph, minimum 12 score to pass audit*																
***SCORING (1 or 0)**																
PERCENTAGE = _____ %																

***Adapted from Europian Guideline on Quality Criteria for Diagnostic Radiographic Images, EUR 16260 EN, 1996*

Mandatory Criteria : PART 1.0 - IMAGE ANNOTATION
If any of Part 1.0 is not fulfilled, it will result in the automatic failure of that radiograph.

Minimum numbers of radiographs to pass are 80% (8 out of 10(for GP's and Health Clinics) or 12 out of 15 (for All Hospitals/ Medical Institutions) radiographs)

2.0 Overall comment

_____

_____

Audited by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Radiologist:
Date:

AUDIT FORM B
IMAGE QUALITY ASSESSMENT : EXTREMITIES RADIOGRAPH FOR ADULT

FACILITY : _____

TYPE OF MACHINE / YEAR OF MACHINE : _____

TYPE OF IMAGE PROCESSOR : **Conventional Processor** ☐ **CR System** ☐ **DR System** ☐

(Choose one only. Pick the main processor used)

MARKING FOR EACH CATEGORY:
(All criteria have to be fulfilled)

a) **1 : YES**
b) **0 : NO**

NUM	CRITERIA	RADIOGRAPH/IMAGE 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
PART 1.0 - IMAGE ANNOTATION																
1.1	**Patient identification**															
1.2	**Date of Examination**															
1.3	**Name of Clinic/Hospital**															
1.4	**Primary anatomical marker**															
PART 2.0 - PATIENT POSITIONING																
2.1	**Correct region of interest included**															
2.2	**Two appropriate projections (AP/ Lateral/ Oblique)**															
PART 3.0 - X-RAY BEAM COLLIMATION																
3.1	**Collimation of image**															
PART 4.0 - IMAGE QUALITY ASSESSEMENT																
4.1	**Optimum exposure** a) Sharp visualization of trabeculae and cortex															
	b) Appropriate visualization of soft tissues															
4.2	**Proximal and distal joints to be included**															
TOTAL MARKS / 10 *For each radiograph, minimum 8 score to pass audit*																
SCORING (1 or 0)																
PERCENTAGE = _____ %																

***Adapted from Europian Guideline on Quality Criteria for Diagnostic Radiographic Images, EUR 16260 EN, 1996*

AUDIT FORM B
IMAGE QUALITY ASSESSMENT : EXTREMITIES RADIOGRAPH FOR ADULT

Mandatory Criteria : PART 1.0 - IMAGE ANNOTATION
If any of Part 1.0 is not fulfilled, it will result in the automatic failure of that radiograph.

Minimum numbers of radiographs to pass are 80% (8 out of 10(for GP's and Health Clinics) or 12 out of 15 (for All Hospitals/ Medical Institutions) radiographs)

2.0 Overall comment

_____

_____

_____

Audited by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Radiologist:
Date:

AUDIT FORM C
IMAGE QUALITY ASSESSMENT : LUMBAR RADIOGRAPH FOR ADULT

FACILITY : _____

TYPE OF MACHINE / YEAR OF MACHINE : _____

TYPE OF IMAGE PROCESSOR
(Choose one only. Pick the main processor used)

: **Conventional Processor** ☐ **CR System** ☐ **DR System** ☐

MARKING FOR EACH CATEGORY:
(All criteria have to be fulfilled)
a) **1 : YES**
b) **0 : NO**

NUM	CRITERIA	RADIOGRAPH/IMAGE 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
PART 1.0 - IMAGE ANNOTATION																
1.1	**Patient identification**															
1.2	**Date of Examination**															
1.3	**Name of Clinic/Hospital**															
1.4	**Primary anatomical marker**															
PART 2.0 - PATIENT POSITIONING																
2.1	**Correct region of interest included**															
PART 3.0 - X-RAY BEAM COLLIMATION																
3.1	**Collimation of image** *a) Lateral view : Superior Inferior margins of collimation should include T12/L1 – T5/S1 joints.*															
	b) AP view : Lateral margins of collimation field should include the SI joints and either one of the psoas muscle outlines shall be visible.															
PART 4.0 - IMAGE QUALITY ASSESSEMENT																

AUDIT FORM C
IMAGE QUALITY ASSESSMENT : LUMBAR RADIOGRAPH FOR ADULT

NUM	CRITERIA	RADIOGRAPH/IMAGE 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
4.1	a) **AP** *Spinous processes at the midline of vertebral column and equidistance from the sacroiliac joints*															
	b) **Lateral** *Superimposed borders of vertebral bodies.*															
4.2	**Optimum exposure** *Should clearly visualize the vertebral bodies and joint spaces without overexposure of other vertebral structures.*															
	TOTAL MARKS / 10 *For each radiograph, minimum 8 score to pass audit*															
	SCORING (1 or 0)															
	PERCENTAGE = _____ %															

***Adapted from Europian Guideline on Quality Criteria for Diagnostic Radiographic Images, EUR 16260 EN, 1996*

Mandatory Criteria : PART 1.0 - IMAGE ANNOTATION
If any of Part 1.0 is not fulfilled, it will result in the automatic failure of that radiograph.

Minimum numbers of radiographs to pass are 80% (8 out of 10 (for GP's and Health Clinics) or 12 out of 15 (for All Hospitals/ Medical Institutions) radiographs)

2.0 Overall comment

_____

_____

Audited by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Radiologist:
Date:

AUDIT FORM D
IMAGE QUALITY ASSESSMENT : CHEST RADIOGRAPH FOR NEONATAL

FACILITY : _____

TYPE OF MACHINE / YEAR OF MACHINE : _____

TYPE OF IMAGE PROCESSOR : **Conventional Processor** ☐ **CR System** ☐ **DR System** ☐

(Choose one only. Pick the main processor used)

MARKING FOR EACH CATEGORY:
(All criteria have to be fulfilled)

a) **1 : YES**
b) **0 : NO**

NUM	CRITERIA	RADIOGRAPH/ IMAGE									
		1	2	3	4	5	6	7	8	9	10
PART 1.0 - IMAGE ANNOTATION											
1.1	Patient identification										
1.2	Date of Examination										
1.3	Name of Clinic/Hospital										
1.4	Primary anatomical marker										
1.5	Exposure Factors indicated on the radiograph/ image (kVp; mAs)										
PART 2.0 - PATIENT POSITIONING											
2.1	Symmetrical positioning of thorax: *a) without rotation*										
	b) without tilting										
2.2	Correctly centered over the region of interest										
PART 3.0 - X-RAY BEAM COLLIMATION											
3.1	Collimation of image with appropriate field size										
PART 4.0 - IMAGE QUALITY ASSESSMENT											
4.1	Reproduction of the chest must extend from just above the apices of the lung to T12 / L1 level.										
4.2	Reproduction of the vascular pattern in central 2/3 of the lung.										
4.3	Contrast and exposure are adequate										

AUDIT FORM D
IMAGE QUALITY ASSESSMENT : CHEST RADIOGRAPH FOR NEONATAL

NUM	CRITERIA	RADIOGRAPH/ IMAGE									
		1	2	3	4	5	6	7	8	9	10
4.4	**Visualisation of :** a) *the trachea*										
	a) the proximal bronchi										
4.5	**Visually sharp :** *a) the diaphragm*										
	b) costo-phrenic angles										
4.6	**Reproduction of:** *a) the spine*										
	b) paraspinal structures										
4.7	**Visualisation of:** *a) the retrocardiac lung*										
	b) the mediastinum										
	TOTAL MARKS : /20 *For each radiograph, minimum 16 score to pass audit*										
	SCORING (1 or 0)										
	PERCENTAGE = _____%										

***Adapted from Europian Guideline on Quality Criteria for Diagnostic Radiographic Images, EUR 16260 EN, 1996*

Mandatory Criteria : PART 1.0 - IMAGE ANNOTATION
If any of Part 1.1 to 1.4 is not fulfilled, it will result in the automatic failure of that radiograph.

Minimum numbers of radiographs to pass are 80% (8 out of 10 radiograph)

2.0 Overall comment

_____

_____

Audited by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Radiologist:
Date:

AUDIT FORM E
IMAGE QUALITY ASSESSMENT : ABDOMINAL RADIOGRAPH FOR NEONATAL

FACILITY : _____

TYPE OF MACHINE / YEAR OF MACHINE : _____

TYPE OF IMAGE PROCESSOR : **Conventional Processor** ☐ **CR System** ☐ **DR System** ☐

(Choose one only. Pick the main processor used)

MARKING FOR EACH CATEGORY:
(All criteria have to be fulfilled)

a) **1 : YES**
b) **0 : NO**

NUM	CRITERIA	RADIOGRAPH/ IMAGE									
		1	2	3	4	5	6	7	8	9	10
PART 1.0 - IMAGE ANNOTATION											
1.1	**Patient identification**										
1.2	**Date of Examination**										
1.3	**Name of Clinic/Hospital**										
1.4	**Primary anatomical marker**										
1.5	**Exposure Factors indicated on the radiograph/ image (kVp; mAs)**										
PART 2.0 - PATIENT POSITIONING											
2.1	**Correctly centred over the region of interest**										
PART 3.0 - X-RAY BEAM COLLIMATION											
3.1	**Collimation of image with appropriate field size**										
PART 4.0 - IMAGE QUALITY ASSESSMENT											
4.1	**Reproduction of the abdomen-** *a) from the diaphragm to the ischial tuberosities including the lateral walls.*										
	b) *the properitoneal fat lines*										
4.2	**Contrast and exposure are adequate**										
	TOTAL MARKS/ /10 For each radiograph, minimum 8 score to pass audit										
	SCORING (1 or 0)										
	PERCENTAGE= ____%										

***Adapted from Europian Guideline on Quality Criteria for Diagnostic Radiographic Images, EUR 16260 EN, 1996*

AUDIT FORM E
IMAGE QUALITY ASSESSMENT : ABDOMINAL RADIOGRAPH FOR NEONATAL

Mandatory Criteria : PART 1.0 - IMAGE ANNOTATION
If any of Part 1.1 to 1.4 is not fulfilled, it will result in the automatic failure of that radiograph.

Minimum numbers of radiographs to pass are 80% (8 out of 10 radiograph)

2.0 Overall comment

Audited by:

.....
Name:
Position:
Date:

Verified by:

.....
Name of Radiologist:
Date:

PGMI CLASSIFICATION OF MAMMOGRAM FILMS/ IMAGES

Programme : Radiology

Area of Concern : Performance Quality and Radiation Safety of Radiology Services

Rationale :

1. The audits on the quality of radiographs are to ensure that the images produced by the facility concerned achieve diagnostic quality for clinical interpretation and in accordance with the ALARA principle.

2. For the purpose of Licensing / Registration requirement.

Objectives : PGMI is a useful performance indicator tool for maintaining high mammographic quality standards.

Poor quality mammogram may result in:

i. incorrect diagnosis
ii. repeat mammogram
iii. unnecessary radiation dose
iv. delayed patient treatment
v. increased cost

Radiographers should be able to identify the main failures, propose corrective actions and thus minimize technical repeats

Definition of Term :

1. Mammogram films

   Mammogram films are processed conventionally.

2. Mammogram images

   Mammogram images are digitally processed via:

   a) Computed Radiography (CR)
   b) Digital Radiography (DDR).

3. The PGMI classification is a quality review model that categorises images into 4 grades:

   P - Perfect ;
   G - Good;
   M - Moderate
   I - Inadequate

Exclusion Criteria : 1. Any previous breast surgery
2. Any breast implants

Target : All medical facilities providing mammography services.

Audit Frequency : Randomly selected 25 cases from January to June and another 25 cases from July to December shall be reviewed and graded according to the PGMI classification.

Criteria For Assessment : Image quality assessment shall be based on the PGMI classification.

1. All breast tissue imaged (fat tissue visualised posterior to glandular tissue)
2. Correct image identification clearly shown
    i. date of examination
    ii. client identification
    iii. side markers
    iv. positional markers
    v. radiographer identification
3. Correct exposure
4. Good compression
5. Absence of movement
6. Correct processing
7. Absence of artefacts
8. No skin folds
9. Symmetrical images

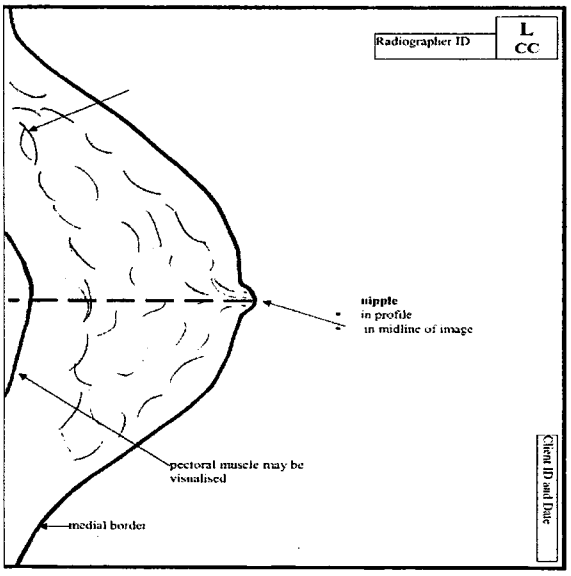
1 (A) **CRITERIA FOR IMAGE ASSESSMENT IN CRANIO-CAUDAL (CC) VIEW**

1. All breast tissue imaged
    i. Nipple in profile
    ii. Nipple in midline of imaged breast

2. Correct film identification clearly shown
    i. Date of the examination
    ii. Client identification
    iii. Side markers
    iv. Positional markers
    v. Radiographer identification

3. Correct exposure
4. Good compression
5. Absence of movement
6. Correct processing
7. Absence of artifacts
8. No skin folds
9. Symmetrical images

CRANIO-CAUDAL VIEW



Posterior Nipple Line (PNL): Nipple to chest wall edge of film. Should be within 1cm of posterior nipple line on the medio-lateral oblique view.

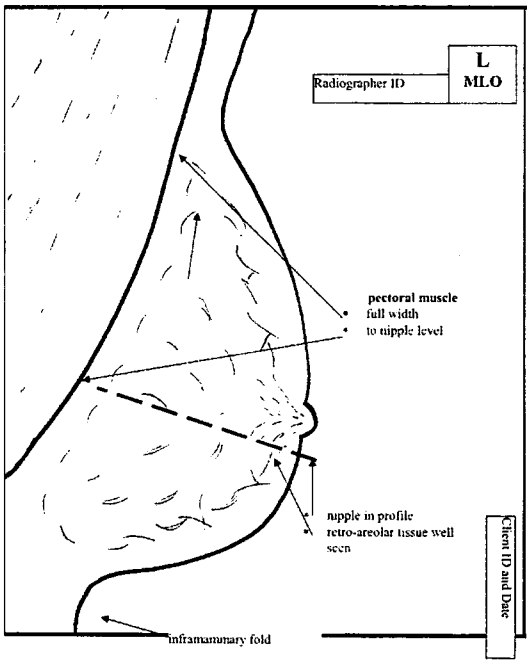
2(A) CRITERIA FOR IMAGE ASSESSMENT IN MEDIO-LATERAL OBLIQUE (MLO) VIEW

1. All breast tissue imaged (fat visualized posterior to glandular tissue)
   i. Pectoral muscle shadow to nipple level
   ii. Full width of pectoral muscle
   iii. Nipple in profile (retro-areolar tissue well separated)
   iv. Infra-mammary fold well demonstrated

2. Correct film identification clearly shown
   i. Date of examination
   ii. Client identification
   iii. Side markers
   iv. Positional markers
   v. Radiographer identification

3. Correct exposure
4. Good compression
5. Absence of movement
6. Correct processing
7. Absence of artifacts
8. No skin folds
9. Symmetrical images

MEDIO-LATERAL OBLIQUE VIEW



Posterior Nipple Line (PNL): Nipple to point at right angles to pectoral muscle. Should be within 1cm of posterior nipple line on the cranio-caudal view.

Scope of Audit : **Images to be audited** (4 views per case) :

1. Right Cranio-Caudal (RCC)
2 Left Cranio-Caudal (LCC)
3. Right Medio-Lateral Oblique (RMLO)
4. Left Medio-Lateral Oblique (LMLO)

Total Number of Mammogram Films / Images Audited : 50 randomly selected cases of mammogram films or images per year.

Methodology : **1. Data Collection:**

i. Selection of mammogram films or images shall be either from conventional or digital processing.

ii. Audit will be conducted in accordance with the pre-determined criteria.

2. Auditing of Mammogram films or images

i. Sample of 50 randomly selected cases of mammogram films or images, (25 cases from January to June and another 25 cases from July to December) shall be reviewed and graded according to the PGMI classification.

ii. This is performed independently by a radiologist and a radiographer who meet the following criteria:

a. Radiologist: at least 3 years working experience in mammography.
b. Radiographer: at least 1 year working experience in mammography and has attended mammography related CME courses.

iii. Results are recorded in the PGMI Classification Form or data sheet (Lampiran 8A).
iv. The reasons for mammography films or images in the Inadequate (I) category shall be recorded and remedial measures adviced.

3. Report and Result of the Audit

i. The radiographer shall prepare the report and it shall be verified by a radiologist.
ii. The audit assessment report shall be sent to JKN before or on January 31 every year to meet the current requirements by Ministry of Health (MOH).

4. **Feedback of the audit (if relevant)**

i. If the medical facility fails to achieve the standard they will be notified in writing (compliance report) by MOH and advised on the corrective measures.
ii. Feedback in writing of the corrective measures taken shall be forwarded back to the authorities within 3 months from the date of receiving compliance report.

Scoring Method : Each mammogram film or image is assessed based on the PGMI classification:

P - Perfect ;
G - Good;
M - Moderate
I - Inadequate

Standard Percentage : The standard is based on the PGMI classification of both CC and MLO views.

A) CLASSIFICATION OF IMAGES (CRANIO-CAUDAL VIEW)

Category	Criteria
P (Perfect)	Both images meet all listed criteria.
G (Good)	• All postero-medial tissue visualized (axillary portion of breast not to be included at expense of medial portion) • Nipple in profile • Nipple in midline of imaged breast • Both images meet all criteria listed from 2 to 6 as listed above. • A minor degree of variation in items 7 to 9 as listed above will be accepted.
M(Moderate)	• Most breast tissue imaged (however all breast tissue must be imaged on MLO view) • Nipple not in profile but clearly distinguishable from surrounding breast tissue (however nipple must be in profile on MLO view) • Nipple not in midline of the imaged breast • Correct film/image identification • Correct exposure • Adequate compression • Absence of movement • Correct processing • Artefacts which do not obscure the image • Skin folds which do not obscure the breast tissue • Asymmetrical images
I (Inadequate)	• Significant part of the breast tissue not imaged • Incomplete or incorrect identification • Incorrect exposure • Inadequate compression which hinders diagnosis • Blurred image • Incorrect processing • Overlying artifacts • Skin folds which obscure the image

B) CLASSIFICATION OF IMAGES (MEDIO-LATERAL OBLIQUE VIEW)

Category	Criteria
P (Perfect)	Both images meet all listed criteria
G (Good)	• All breast tissue imaged • Pectoral muscle well demonstrated • Nipple in profile • Infra-mammary fold well demonstrated • Both images meet all criteria listed from 2 to 6 as above . • A minor degree of variation in items 7 to 9 as listed above will be accepted.
M (Moderate)	• Most breast tissue imaged • Pectoral muscle not to nipple level but posterior breast tissue adequately shown • Nipple not in profile but clearly distinguishable from retro-areolar tissue (however the nipple should be well demonstrated in CC view). • Infra-mammary fold not clearly demonstrated but breast tissue adequately shown • Correct film identification • Correct exposure • Adequate compression • Absence of movement • Correct processing • Artefacts which do not obscure the image • Skin folds which do not obscure the breast tissue • Asymmetrical images
I (Inadequate)	• Part of the breast not imaged • Incomplete or incorrect identification • Incorrect or inadequate exposure • Inadequate compression which hinders diagnosis • Blurred image • Incorrect processing • Overlying artifacts • Skin folds which obscure the image

The acceptable quality standards are as follow :

i. Images with P, G, M categories shall be > 97%

$$\frac{\text{Total number of cases in P,G and M categories}}{\text{Total number of randomly selected 50 mammogram cases}} \times 100\%$$

ii. Images with P and G categories shall be > 75%

$$\frac{\text{Total number of cases in P, and G categories}}{\text{Total number of randomly selected 50 mammogram cases}} \times 100\%$$

iii. Images with I (Inadequate) category shall be < 3%

$$\frac{\text{Total number of cases in I categories}}{\text{Total number of randomly selected 50 mammogram cases}} \times 100\%$$

Form : Lampiran 8A Form: PGMI Classification Form For Mammography

PGMI Classification Form For Mammography

FACILITY : _____

MACHINE MODEL / YEAR OF MACHINE : _____

YEAR OF INSTALLATION :

TYPE OF IMAGE PROCESSOR *(Choose one only. Pick the main processor used)* : **FFDM** ☐ **CR System** ☐ **Conventional** ☐

IMAGE PROCESSOR TYPE/MODEL : _____

No.	MRN	Views				Radiographer's Overall Rating	Views				Radiologist's Overall Rating	*Final Rating
		R CC	L CC	R MLO	L MLO		R CC	L CC	R MLO	L MLO		

Total:

P	
G	
M	
I	

PGMI Grades	Total No. of Cases (*Final Rating)	Acceptable Quality Standard
P,G,M		
P,G		
I		

Exclusion Criteria:

1. Any previous breast operation
2. Any breast implants

*Final rating: Conclusion after discussion between radiologist and radiographer

Remarks: _____

Corrective Action: _____

Audited by:

.....
Name:
Position: Radiographer
Date:

Verified by:

.....
Name:
Position: Radiologist
Date:

CONTINUOUS MEDICAL EDUCATION (CME)

1. CME courses of at least 4 hours per year are compulsory for all workers.

2. CME courses should cover any of the following topics:

   2.1 Legislation and Regulation of Act 304
   2.2 Radiation Safety Awareness
   2.3 Quality Assurance Program Management
   2.4 X-Ray Equipment and Associated Facilities
   2.5 Clinical Practices and Radiologic Correlation
   2.6 Requirements and Criteria for Image Quality
   2.7 Interpretation of Clinical Images
   2.8 Current Developments of Imaging Modalities and Radiation Protection

3. All CME courses must be approved by Medical Radiation Surveillance Division of MOH and must include at least two of the above topics.

4. Only maximum of 2 online CME courses per year can be accepted. This will be taken as equivalent to 2 hours.

5. Seminars, workshops or meetings which include the above topics are accepted.

6. Courses organized by the MOH, Universities, Institutions and recognized Professional Bodies may be accepted.

7. All CME courses attended must have supporting documents for examples attendance sheet, events certificate, etc. which must be submitted to JKN every 12 months to meet the current requirements by the KKM appropriate authority.

8. Topics and suggested subtopics are shown in Table 1.

Table 1: Detail Sub-Topic

TOPIC / SUB-TOPIC
1.1 LEGISLATION AND REGULATIONS OF ACT 304
Sub-topic
1.1.1 Atomic Energy Licensing Act 1984 (Act 304)
1.1.2 Radiation Protection (Licensing) Regulations 1986
1.1.3 Atomic Energy Licensing (Radioactive Waste Management) Regulations 2011
1.1.4 Atomic Energy Licensing (Basic Safety Radiation Protection) Regulations 2010
1.1.5 Atomic Energy Licensing (Transport) Regulations 1988
1.1.6 Circulars and Guidelines
1.1.7 Current Regulatory Requirement Under Act 304 in Medical Purposes

1.2 RADIATION SAFETY AWARENESS
Sub-topic
1.2.1 Basic Information on Ionizing Radiation
1.2.2 Radiation Hazards and Effects of Ionizing Radiation on Man
1.2.3 General Radiation Protection Principles and Medical Exposures
1.2.4 Radiation Protection and Safety Measures
1.2.5 Good Clinical Practice : Radiological and Interventional Procedures
1.2.6 Radiation Safety Audit
1.2.7 Radiation Protection Program
1.3 X-RAY EQUIPMENT AND ASSOCIATED FACILITIES
Sub-topic
1.3.1 X-Ray Equipment, Components and Production of X - Ray
1.3.2 Characteristics of X - Ray, Effects and Control
1.3.3 Maintenance and Calibration of Equipment
1.3.4 Quality Control Measurement
1.3.5 Image Processing
1.4 CLINICAL PRACTICES AND RADIOLOGIC CORRELATION
Sub-topic
1.4.1 Introduction to Radiography
1.4.2 Brief Anatomy and Topography
1.4.3 Tips for Difficult Clinical Presentation
1.4.4 Hands on: for Difficult Clinical Presentation
1.4.5 CR and DR Technology
1.4.6 Patient Care and Handling
1.4.7 Patient Preparation for Radiological Procedures
1.4.8 Appropriateness of Imaging
1.4.9 Clinical Procedure and Radiologic Correlation
1.5 REQUIREMENTS AND CRITERIA FOR QUALITY IMAGES
Sub-topic
1.5.1 Image Production and Quality
1.5.2 Clinical Practice : Care and Maintenance Image Processor and Image Receptor
1.5.3 Criteria for Getting a Good Radiographs
1.5.4 Image Analysis and Critique

1.6 QUALITY ASSURANCE PROGRAMME MANAGEMENT
Sub-topic
1.6.1 Quality Assurance Programme and Responsibility
1.6.2 Quality Control Measurement
1.6.3 Acceptance Testing, Commissioning and Maintenance
1.6.4 Performance Indicator in Diagnostic Radiology
1.6.5 Medical Audit: Standard of Acceptable Image Quality
1.7 INTERPRETATION OF CLINICAL IMAGES
Sub-topic
1.7.1 Imaging Artifacts
1.7.2 Radiological Finding of Various Pathology
1.7.3 Normal Radiological Anatomy and Normal Variants
1.8 CURRENT DEVELOPMENTS OF IMAGING MODALITY AND RADIATION PROTECTION
Sub-topic
1.8.1 Current Radiation Protection and Safety in Medical Practices
1.8.2 Recent Advances in Radiology

Carta Alir Pemantauan Pelaksanaan QAP

**Nota :*

1) *Laporan Indikator (borang harian dan bulanan), QC, Audit dan CME hendaklah dihantar kepada JKN sebelum atau pada 31 Januari setiap tahun bagi memenuhi keperluan semasa pihak berkuasa KKM*

2) *Keperluan lain bergantung kepada tarikh sah dokumen berkaitan.*