



# CURRENT LEGISLATIVE REQUIREMENT UNDER ACT 304 FOR MEDICAL PURPOSE



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Medical Radiation Surveillance Division  
Ministry of Health Malaysia

16 Mac 2021



## Contents

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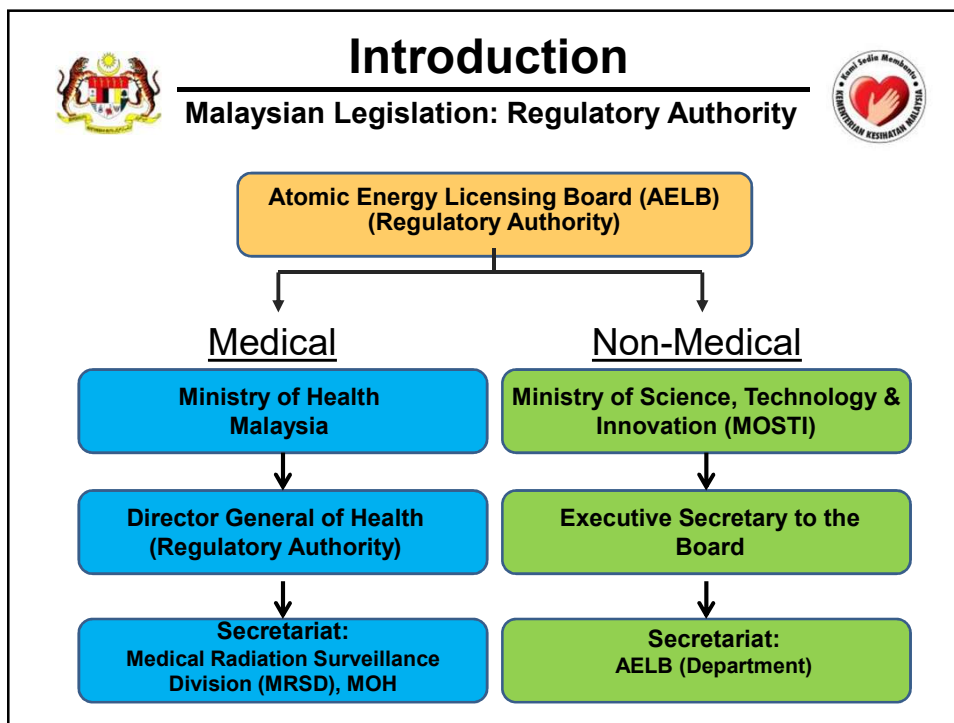
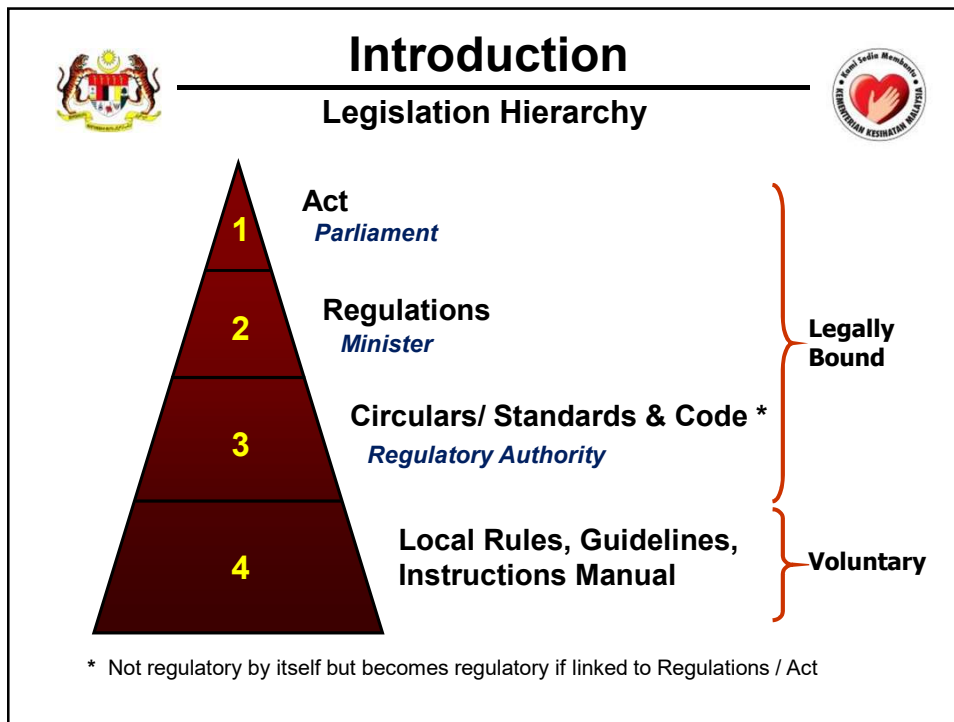


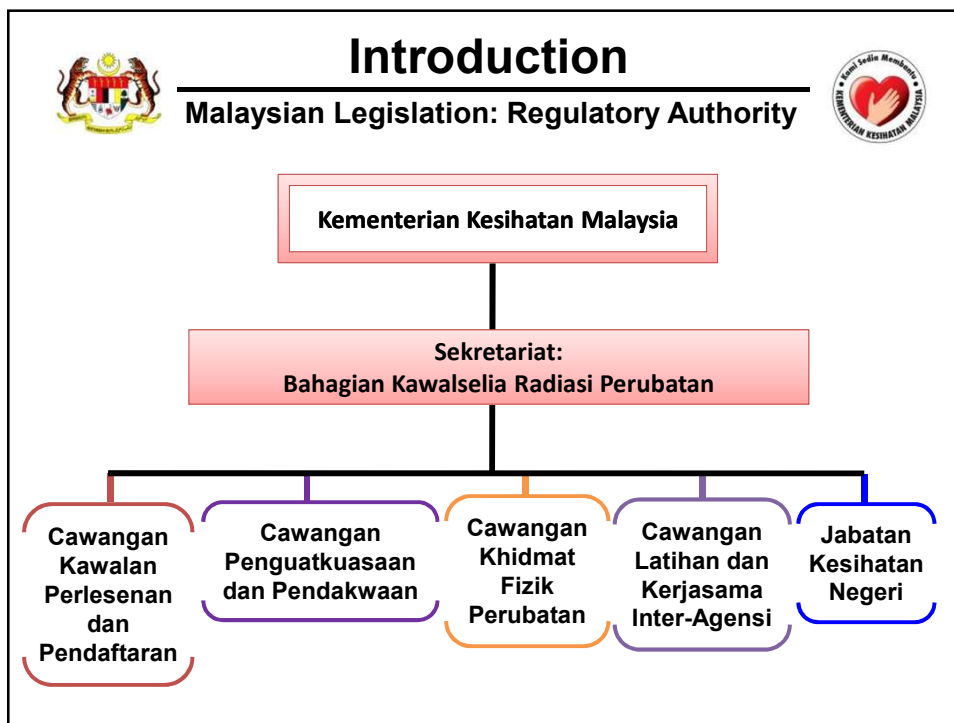
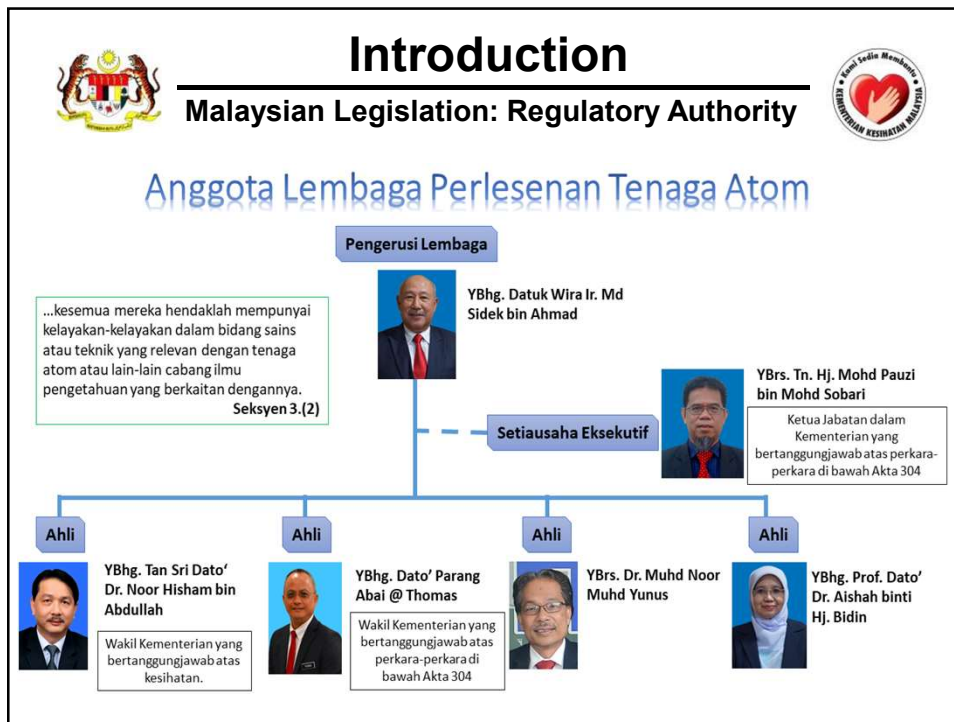
➤ Introduction

- Legislation Hierarchy
- Malaysian Legislation
  - Regulatory Authority
  - Act
  - Regulations

➤ Licensing For Irradiating Apparatus (Medical Purpose)

➤ Latest Quality Assurance Programme (QAP) in Radiology







## Introduction

### Malaysian Legislations: Acts



#### 1) Radioactive Substance Act 1968

- First legislation regulating the use of ionizing radiation.
- MOH controls the use of ionizing radiation for medical and non-medical.



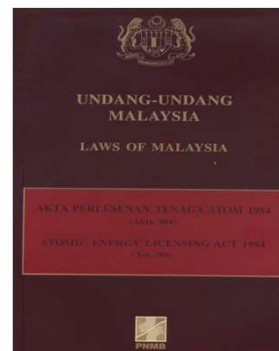
## Introduction

### Malaysian Legislations: Acts



#### 2) Atomic Energy Licensing Act 1984 (Act 304)

- Replaced and superseded the Radioactive Substance Act 1968.
- Act under MOSTI.
- GAZETTED: 28 JUNE 1984
- GOALS: Protection against people and the environment from the effects of the danger of the ionizing radiation source.





## Introduction

### Malaysian Legislations: Acts



Sec. 12.(1) Without prejudice to the requirements of any other law, no person shall:

- a) site, construct or operate a nuclear installation
- b) deal in, possess or dispose of any radioactive material, nuclear material, prescribed substance or irradiating apparatus

unless he is the holder of a valid license



## Introduction

### Malaysian Legislations: Acts



Sec. 40.(2) Any person who commits an offence under this Act is, on conviction, where no penalty is expressly provided therefor, liable to imprisonment for a term not exceeding ten (10) years or a fine not exceeding one hundred thousand ringgit (RM100,000.00) or both.





## Introduction

### Malaysian Legislations: Regulations



- 1) Radiation Protection (Licensing) Regulations 1986
- 2) Radiation Protection (Basic Safety Standard) Regulations 1988 – superseded by
  - ⇒ Atomic Energy Licensing (Basic Safety Radiation Protection) Regulations 2010
- 3) Radiation Protection (Transports) Regulations 1989
- 4) Atomic Energy Licensing (Radioactive Waste Management) Regulations 2011



## Licensing For Irradiating Apparatus (Medical Purpose)



## Contents



- Classification of Licenses
- General Conditions For Obtaining a License
  - X-Ray Room
  - Irradiating Apparatus
  - Personnel
- Procedure to apply for a license
- License & Application Fees




## Classification of Licenses

Radiation Protection (Licensing) Regulations 1986




- Class A** A license to manufacture, trade in, produce, process, purchase, own, possess, use, transfer, handle, sell or store radioactive material
- Class B** A license to manufacture, trade in, ..... or store nuclear material
- Class C** A license to manufacture, trade in, ..... or store irradiating apparatus
- Class D** A license to transport radioactive material, nuclear material, prescribed substances or their waste
- Class E** A license to export or import radioactive material, nuclear material, prescribed substances, irradiating apparatus or their waste



# Classification of Licenses

## Radiation Protection (Licensing) Regulations 1986




**Class F** A license to locate, build or operate a nuclear installation

**Class G** A license to:

- (a) Disposal of radioactive materials, nuclear material, prescribed substances or their waste;
- (b) Store of radioactive materials, nuclear material, prescribed substances or their waste before disposal; or
- (c) Dissolve a manufacturing installation, nuclear installation, waste treatment facilities, irradiating apparatus or seal source apparatus.

**Class H** A license issued by the appropriate authorities to control activities not covered by class A to G, including both class.



026624  
Asal

AKTA PERLESENAN TENAGA ATOM 1984  
PEPERATURAN-PERATURAN PERLINDUNGAN SINARAN (PERLESENAN) 1986

**LESEN**  
(Permit No. 18)

BORANG LPTA/BL1

**KELAS LESEN C**

Menurut Akta Perlesenan Tenaga Atom 1984 dan peraturan-peraturan yang dibuat di bawahnya, (menjadi Perlesenan Tenaga Atom) untuk Pengarah Kesihatan dengan ini mengemukakan lesen seperti berikut:


Nombor Lesen: KKM/R/0809	Tarikh mula: 12/10/2017
Nombor Fail: W/WP0601	Tarikh tamat: 11/10/2019
Nama Pemegang Lesen: PROF. DATUK DR. HJ. MOHAMED HANIFFA B. HJ. ABDULLAH	
Nama Pemegang Lesen: [REDACTED]	
Alamat Surat Menyurat: MAHSA UNIVERSITY COLLEGE (DENTAL), d/o DENTAL FACULTY, MAHSA UNIVERSITY, JALAN SP2, BANDAR SAUJANA PUTRA, 42610 HENJAROM, SELANGOR	
Nombor Telefon: 03-5102 2200	
Alamat Kemudahan/Premis: MAHSA DENTAL CLINIC, LOT UG 20-23, WILAYAH SHOPPING CENTRE, JALAN DANG WANGI, 50100 KUALA LUMPUR, WILAYAH PERSEKUTUAN	
Nama Penyelia: DR. K. VIJAYAMOZHAR	
Nombor Kad Pengenalan/Pasport: [REDACTED]	
Nama Pengawal Perlindungan Sinaran: DR. K. VIJAYAMOZHAR	
Nombor Kad Pengenalan/Pasport: [REDACTED]	
Tujuan: <b>MENSTOR MENGGUNA</b>	


(Tertakluk kepada status Radas Penyinaran / Bahan Radioaktif (Lampiran A))


Butir-butir mengenai Radas/Bahan/Pemasangan: Rujuk Lampiran A

Lesen ini adalah tertakluk kepada Akta Perlesenan Tenaga Atom 1984 dan peraturan-peraturan yang dibuat di bawahnya dan syarat-syarat seperti yang dilampirkan: Rujuk Lampiran B

Tarikh dikeluarkan: 16/10/2017

  
**DATUK DR. NOOR HISHAM BIN ABDULLAH**  
 Ketua Pengarah Kesihatan





Example of License

Class of license

Period of license



Licence holder

Mailing address


Address of installation of x-ray

X-ray purpose



Asal



**LAMPIRAN A**  
Keterangan Berkenaan Radas Penyinaran Yang Disediakan


Bil.	Model	KV	mA	W	No. Siri		Jenis Radas Penyinaran	Status
					Panel Kawalan	Kepala Tab		
1.	DRIST RAY	76	7	1.2	SP-533	SP-533	LITRA ORAL	R/C
2.	SHUREHA PANDORA 15 WTR	85	12	2	SP-035	SP-035	DRG	R/C

No. Fail : 9/09/0501  
 No. Lesen : KKA/R/0809


1) File no.  
 2) License no.

1) Model  
 2) Maximum exposure parameter (kVp; mA; kW)  
 3) Control panel serial no.  
 4) X-ray tube serial no.  
 5) Type of irradiating apparatus  
 6) Status of license


Example of Appendix A

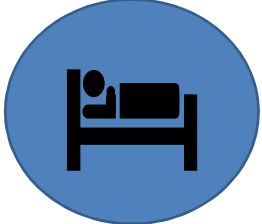
  
 DR. MOHD HISHAM BIN ABDULLAH  
 (Tandatangan)  
 Setiausaha Eksekutif/  
 Ketua Pengarah Kesihatan

NOTA:  
 L - LIPIS  
 S - NEGARA SABAJA  
 R/C - NEGARA I DAN NEGATOR  
 S/C - NEGATOR DAN NEGATOR  
 S/J - NEGATOR DAN NEGATOR

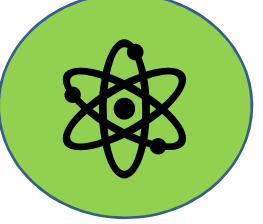


## General Conditions For Obtaining A License

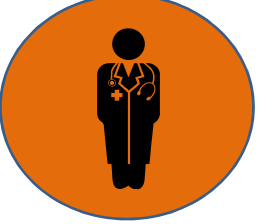




**X-ray Room**



**Irradiating Apparatus**



**Personnel**



**General Conditions For Obtaining A License**



**X-ray Room**

**X-Ray Room - Design consideration**

General requirements (BSRP, 2010):

Reg. 45. (1) The radiological facilities used for medical exposure shall be so designed in accordance with the standard of radiation protection for medical X-ray diagnosis as recognized by the appropriate authority.



*Guidelines to Obtain Class C License*



**General Conditions For Obtaining A License**



**X-ray Room – Dimension and lead thickness**

**Dimension of the room where the apparatus will be located**

Type of irradiating apparatus	Dimension of the room (internal)	Dimension of the darkroom (internal)	Thickness of shielding at the door & wall	Dimension & thickness of lead at the wall (behind chest)	Dimension of lead glass window (thickness 2 mm Pb equivalent)	Dimension & thickness of lead at the floor (if the premise is at the upper floor)
General X-ray (control panel inside – without table)	2.5 m x 4.0 m	1.5 m x 2.0 m	2 mm *Pb eq (*lead equivalent)	1.2 m x 1.2 m x 2 mm Pb eq	>100 kVp; 35 cm x 30 cm < 100 kVp; 25 cm x 20 cm	1.2 m x 2.5 m x 2 mm Pb eq
General X-ray (control panel inside – with table)	3.0 m x 5.0 m					
General X-ray (control panel outside – without table)	2.5 m x 3.5 m					
General X-ray (control panel outside – with table)	2.5 m x 4.0 m					



## General Conditions For Obtaining A License

### X-ray Room – Dimension and lead thickness



#### Dimension of the room where the apparatus will be located

Type of irradiating apparatus	Dimension of the room (internal)	Dimension of the darkroom (internal)	Thickness of shielding at the door & wall	Dimension & thickness of lead at the wall (behind chest)	Dimension of lead glass window (thickness 2 mm Pb equivalent)	Dimension & thickness of lead at the floor (if the premise is at the upper floor)
Dental X-ray	2.0 m x 3.0 m	Not applicable	1 mm Pb eq	Not applicable	Not applicable	Not applicable
X-ray OPG	2.5 m x 3.5 m		1.5 mm Pb eq			
Fluoroscopy	6.0 m x 4.0 m	1.5 m x 2.0 m	2 mm Pb eq		100 cm x 50 cm	1.2 m x 2.5 m x 2 mm Pb eq
Mammography	2.5 m x 3.5 m		1 mm Pb eq		35 cm x 30 cm	Not applicable
Angiography	6.5 m x 4.5 m		2 mm Pb eq		100 cm x 50 cm	1.2 m x 2.5 m x 2 mm Pb eq
CT Scanner	5.5 m x 4.0 m					

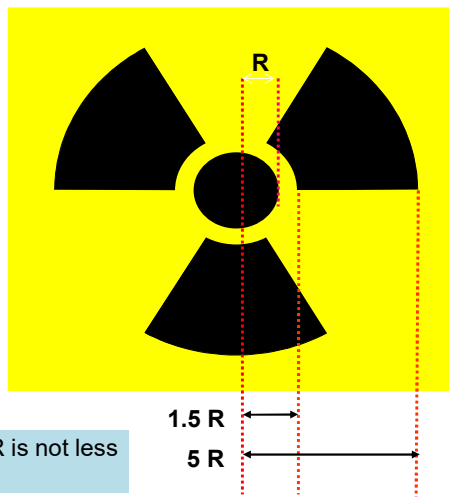


## General Conditions For Obtaining A License

### X-ray Room – Warning Signage



- ❑ All entrance to x-ray room should be marked with a warning signage.
- ❑ Consists of a three-blade design, it should be remembered that black is for the three-blades design and yellow for the background.



\* R is the radius of the inner circle and 5R is not less than 7.5 cm.

MS 838:2007



## General Conditions For Obtaining A License

### X-ray Room – Warning Light



- ❑ All entrance to x-ray room should have a warning light & should be lit before exposure.
- ❑ Warning Lights should be yellow.



MS 838: 2007



## General Conditions For Obtaining A License

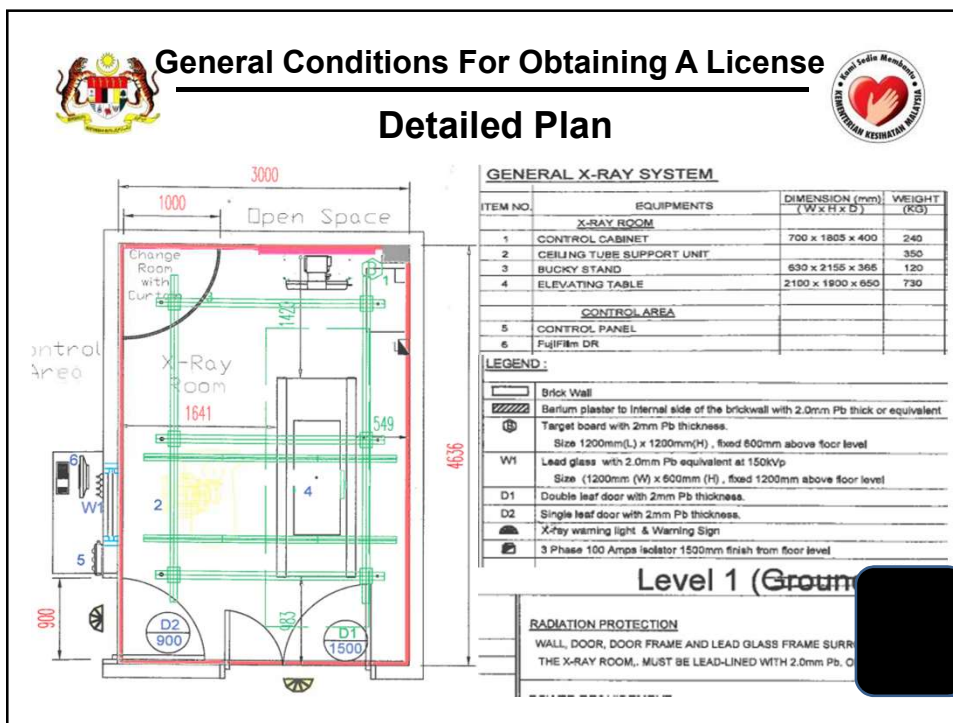
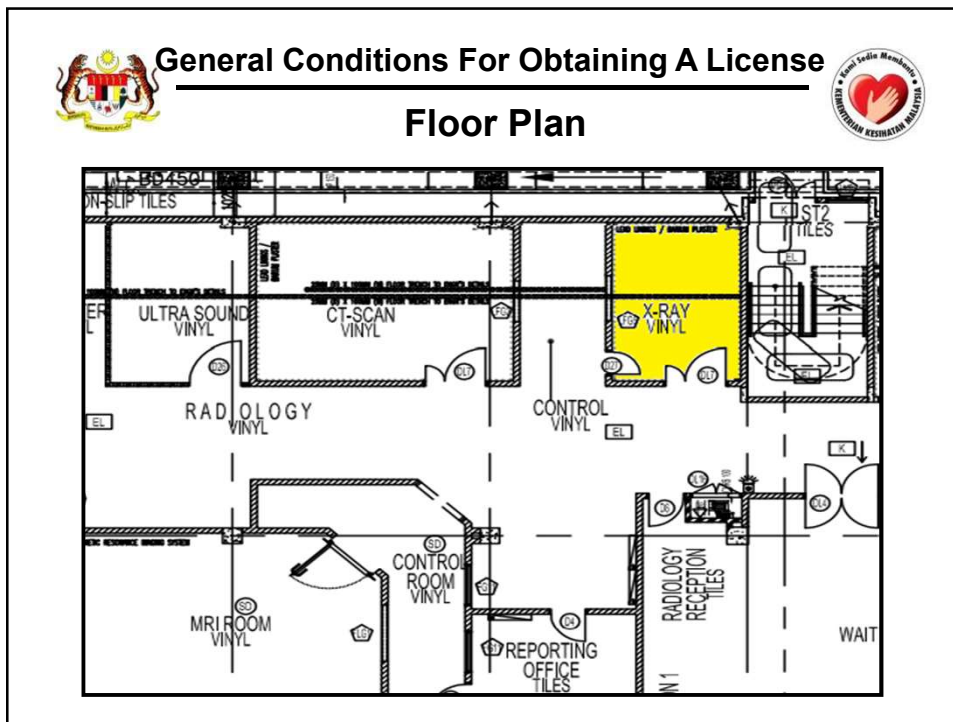
### Dark Room – Dimension & Location

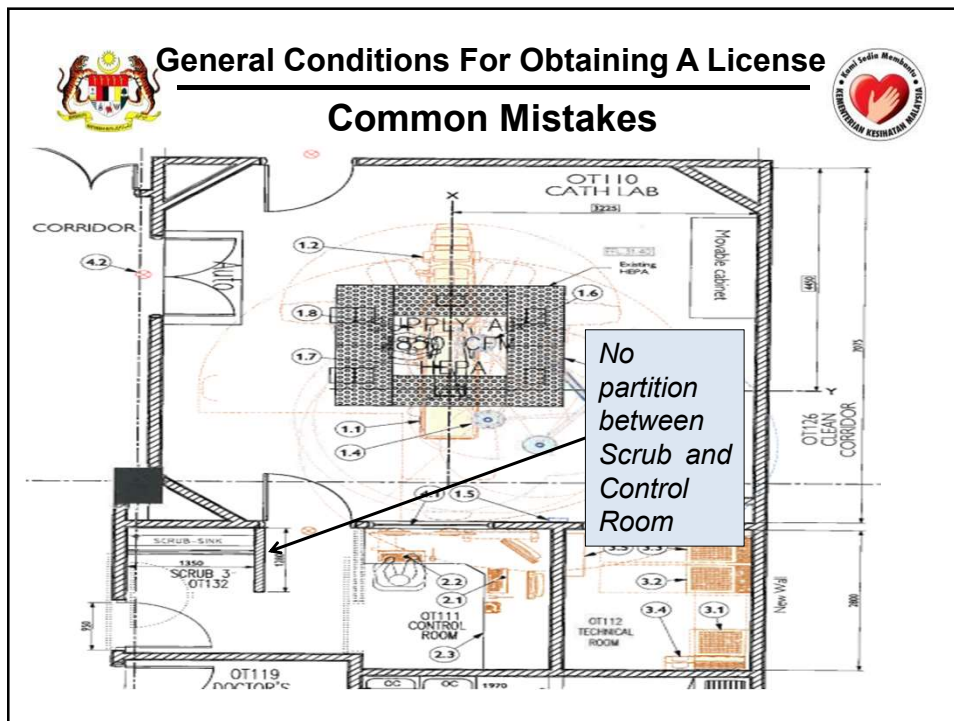
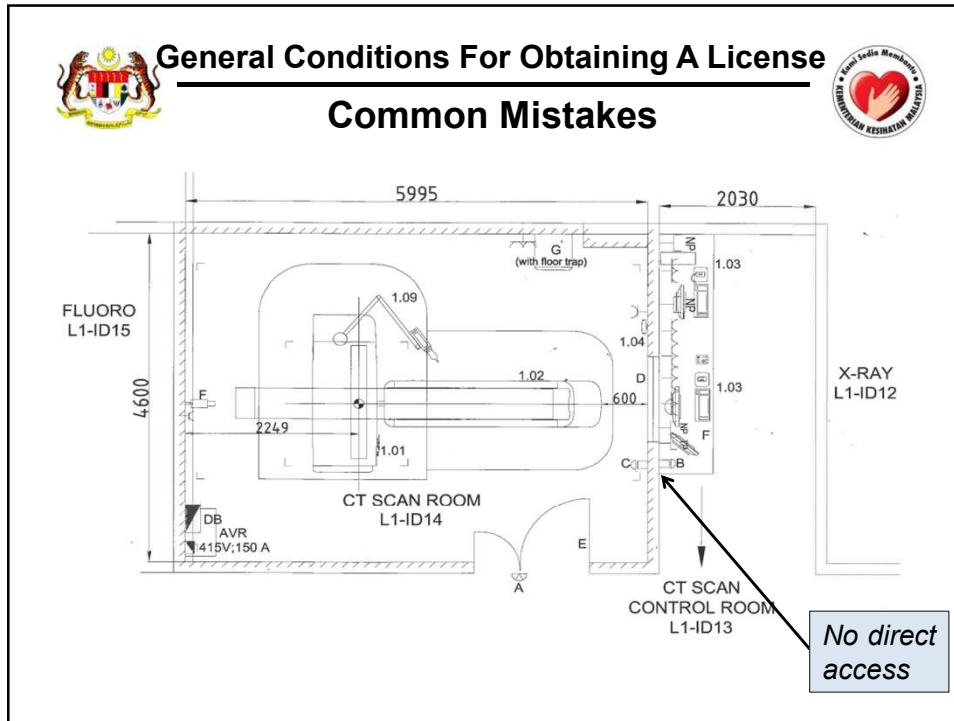


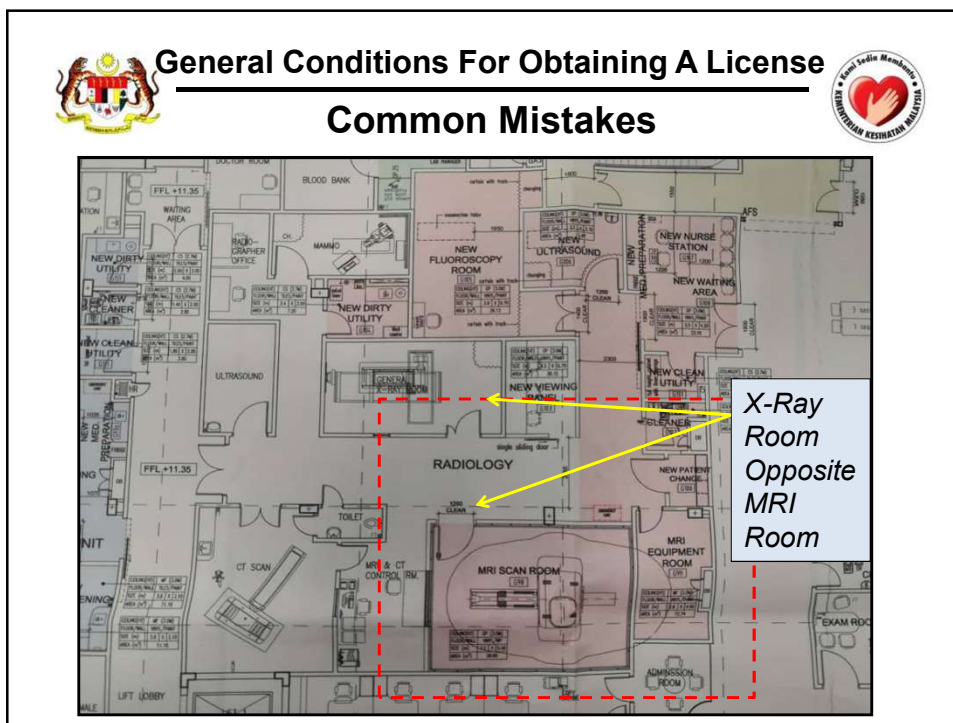
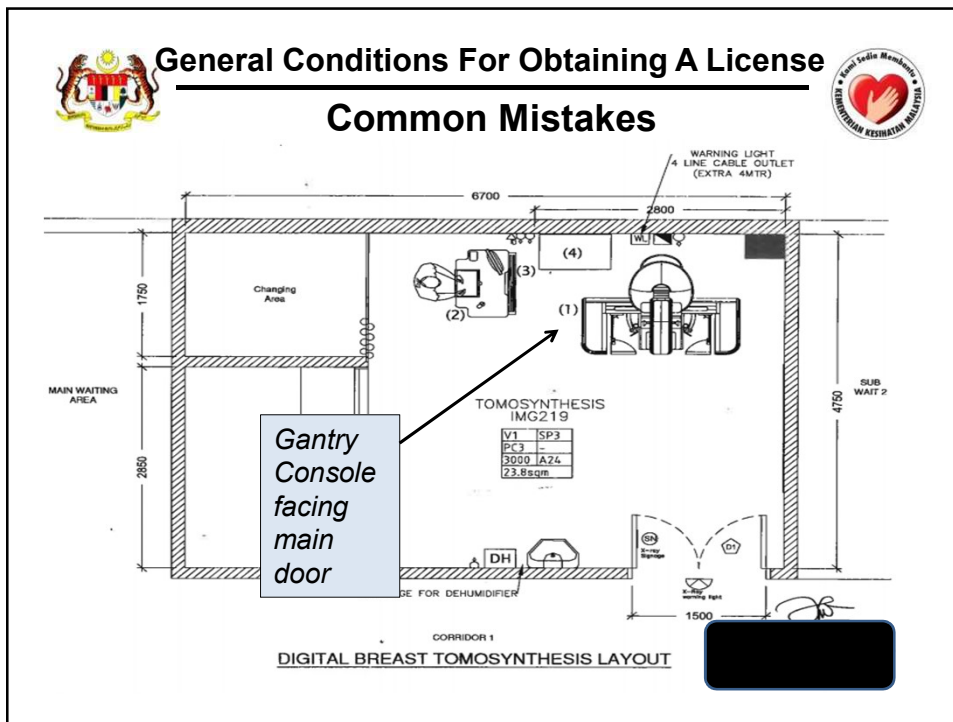
- ❑ Minimum Dimension = 1.5 m x 2.0 m
- ❑ Dark room location should not be facing the direction of the x-ray tube (chest stand).



MS 838:2007









## General Conditions For Obtaining A License



### **Circular To TKPK (Medical) & TKPK (Public Health) – 15.1.2001**

- ❑ All plans for facilities under Act 304 to be submitted and approved by Medical Radiation Surveillance Division before commencement of installation/renovation.
- ❑ All related equipment and facilities to be tested, commissioned and verified to conform to safety and performance standards before clinical use.



## General Conditions For Obtaining A License



### **Irradiating Apparatus**

Reg. 46. The licensee shall, ..., ensure that:

- (a) the irradiating apparatus system used for diagnostic radiology has been approved by the appropriate authority;
- (b) the irradiating apparatus and their accessories are designed and manufactured so as to facilitate the keeping of medical exposures as low as reasonably achievable consistent with obtaining adequate diagnostic information;





## General Conditions For Obtaining A License



### Irradiating Apparatus

Cont...

#### Irradiating Apparatus

(c) the operational parameters for irradiating apparatus such as generating tube potential, filtration, focal spot position, source image receptor distance, field size indication and either tube current and time or their product are clearly and accurately indicated;

(d) the radiographic equipment is provided with devices that automatically terminate the irradiation after a preset time, tube current time product or dose is reached; and



## General Conditions For Obtaining A License



### Irradiating Apparatus

Cont...

#### Irradiating Apparatus

(e) the fluoroscopic equipment is provided with a device that energizes the x-ray tube only when continuously depressed such as a dead man's switch and is equipped with indicators of the elapsed time or entrance surface dose monitors.



## General Conditions For Obtaining A License

### Personnel



#### Personnel – License holder

Sec. 12.(3) A license for using any radioactive material, nuclear material, prescribed substance or irradiating apparatus for diagnostic or therapeutic purposes may be issued ONLY to:

- Registered medical practitioner;
- Registered veterinary surgeon;
- Radiologist;
- Radiotherapist; or
- Registered dentist.



**Act 304**



## General Conditions For Obtaining A License

### Personnel



#### Personnel – Person who operates the machine

Reg. 12. (a) the applicant shall employ a person or persons having the necessary knowledge, skill and training to ensure that the activities sought to be licensed are carried out in such manner as to protect the health of workers and members of the public.

**Radiation Protection (Licensing) Regulations**



## General Conditions For Obtaining A License **Personnel**



### Personnel – Person who operates the machine

Surat Pekeliling KPK Bil. 28/2010

*Keperluan Mendapatkan Khidmat Juru X-Ray  
Berkelayakan Sebagai Pengendali Radas Penyinaran  
Bagi Klinik Pengamal Perubatan dan Institusi  
Perubatan Swasta Di Bawah Akta 304*



## Procedure To Apply A License



STEP 1

Application for **BUY & STORE**  
Irradiating Apparatus





STEP 2

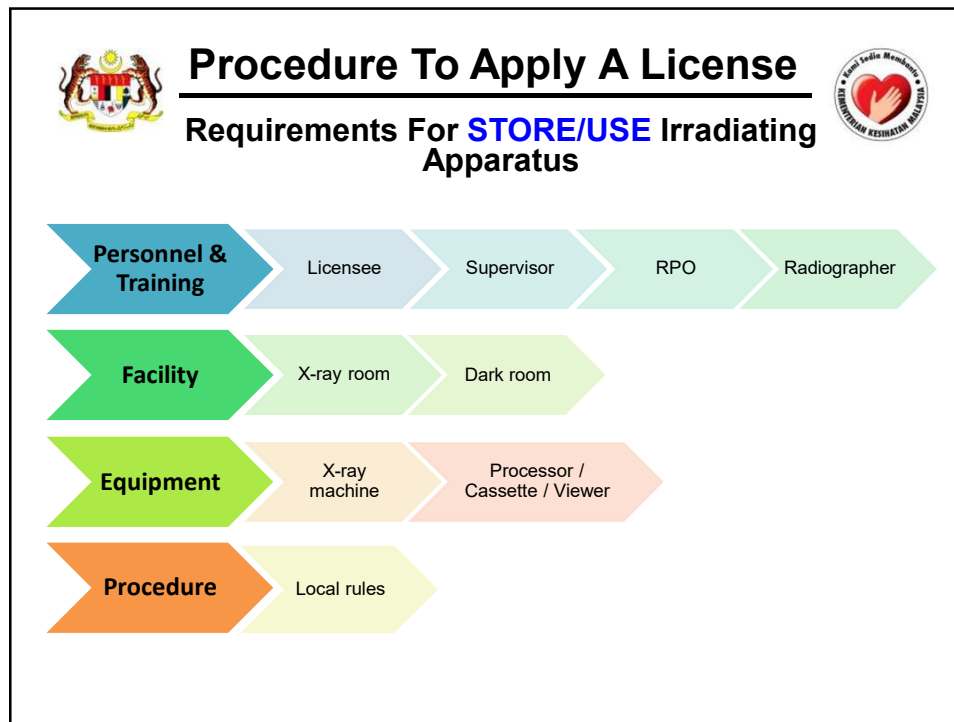
Requirement for **USE** of  
Irradiating Apparatus

Application for <b>BUY &amp; STORE</b> Irradiating Apparatus		
 <b>SENARAI SEMAK DOKUMEN PERLESENAN RADIOLOGI</b> <b>PERMOHONAN LESEN <u>BARU</u> BAGI RADAS PENYINARAN</b> 		
Bil	Dokumen	Tandakan (✓)
1.	Borang Permohonan Untuk Mendapatkan, Meminda atau Membaharui Lesen (Borang LPTA/BP/3) <i>Nota: Borang yang lengkap diisi beserta fi permohonan RM15 hendaklah dihantar ke Lembaga Perlesenan Tenaga Atom (LPTA) (Seksyen 16(1) Akta 304 &amp; Peraturan (13) P.U. (A) 149.)</i> <i>*Pihak Lembaga akan memanjangkan dokumen berkenaan kepada Bahagian Kawalselia Radiasi Perubatan, KKM</i>	
2.	Salinan sijil kelayakan akademik bagi pemohon/ pemegang lesen/ penyelia/ pegawai perlindungan sinaran	
3.	Salinan sijil kepakaran/ <i>National Specialist Registry (NSR)</i> pemohon/ pemegang lesen/ penyelia/ pegawai perlindungan sinaran (jika berkenaan)	
4.	Salinan sijil amalan tahunan (APC) tahun semasa pemohon/ pemegang lesen/ pegawai perlindungan sinaran yang menyatakan alamat semasa pemohon/ pemegang lesen/ alamat klinik/ hospital yang dimohon (disahkan oleh pihak MMC/MDC/MVC)	
5.	Jadual penyeliaan/bertugas yang mengandungi hari (untuk minggu hari bekerja), waktu dan tempat amalan seperti tercatat dalam APC <i>Nota: Sekiranya tempat amalan melebihi 1 tempat</i>	
6.	Katalog/ <i>product data/ technical data sheet</i> radas penyinaran yang dimohon	
7.	Katalog/ <i>product data/ technical data sheet/ model</i> jenis pemrosesan (e.g <i>DR/CR/ dark room</i> )	
8.	Salinan Sijil dan Lampiran A Lesen Pembekal yang sah <i>*Sila pastikan pembekal berlesen dengan pihak Jabatan LPTA</i>	

Application for <b>BUY &amp; STORE</b> Irradiating Apparatus		
 <b>SENARAI SEMAK DOKUMEN PERLESENAN RADIOLOGI</b> <b>PERMOHONAN LESEN <u>BARU</u> BAGI RADAS PENYINARAN</b> 		
	(a) Pelan Premis ( <i>layout plan</i> ) –pelan kejuruteraan ( <i>proper software drawing</i> ) yang menunjukkan susun atur & lokasi bilik X-ray, bilik gelap/bilik image processor serta ruang-ruang yang berdekatan (termasuk ruang di sebelah, di atas dan di bawah)	
9.	(b) Pelan <i>Sectional View</i> (jika berkenaan)	
	(c) Pelan terperinci bilik X-ray- pelan kejuruteraan yang menyatakan dengan jelas skala, unit, kedudukan sebenar radas penyinaran yang akan dipasang dan digunakan serta keperluan perlindungan sinaran	
<i>Nota: Semua pelan yang berkaitan bagi perkara (a), (b) dan (c) yang dikemukakan perlulah dokumen asal serta ditandatangani dan disahkan oleh pemohon/ pemegang lesen</i>		
10.	Laporan pengiraan perisai bilik x-ray yang disahkan oleh Juruperunding Fizik Perubatan Kelas H yang diluluskan oleh KKM bagi kes bilik X-ray yang tidak memenuhi saiz minimum (jika berkenaan)	
11.	Borang atau surat berkaitan kelulusan menubuhkan/ menyenggarakan/ mengendalikan/ menyediakan/ peluasan / perubahan klinik atau hospital swasta daripada pihak Cawangan Kawalan Amalan Perubatan Swasta (CKAPS), KKM <i>Nota: Tidak Berkaitan bagi perkhidmatan Veterinar</i>	
12.	Dokumen Program Perlindungan Sinaran yang akan diterima pakai	
13.	Maklumat tambahan berkaitan keperluan perlindungan sinaran semasa sekiranya melibatkan teknologi dan prosedur baru. <i>Sekiranya berkaitan, sila lampirkan:</i> .....	

Requirement for <b>USE</b> of Irradiating Apparatus		
 <b>SENARAI SEMAK DOKUMEN PERLESENAN RADIOLOGI</b> <b>PERMOHONAN MENGGUNA RADAS PENYINARAN</b> 		
Bil	Dokumen	Tandakan (✓)
1	1.1 Pemegang Lesen/Penyelia/Pegawai Perlindungan Sinaran	
	a) Salinan Sijil Kepakaran/ NSR (jika berkenaan)	
	b) Salinan Sijil Kehadiran Kursus Perubatan Sinar-X Untuk Pengamal Perubatan Am (40 jam kredit) anjuran Agensi Nuklear Malaysia/ mana-mana institusi yang diiktiraf KKM (selain Pakar Perubatan)	
	c) Salinan laporan pemeriksaan perubatan menggunakan Buku LPTA/BM/5 (A)	
	1.2 Pengendali Radas Penyinaran	
	a) Salinan Sijil Kelayakan/ Akademik Juru X-ray (daripada institusi yang diiktiraf KKM)	
	b) Salinan Sijil Kepakaran dalam Bidang Pergigian (e.g <i>orthodontics/ maxillofacial</i> ) daripada institusi yang diiktiraf oleh Kementerian Kesihatan Malaysia (KKM); <b>atau</b> Salinan Sijil Latihan Khusus dalam <i>OPG/ CBCT</i> daripada institusi yang diiktiraf oleh KKM. <i>Nota: Bagi tujuan penggunaan radas OPG/ CBCT sahaja</i>	
	c) <i>Log Book Training</i> (sekurang-kurangnya 2 minggu latihan mammografi) yang disahkan oleh Pakar Radiologi & Penyelia ( <i>Senior Radiographer</i> yang berkeelayakan dalam mammografi)	
	d) Salinan laporan pemeriksaan perubatan menggunakan Buku LPTA/BM/5(A)	
	e) Salinan bukti perkhidmatan pemantauan dos personel (seperti OSL dosimeter) disediakan <i>Nota: Tidak Berkaitan bagi Pergigian</i>	
	1.3 Penyelia (selain Pakar Radiologi) <i>Nota: Selain di Jabatan Radiologi</i>	
	a) Salinan APC	
	b) Salinan sijil kelayakan/ kepakaran/ NSR dalam bidang berkaitan	

Requirement for <b>USE</b> of Irradiating Apparatus		
 <b>SENARAI SEMAK DOKUMEN PERLESENAN RADIOLOGI</b> <b>PERMOHONAN MENGGUNA RADAS PENYINARAN</b> 		
2	(a) Sijil kawalan kualiti (QC) berserta laporan pengujian penuh bagi prestasi dan keselamatan sinaran radas penyinaran dan kemudahan berkaitan yang disahkan oleh Juruperunding Fizik Perubatan yang diiktiraf oleh KKM <b>atau</b>	
	(b) Laporan ujian prestasi bagi radas penyinaran pergigian oleh Syarikat Pembekal yang diluluskan oleh LPTA.* <i>Nota: Sekiranya kalibrasi dijalankan oleh pihak pembekal, sila kemukakan Salinan Sijil Lesen dan Lampiran A terkini syarikat pembekal radas penyinaran yang dilesenkan oleh LPTA</i> <b>*(Pergigian dan Veterinar sahaja)</b>	
3.	Keperluan perlindungan sinaran; seperti <i>personal protective equipment</i> (PPE) kepada pekerja dan pesakit.	
4.	Pengendalian Standard (SOP) dan/ atau <i>Local Rules</i> yang telah dikemaskini jika melibatkan tambahan radas penyinaran berlainan bagi tujuan klinikal.	
5.	Dokumen/ maklumat tambahan berkaitan keperluan perlindungan sinaran semasa sekiranya melibatkan teknologi dan prosedur baharu (eg. keperluan radas penyinaran jenis <i>overcouch, hybrid</i> )	



The diagram illustrates the requirements for applying for a license to store/use irradiating apparatus, organized into four main categories:

- Personnel & Training:** Licensee, Supervisor, RPO, Radiographer
- Facility:** X-ray room, Dark room
- Equipment:** X-ray machine, Processor / Cassette / Viewer
- Procedure:** Local rules



## Procedure To Apply A License

### Requirements For **STORE/USE** Irradiating Apparatus



#### 1) Licensee

##### Private Medical Practitioner (GP's) / Health Clinic

- Registered Medical Practitioner
- Must attend 40 credit hours training programme (new application) and CME every year

##### All Hospital / Medical Institution

- Registered Medical Practitioner / Director / Radiologist
- Must attend CME every year



## **Procedure To Apply A License**

### **Requirements For STORE/USE Irradiating Apparatus**



#### **2) Supervisor**

Private Medical Practitioner (GP's) / Health Clinic

- Registered Medical Practitioner
- Must attend 40 credit hours training programme (new application) and CME every year

All Hospital / Medical Institution

- Radiologist
- Must attend CME every year



## **Procedure To Apply A License**

### **Requirements For STORE/USE Irradiating Apparatus**



#### **3) Radiation Protection Officer (RPO)**

Private Medical Practitioner (GP's) / Health Clinic

- Registered Medical Practitioner
- Must attend CME every year

All Hospital / Medical Institution

- Medical Physicist/Radiologist/Radiographer/Medical Officer
- Must attend CME every year



## Procedure To Apply A License

### Requirements For **STORE/USE** Irradiating Apparatus



#### 4) Radiographer

Private Medical Practitioner (GP's) / Health Clinic All  
Hospital / Medical Institution

- Must attend CME every year
- Personnel dose monitoring
- Medical examination (at least once in 3 years)



## Procedure To Apply A License

### Requirements To **Amend** A License



**Transfer Of Irradiating Apparatus To A New Premise**

**Purchase Of Additional Irradiating Apparatus**

**Decommissioning Of Irradiating Apparatus**

**Replacement Of Irradiating Apparatus by Decommissioning**



## Transfer Of Irradiating Apparatus To A New Premise



### SENARAI SEMAK DOKUMEN PERLESENAN RADIOLOGI PERMOHONAN PEMINDAHAN RADAS PENYINARAN SEDIA ADA ATAU PREMIS



Bil.	Dokumen	Tandakan (✓)
1.	Surat hasrat daripada pemohon/ Pemegang Lesen	
2.	Fi Permohonan Pemindahan Radas Penyinaran/ Premis: <b>RM200</b> Bayaran boleh dibuat dalam bentuk kiriman wang/ bank draf di atas nama <b>KEMENTERIAN KESEHATAN MALAYSIA</b> ataupun secara <i>online payment</i> melalui Sistem <i>RADIA Private Sector Licensing</i> (radia.moh.gov.my) <i>Nota: Fi lesen RM200 hendaklah dihantar ke Bahagian Kawalselia Radiasi Perubatan, KKM (Peraturan (15) P.U. (A) 149.)</i>	
3.	Salinan siji amalan tahunan (APC) tahun semasa pemohon/ pemegang lesen/ penyelia/ pegawai perlindungan sinaran yang menyatakan alamat semasa amalan termasuk alamat klinik/ hospital baru yang akan berpindah (disahkan oleh pihak MMC/MDC/MVC)	
4.	Pelan lokasi pemindahan radas penyinaran	
	(a) Pelan Premis ( <i>layout plan</i> ) – pelan kejuruteraan ( <i>proper software drawing</i> ) yang menunjukkan susun atur & lokasi bilik X-ray, bilik gelap/bilik image processor serta ruang-ruang yang berdekatan (termasuk ruang di sebelah, di atas dan di bawah)	
	(b) Pelan <i>Sectional View</i> ( <i>jika berkenaan</i> )	
	(c) Pelan terperinci bilik X-ray - pelan kejuruteraan yang menyatakan dengan jelas skala, unit, kedudukan sebenar radas penyinaran yang akan dipasang dan digunakan serta keperluan perlindungan sinaran	
	<b>Nota: Semua pelan yang berkaitan bagi perkara (a), (b) dan (c) yang dikemukakan perlulah dokumen asal serta ditandatangani dan disahkan oleh pemohon/ pemegang lesen</b>	
5.	Laporan pengiraan perisai bilik X-ray yang disahkan oleh Juruperunding Fizik Perubatan Kelas H yang diluluskan oleh KKM bagi kes bilik X-ray yang tidak memenuhi saiz minimum. ( <i>jika berkenaan</i> )	
6.	Borang atau surat berkaitan kelulusan menubuhkan/ menyanggarkan/ mengendalikan/ menyediakan/ peluasan / perubahan klinik atau hospital swasta daripada pihak Cawangan Kawalan Amalan Perubatan Swasta (CKAPS), KKM <i>Nota: Tidak Berkaitan bagi perkhidmatan Veterinar</i>	
7.	Lesen dan Lampiran A ASAL <b>Nota: Lesen dan Lampiran A perlu dikembalikan bagi tujuan pindaan</b>	
	<b>Nota: Jika melibatkan pemindahan ke premis yang sedia ada, sila pastikan premis tersebut telah memiliki lesen radas penyinaran yang sah, sekurang-kurangnya berstatus MENSTOR</b>	

## Purchase Of Additional Irradiating Apparatus



### SENARAI SEMAK DOKUMEN PERLESENAN RADIOLOGI PERMOHONAN PENAMBAHAN RADAS PENYINARAN SEDIA ADA



Bil	Dokumen	Tandakan (✓)
1.	Borang Permohonan Untuk Mendapatkan, Meminda atau Membaharu Lesen (Borang LPTA/BP/3)	
2.	Fi Permohonan sebanyak RM15.00 Bayaran boleh dibuat dalam bentuk kiriman wang/ bank draf di atas nama <b>KEMENTERIAN KESEHATAN MALAYSIA</b> ataupun secara <i>online payment</i> melalui Sistem <i>RADIA Private Sector Licensing</i> (radia.moh.gov.my) <i>Nota: Bergantung kepada bilangan dan jenis radas penyinaran</i> <i>Nota: Fi permohonan RM 15 hendaklah dihantar ke Bahagian Kawalselia Radiasi Perubatan, KKM (Peraturan (15) P.U. (A) 149.)</i>	
3.	Fi Lesen: RM..... Bayaran boleh dibuat dalam bentuk kiriman wang/ bank draf di atas nama <b>KEMENTERIAN KESEHATAN MALAYSIA</b> ataupun secara <i>online payment</i> melalui Sistem <i>RADIA Private Sector Licensing</i> (radia.moh.gov.my) <i>Nota: Bergantung kepada bilangan dan jenis radas penyinaran</i>	
4.	Katalog/ <i>product data/ technical data sheet</i> radas penyinaran yang dimohon	
5.	Salinan Siji dan Lampiran A Lesen Pembekal yang sah <i>*Sila pastikan pembekal berlesen dengan pihak Jabatan LPTA</i>	
6.	(a) Pelan Premis ( <i>layout plan</i> ) – pelan kejuruteraan ( <i>proper software drawing</i> ) yang menunjukkan susun atur & lokasi bilik X-ray, bilik gelap/bilik image processor serta ruang-ruang yang berdekatan (termasuk ruang di sebelah, di atas dan di bawah)	
	(b) Pelan <i>Sectional View</i> ( <i>jika berkaitan</i> )	
	(c) Pelan terperinci bilik X-ray - pelan kejuruteraan yang menyatakan dengan jelas skala, unit, kedudukan sebenar radas penyinaran yang akan dipasang dan digunakan serta keperluan perlindungan sinaran	
	<b>Nota: Semua pelan yang berkaitan bagi perkara (a), (b) dan (c) yang dikemukakan perlulah dokumen asal serta ditandatangani dan disahkan oleh pemohon/ pemegang lesen</b>	
7.	Lesen dan Lampiran A ASAL <b>Nota: Lesen dan Lampiran A perlu dikembalikan bagi tujuan pindaan</b>	
8.	Lain-lain: Prosedur Pengendalian Standard (SOP) dan/ atau <i>Local Rules</i> yang telah dikemaskini jika melibatkan tambahan radas penyinaran berlainan bagi tujuan klinikal. Maklumat tambahan berkaitan keperluan perlindungan sinaran semasa sekiranya melibatkan teknologi dan prosedur baharu. <i>Sekiranya berkaitan, sila lampirkan</i> Lain-lain dokumen berkaitan:.....	

## Decommissioning Of Irradiating Apparatus



SENARAI SEMAK DOKUMEN PERLESENAN RADIOLOGI



PERMOHONAN PELUPUSAN RADAS PENYINARAN

Bil	Dokumen	Tandakan (✓)
1.	Surat hasrat melupuskan radas penyinaran berkenaan daripada pemohon/pemegang lesen	
2.	*Borang Notifikasi Pelupusan (Borang A). Perlu dikemukakan dalam tempoh 2 bulan sebelum pelupusan dilaksanakan. *Sila rujuk Tatacara Pelupusan Radas Penyinaran dan Peranti Yang Menggunakan Bahan Radioaktif	
3.	*Borang Pengesahan Pelupusan (Borang B) Perlu dikemukakan dalam tempoh 2 minggu / 14 hari bekerja selepas pelupusan dilaksanakan beserta dokumen sokongan pelupusan dan/ atau salinan Nota Kosainan Bagi Buangan Terjadual [Jadual Keenam, PPKAS (BT) 2005]. *Sila rujuk Tatacara Pelupusan Radas Penyinaran dan Peranti Yang Menggunakan Bahan Radioaktif	
4.	Lesen dan Lampiran A ASAL <i>Nota: Lesen dan Lampiran A perlu dikembalikan bagi tujuan pindaan</i>	
5.	Sekiranya premis berhasrat untuk menamatkan perkhidmatan X-ray secara kekal, sila kemukakan surat hasrat yang ditandatangani oleh Pemegang Lesen. (jika berkaitan)	

Nota: Permohonan pelupusan adalah terdiri daripada dua kategori berikut:

- a) Premis masih berlesen bagi radas-radas penyinaran lain di bawah Akta 304
  - Sila kemukakan dokumen dari **perkara (1) hingga perkara (4) sahaja**
- b) Premis yang ingin menamatkan perkhidmatan X-ray secara kekal
  - Sila kemukakan dokumen dari **perkara (1) hingga perkara (5)**

## Replacement Of Irradiating Apparatus by Decommissioning



PERMOHONAN PENGGANTIAN RADAS PENYINARAN  
ATAU KOMPONEN SECARA PELUPUSAN




Bil	Dokumen	Tandakan (✓)
<b>Keperluan Membeli/Menstor Radas Baru dan Melupus Radas</b>		
1.	Borang Permohonan Untuk Mendapatkan, Meminda atau Membaharu Lesen (Borang LPTA/BP/3)	
2.	Fi Permohonan sebanyak RM15.00 Bayaran boleh dibuat dalam bentuk kiriman wang/ bank draf di atas nama <b>KEMENTERIAN KESIHATAN MALAYSIA</b> ataupun secara <i>online payment</i> melalui Sistem <i>RADIA Private Sector Licensing</i> (radia.moh.gov.my) <i>Nota: Fi permohonan RM15 hendaklah dihantar ke Bahagian Kawatelia Radiasi Perubatan, KKM (Peraturan 14) P.U. (A) 149.</i>	
3.	Lesen dan Lampiran A ASAL <i>Nota: Lesen dan Lampiran A perlu dikembalikan bagi tujuan pindaan</i>	
4.	*Borang Notifikasi Pelupusan (Borang A). Perlu dikemukakan dalam tempoh 2 bulan sebelum pelupusan dilaksanakan. *Sila rujuk Tatacara Pelupusan Radas Penyinaran dan Peranti Yang Menggunakan Bahan Radioaktif	
5.	Salinan Sijil dan Lampiran A Lesen Pembekal yang sah *Sila pastikan pembekal berlesen dengan pihak Jabatan LPTA	
6.	Katalog <i>product data/ technical data sheet</i> radas penyinaran yang dimohon	
7.	(a) Pelan Premis ( <i>layout plan</i> ) – pelan kejuruteraan ( <i>proper software drawing</i> ) yang menunjukkan susun atur & lokasi bilik X-ray, bilik gelap/bilik image processor serta ruang-ruang yang berdekatan (termasuk ruang di sebelah, di atas dan di bawah) (b) Pelan <i>Sectional View</i> (jika berkaitan) (c) Pelan terperinci bilik X-ray - pelan kejuruteraan yang menyatakan dengan jelas skala, unit, kedudukan sebenar radas penyinaran yang akan dipasang dan disuarakan serta keperluan perlindungan sinaran <i>Nota: Semua pelan yang berkaitan bagi perkara (a), (b) dan (c) yang dikemukakan perlulah dokumen asal serta ditandatangani dan disahkan oleh pemohon/ pemegang lesen</i>	
<b>Keperluan Menstor/Mengguna Radas Baru</b>		
8.	*Borang Pengesahan Pelupusan (Borang B) Perlu dikemukakan dalam tempoh 2 minggu / 14 hari bekerja selepas pelupusan dilaksanakan beserta dokumen sokongan pelupusan dan/ atau salinan Nota Kosainan Bagi Buangan Terjadual [Jadual Keenam, PPKAS (BT) 2005]. *Sila rujuk Tatacara Pelupusan Radas Penyinaran dan Peranti Yang Menggunakan Bahan Radioaktif	
9.	Sijil kawalan kualiti (QC) beserta laporan pengujian penuh bagi prestasi dan keselamatan sinaran radas penyinaran yang disahkan oleh Juruperunding Fizik Perubatan yang diiktiraf oleh KKM.  <b>Atau</b> Laporan ujian prestasi bagi radas penyinaran perģigian oleh Syarikat Pembekal yang diluluskan oleh LPTA <i>Nota: Sekiranya kalibrasi dijalankan oleh pihak pembekal, sila kemukakan Salinan Sijil Lesen dan Lampiran A terkinis syarikat pembekal radas penyinaran yang disahkan oleh LPTA. *(Perģigian dan Veterinar sahaja)</i>	

Nota: Perkara (5), (6) dan (7) tidak perlu dikemukakan bagi proses penggantian yang melibatkan **pelupusan komponen** (eg. kepala tuis/ operator).




## Procedure To Apply A License

Requirements To **Update** A License Status




**Transfer Of Irradiating Apparatus In The Same Premise**

**Termination / Exchange / New Employment**



## Requirements To Update A License Status



**Transfer Of Irradiating Apparatus In The Same Premise**

- Letter of intent.
- Layout plan of the premise.
- Detailed plan of the X-ray room where the irradiating apparatus will be located.



## Requirements To Update A License Status



### Termination / Exchange / New Employment

#### (1) Termination Of Employment

- Letter of intent.
- Radiation workers information including full name & IC number.
- Medical examination report using LPTA/BM/5 form.
- Return LPTA/BM/5 Book (for retired personnel or personnel who are no longer a radiation worker).




## Requirements To Update A License Status



### Termination / Exchange / New Employment


#### (2) Exchange / New Employment

- Letter of intent.
- Radiation workers information including full name & IC number.
- Copy of academic qualification certificate.
- Medical examination report using LPTA/BM/5 form.
- Proof of personnel dose monitoring such as Optically Stimulated Luminescence (OSL), Thermoluminescence Dosimeter (TLD) or other approved equipment.



## Application Checklist


**Softcopy can be downloaded:**




**Senarai Semak Permohonan**

- Senarai Semak Dokumen Permohonan Pendaftaran Kemudahan Sinaran Mengion bagi Perkhidmatan Radiologi Diagnostik Di Fasilitas Perubatan Kerajaan Selaras Ketetapan di Bawah Akta Perlesenan Tenaga Atom 1984
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Pelupusan Radas)
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Pendaftaran Juru X-ray dan Lain-lain)
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Penggantian Melibatkan Pelupusan Radas)
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Permohonan Baru)
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Permohonan Jual Radas)
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Permohonan Membaharui)
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Permohonan Menggunakan)
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Permohonan Pindah Radas)
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Permohonan Tambah Radas)
- Tahun 2019 - Senarai Semak Perlesenan Radiologi Swasta (Permohonan Tukar Pemegang Lesen)
- Tahun 2019 - Senarai Semak Permohonan Juruperunding Fizik Perubatan (Permohonan Pembelian Bahan Radioaktif)
- Tahun 2020-Senarai Semak Perlesenan Radiologi Swasta (Permohonan Menjalankan Saringan Kesihatan Menggunakan Klinik X-ray Bergerak)

**[www.radia.moh.gov.my](http://www.radia.moh.gov.my)**



## License & Application Fees



Category / Type of Irradiating Apparatus		License fee per year in RM
<b>1</b>	Dental X-ray units, mobile & fixed medical x-ray units, mobile veterinary X-ray units	<b>RM100 for the first apparatus RM20 for every additional apparatus</b>
<b>2</b>	X-ray therapy units not operable above 500kVp	<b>RM300 for the first apparatus RM60 for every additional apparatus</b>
<b>3</b>	CT Scanner units, Accelerators, X-ray therapy units operable above 500kVp	<b>RM1000 for the first apparatus RM200 for every additional apparatus</b>
<b>Application Fee</b>		<b>RM15</b>

Reg. 15 of Radiation Protection (Licensing) Regulations 1986



## Latest Quality Assurance Programme (QAP) in Radiology



### Quality Assurance Programme (QAP)



Anything which can potentially lead to **extra irradiation** of either **patient, staff or general public** has to be meticulously monitored.





## Quality Assurance Programme (QAP)



Revised Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (BSS), as well as UNSCEAR, indicate that:

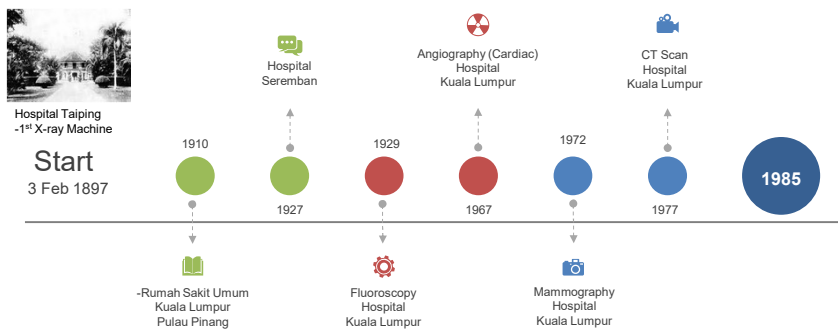
QA for medical exposure is an essential criterion for improving radiation safety in the medical application of ionizing radiation.

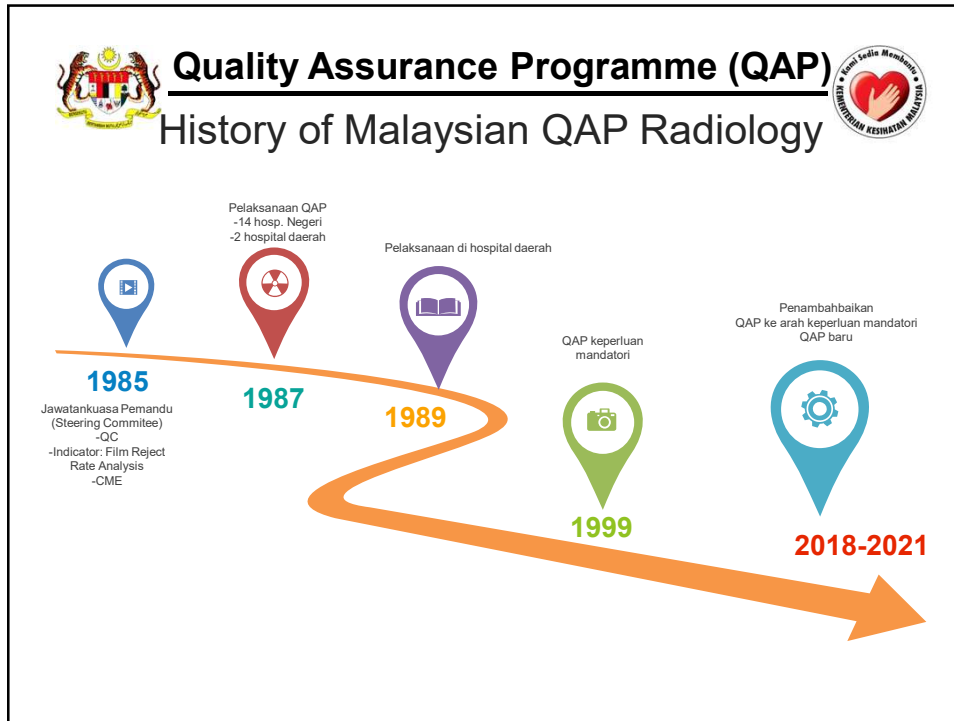


## Quality Assurance Programme (QAP)



### History Installation of X-ray Machine: Malaysia





**Quality Assurance Programme (QAP)**  
Legal requirements

Reg. 53. (1) ... the licensee SHALL establish a comprehensive QAP for medical exposure with the participation of appropriate qualified experts in the relevant fields as specified by the appropriate authority.

651 P.U. (A) 46.  
ATOMIC ENERGY LICENSING ACT 1984  
ATOMIC ENERGY LICENSING (BASIC SAFETY RADIATION PROTECTION) REGULATIONS 2010  
ARRANGEMENT OF REGULATIONS  
PART I  
PRELIMINARY  
Regulation  
1. Citation and commencement  
2. Application  
3. Interpretation  
PART II  
SYSTEM OF RADIOLOGICAL PROTECTION  
4. Justification of practice  
5. Optimization of protection and safety  
6. Dose constraint  
7. Dose limit  
8. Dose limit for workers  
9. Dose limit for members of the public  
10. Dose limit for apprentices and students  
11. Dose limit in special circumstances  
12. Verification of compliance with dose limit  
13. Evaluation of equivalent dose and effective dose  
14. Other methods of compliance with dose limit  
PART III  
OCCUPATIONAL EXPOSURE  
15. Responsibilities of licensee and employer  
16. Employment of radiation protection officer and qualified expert  
17. Classification of working areas  
18. Administrative procedures in supervised area and controlled area





## Quality Assurance Programme (QAP)



Pekeliling Keperluan Tambahan Perlesenan di bawah Akta 304 bagi Perkhidmatan Radiologi Khusus yang diberikan oleh Institusi – Institusi Perubatan Swasta (1999)

### Hospital-Hospital/ Klinik-Klinik Radiologi Swasta

No	Requirements	Implementation Schedule
1.	<b>Operators/Personnel</b> 1.1 Employment of at least one qualified radiographer 1.2 Employment of qualified female radiographers trained in mammography to perform mammography procedures 1.3 Direct supervision/service of at least one radiologist for specialised radiological procedures	1/1/2000
2.	<b>QAP</b> 2.1 Quality control (QC) of equipment, processors and associated facilities 2.2 Monitoring and analysis of film reject rate 2.3 Continuous Professional Education	1/1/2000





## Quality Assurance Programme (QAP)









Pekeliling Keperluan Tambahan Perlesenan di bawah Akta 304 bagi Perkhidmatan Radiologi Diagnostik yang diberikan oleh Institusi – Institusi Perubatan Swasta (1999)



### Klinik-Klinik Pengamal Perubatan Am (GP)

No	Requirements	Implementation Schedule
1.	<b>Operators/Personnel</b> 1.1 Only trained operators/personnel are allowed to conduct X-ray examinations 1.2 Service/supervision of radiologist	1/1/2000 by 2004
2.	<b>Audit of X-ray Radiographs</b>	1/1/2000
3.	<b>QAP</b> 3.1 Quality control (QC) of equipment, processor and associated facilities 3.2 Monitoring and analysis of film reject rate 3.3 Continuous Professional Education	1/1/2000 1/1/2000 1/1/2000
4.	<b>Training</b> 4.1 Training of new applicants/operators 4.2 CME at least once a year	1/1/2000 Next renewal

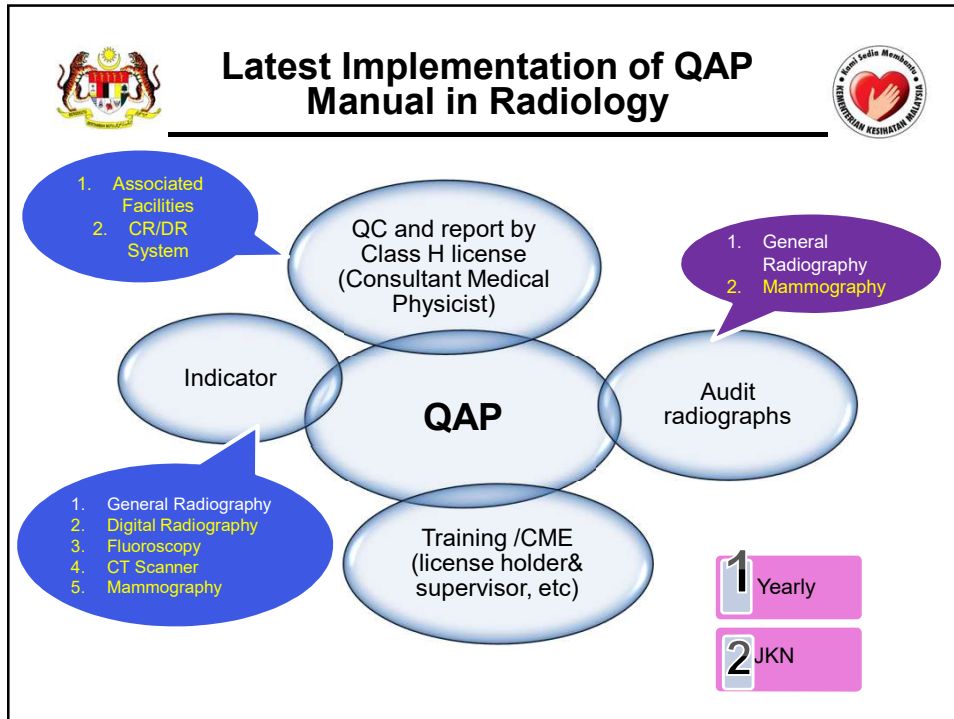
 **Quality Assurance Programme (QAP)** 

### Benefits?

 **Quality Assurance Programme (QAP)** 

- ✓ Perfect results every time
- ✓ Reduced radiation dose
- ✓ Improved diagnostic quality
- ✓ Reduced costs




**Latest QAP in Radiology**

**Contents**


- Introduction
- Objectives of QAP Implementation
- Scopes of QAP Implementation
- QAP Implementation under Act 304
  - ✓ Indicators
  - ✓ Quality Control (QC) of Irradiating Apparatus and Related Facilities
  - ✓ Audit Radiographs
  - ✓ Continuous Medical Education (CME)
- Record Management
- Monitoring of QAP Implementation
- Definitions
- Abbreviations
- References

**MANUAL PELAKSANAAN PROGRAM JAMINAN KUALITI (QAP) DALAM PERKHIDMATAN RADIOLOGI**

Disediakan oleh:  
Kumpulan Kerja Pelaksanaan Program Jaminan Kualiti Dalam Perkhidmatan Radiologi Di Seluruh Jajid Persebaran, Tanggal 15/09/2016 (JAKR-016)  
Kementerian Kesihatan Malaysia  
September 2016




## Latest QAP in Radiology




**Objectives of QAP Implementation**

- 1) Improve the quality of radiological services.
- 2) Ensure optimum ionizing radiation to produce quality images.
- 3) Ensure effective use of resources.
- 4) Meet and comply with regulatory requirements and relevant laws under the Atomic Energy Licensing Act 1984.





## Latest QAP in Radiology Indicators



**Element 1: Indicators**

- ✓ General Radiography (10% → 2.5%)
- ✓ Digital Radiography and Computed Radiography
- ✓ Fluoroscopy
- ✓ Computed Tomography (CT)
- ✓ Mammography





KEMENTERIAN KESIHATAN MALAYSIA

**4. PELAKSANAAN QAP DI BAWAH AKTA 304**

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

**4.1 INDIKATOR**

Indikator QAP sedia ada iaitu analisa kadar penolakan film masih digunakan 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.	Modality	Indikator	Standard	Rujukan
1.	Radiografi Am, General Radiography	Peratus Penolakan Radiografi Am Percentage of Rejected Radiographs	≤ 2.5%	Lampiran 1A Appendix 1A
2.	Radiografi Digital, Digital Radiography	Peratus Pengambilan Semula Radiografi Digital Percentage of Retakes for Digital Radiography	≤ 2.5%	Lampiran 2A Appendix 2A
3.	Fluoroskopi, Fluoroscopy	Peratus Prosedur Fluoroskopi yang mana Dos Rata-rata Melebihi Aras Rujukan Diagnostik Malaysia (Malaysian Diagnostic Reference Level - DRL) Percentage of Fluoroscopy Procedures where Report Dose Exceeds the Malaysian Diagnostic Reference Level (DRL)	≤ 20%	Lampiran 3A Appendix 3A Appendix 3B Appendix 3C





# Implementation of QAP Manual in Radiology



LAMPIRAN 2A

## Indicator 2: Digital Radiography

**REPORT OF PERCENTAGE OF RETAKES FOR DIGITAL RADIOGRAPHY**

FACILITY : \_\_\_\_\_  
 ROOM NO. / LOCATION : \_\_\_\_\_  
 YEAR : \_\_\_\_\_  
 STANDARD : ≤ 2.5%

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																	
OTHERS	13. Processing Fault																	
	14. Miscellaneous. Please specify: _____																	
Total number of error																		
Total number of repeat exposure (A)																		
Total number of images (B)																		
Percentage (%) (A-B) x 100%																		

COMMENT : \_\_\_\_\_  
 CORRECTIVE ACTION : \_\_\_\_\_

Reported by: \_\_\_\_\_ Verified by: \_\_\_\_\_  
 Name: \_\_\_\_\_ Name of Supervisor\*: \_\_\_\_\_  
 Position: \_\_\_\_\_ Date: \_\_\_\_\_  
\*Supervisor: Radiologist, Ketua Juru X-ray atau Orang Yang Bertanggungjawab.

LAMPIRAN 2A

**REPORT OF PERCENTAGE OF RETAKES FOR DIGITAL RADIOGRAPHY**

FACILITY : SKHCG/RSR  
 ROOM NO. / LOCATION : RAD/IGOR/RAJ/RAJ/1  
 YEAR : 2020  
 STANDARD : ≤ 2.5%

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		2					1									3	3.06												
	3. Double Exposure																													
	4. Wrong Technique / <i>posisi tangan</i>	7	12	1	3	5	7	4			6	3	5	6	5	6	63	64.29												
	5. Wrong Patient/ Exam																													
	6. No Primary/ Wrong Marker																													
	7. Collimation Error																													
	8. Patient Movement	3		1	2	1		2	1	1	1	1	1	1	1	1	16	16.33												
	9. Patient Related Artifact		2	2					1								9	9.18												
EQUIPMENT	10. Equipment Fault (X-Ray Tube/ Grid/ Bucky)		1										2			9	9.18													
	11. Detector/ Imaging Plate															1	1.02													
	12. Image Artifact																													
OTHERS	13. Processing Fault	1												1	1	4	4.08													
	14. Miscellaneous. Please specify: <i>poor inspiration</i>													1	1	2	2.04													
Total number of error																	3	4	3	3	2	1	4	3	2	2	4	4	7	

	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.	TOTAL	PERCENTAGE (%)
Total number of images (B)	11	17	4	6	6	7	9	6	9	8	7	8	98	
Percentage (%) (A-B) x 100%	0.22	1.37	0.42	1.08	0.88	0.75	0.29	0.52	0.24	0.80	0.67	0.85		0.24%

COMMENT : \_\_\_\_\_  
 CORRECTIVE ACTION : \_\_\_\_\_

Reported by: \_\_\_\_\_ Verified by: \_\_\_\_\_  
 Name: \_\_\_\_\_ Name of Supervisor\*: \_\_\_\_\_  
 Position: \_\_\_\_\_ Date: 03/01/2021  
\*Supervisor: Radiologist, Ketua Juru X-ray atau Orang Yang Bertanggungjawab.

LAMPIRAN 2A

**REPORT OF PERCENTAGE OF RETAKES FOR DIGITAL RADIOGRAPHY**

FACILITY : JESSELTON MEDICAL CENTRE  
 ROOM NO. / LOCATION : GENERAL X-RAY  
 YEAR : 2020  
 STANDARD : ≤2.5%

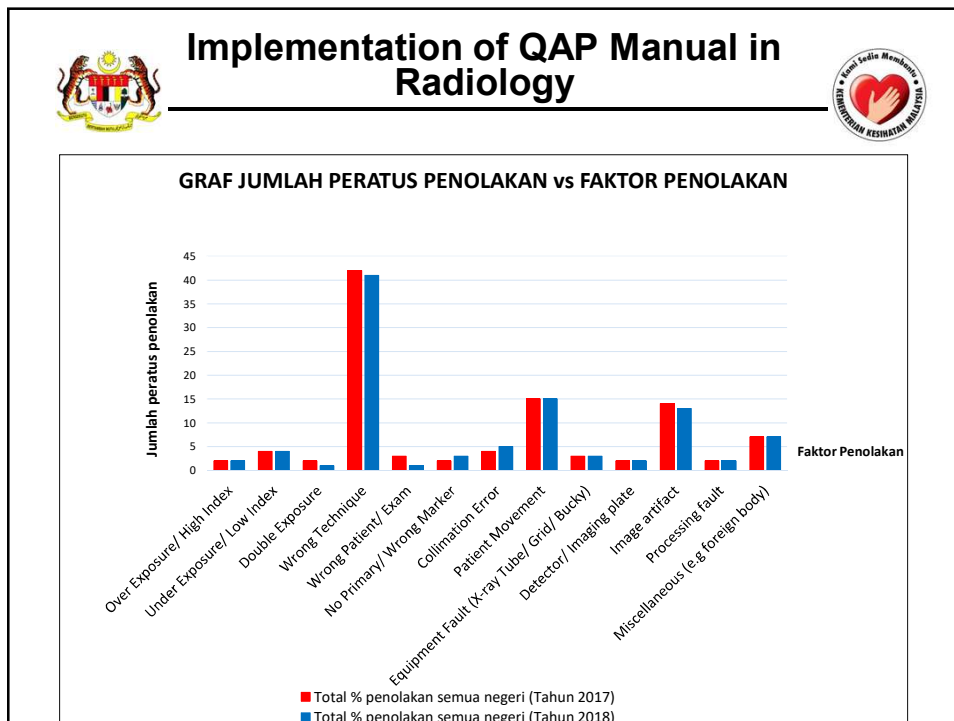
TYPE OF ERROR	MONTHS												TOTAL	PERCENTAGE (%)
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec		
<b>HUMAN FAULTS</b>														
1. Over Exposure/ High Index	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
2. Under Exposure/ Low Index	1	1	2	0	1	0	3	1	1	0	0	2	14	7.65
3. Double Exposure	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
4. Wrong Technique	16	15	8	4	9	14	12	16	6	7	5	121	121	66.12
5. Wrong Patient/ Exam	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
6. No Primary/Wrong Marker	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
7. Collimation Error	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
8. Patient Movement	1	2	3	1	1	0	3	0	0	0	0	16	16	8.74
9. Patient related artifact	0	3	2	1	1	1	0	1	0	0	1	12	12	6.56
<b>EQUIPMENT</b>														
10. Equipment Fault (X-Ray Tube/ Grid/ Bucky)	3	2	2	0	0	1	0	0	0	1	1	12	12	6.56
11. Detector/Imaging Plate	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
12. Image Artifact	2	0	0	0	0	0	2	2	0	2	0	8	8	4.37
13. Processing Fault	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
<b>OTHERS</b>														
14. Miscellaneous. Please specify.....	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00
<b>Total number of error</b>	<b>23</b>	<b>23</b>	<b>17</b>	<b>6</b>	<b>12</b>	<b>16</b>	<b>22</b>	<b>23</b>	<b>13</b>	<b>8</b>	<b>11</b>	<b>9</b>	<b>183</b>	<b>100</b>

TOTAL NUMBER	MONTHS												TOTAL	PERCENTAGE (%)
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec		
Total number of repeat exposure (A)	23	23	17	6	12	16	22	23	13	8	11	9	183	100
Total number of images (B)	950	982	704	344	614	885	991	1014	947	533	639	701	9304	
Percentage (%) (A/B) x 100%	2.42	2.34	2.41	1.74	1.95	1.81	2.22	2.27	1.37	1.50	1.72	1.28	1.92	

**COMMENT** : The retakes percentage is higher for the month of July and August as we have new Radiographer started working in our centre in June 2020.

**CORRECTIVE ACTION** : Senior Radiographers to assist and guide the new Radiographer accordingly and it has shown improvement from September 2020 onwards.









# Implementation of QAP Manual in Radiology



## Indicator 3: Fluoroscopy

Examination Type	DRLs in KAP (mGy.m <sup>2</sup> )
<b>Angiography</b>	
Cardiac	5.4
Non-Cardiac	5.2
<b>Conventional Studies</b>	
ERCP	0.8
GI Lower	0.7
GI Upper	0.9
MCU	1.4
<b>Interventional Studies</b>	
Cerebral	8.7
ESWL	0.8
PTCA	15.7
Vascular	5.9
Others	2.0

**LAMPIRAN 3A**

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

FACILITY : Fluoroscopic  
 DEPARTMENT : Radiology  
 MONTH/YEAR : 8/2018  
 UNIT :  
 MACHINE MODEL : Artis - Zee (Siemens)

79 cases  
14 exceeded.

NO.	Examination Date	Examination No. / Examination No.	Examination Type	KAP Value (mGy.m <sup>2</sup> )		Exceed DRL	
				Actual	DRL	Yes	No
1	1/8/2018	M872544	Proctogram	0.5115	511.50 uGy.m <sup>2</sup>	/	/
2	1/8/2018	N719288	Proctogram	0.7115	711.50 uGy.m <sup>2</sup>	/	/
3	1/8/2018	N721618	Proctogram	2.900	2900.00 uGy.m <sup>2</sup>	/	/
4	2/8/2018	N710594	Cystogram	0.731	731.00 uGy.m <sup>2</sup>	/	/
5	3/8/2018	N703301	HSG	0.210	210.00 uGy.m <sup>2</sup>	/	/
6	3/8/2018	M993523	HSG	0.22	220.00 uGy.m <sup>2</sup>	/	/
7	3/8/2018	M053766	Barium Swallow	0.018	18.00 uGy.m <sup>2</sup>	/	/
8	6/8/2018	N647311	HSG	0.228	228.00 uGy.m <sup>2</sup>	/	/
9	6/8/2018	N712803	Cystogram	0.067	66.74 uGy.m <sup>2</sup>	/	/
10	6/8/2018	N252420	Barium Swallow	0.018	18.00 uGy.m <sup>2</sup>	/	/
11	7/8/2018	N714191	HSG	0.102	102.00 uGy.m <sup>2</sup>	/	/
12	7/8/2018	N638740	Barium Swallow	3.044	3044.00 uGy.m <sup>2</sup>	/	/
13	7/8/2018	N746727	Barium Swallow	0.0141	14.09 uGy.m <sup>2</sup>	/	/
14	7/8/2018	M742195	Barium Swallow	0.640	640.09 uGy.m <sup>2</sup>	/	/
15	7/8/2018	N715390	MCUG	0.0261	26.10 uGy.m <sup>2</sup>	/	/
16	7/8/2018	N571649	HSG	0.100	100.90 uGy.m <sup>2</sup>	/	/
Total							

**Malaysian standard DRL value :**  
**Angiography (Diagnostic)**  
 Cardiac: 5.44 mGy.m<sup>2</sup>  
 Non-Cardiac: 5.22 mGy.m<sup>2</sup>  
**Conventional Studies**  
 GI Lower: 0.68 mGy.m<sup>2</sup>  
 GI Upper: 0.9 mGy.m<sup>2</sup>  
 MCU: 1.41 mGy.m<sup>2</sup>  
 ERCP: 0.83 mGy.m<sup>2</sup>  
**Interventional Studies**  
 Cerebral: 8.70 mGy.m<sup>2</sup>  
 ESWL: 0.81 mGy.m<sup>2</sup>  
 PTCA: 15.70 mGy.m<sup>2</sup>  
 Vascular: 5.87 mGy.m<sup>2</sup>  
 Others\*\*: 2.01 mGy.m<sup>2</sup>

\*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

**LAMPIRAN 3B**

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

FACILITY: LITHO  
 DEPARTMENT: UROLOGY DEPARTMENT  
 MACHINE MODEL: I-MOVE  
 YEAR: 2019

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.	3	0	33.33%
Feb.	1	0	0%
Mar.	2	2	100%
Apr.	6	2	33.33%
May	8	0	0%
June	6	3	50%
July	6	3	50%
Aug.	6	4	66.66%
Sept.	6	4	66.66%
Oct.	2	2	66.66%
Nov.	3	3	50%
Dec.	2	2	100%
<b>TOTAL</b>	<b>55</b>	<b>26</b>	<b>47.27%</b>

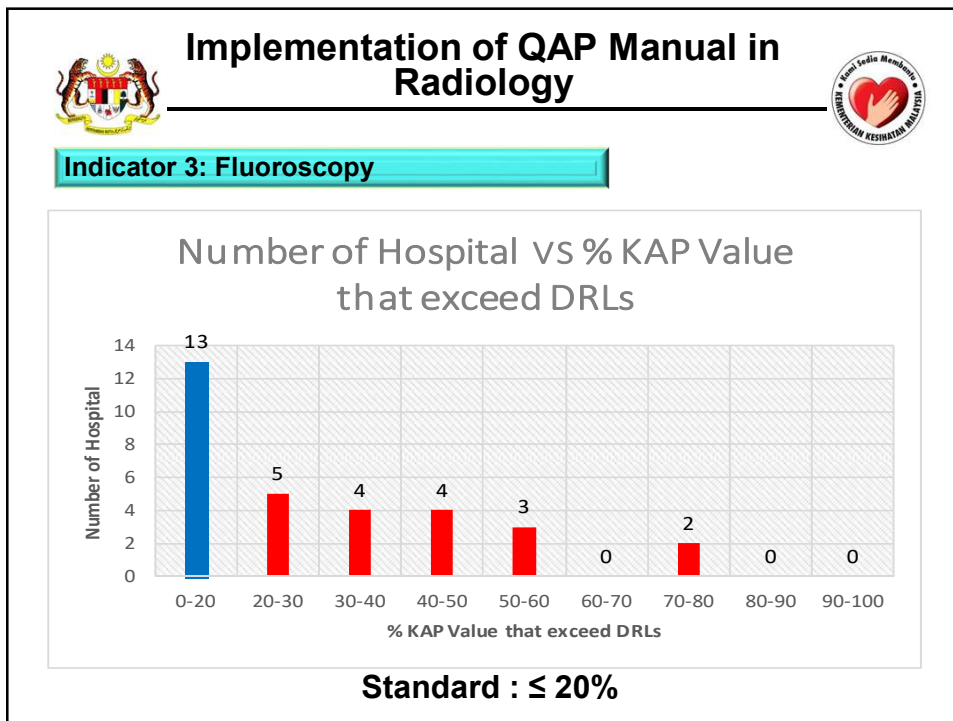
(N) (N)

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

**SHORTFALL IN QUALITY**

Causes: Long procedure.  
 Corrective Action: All cases depend on the urologist on duty.

Reported by: [Signature] Name: SYDEADAH BT Yusoff  
 Verified by: [Signature] Name of Radiologist: [Signature]





LAMPIRAN 4A

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

Facility: Computed Tomography Month/Year: JAN 2019  
 Department: Radiology  
 Machine Model: [REDACTED]  
 Year of Installation: 2011, NOVEMBER

No.	Examination date	CT Scan No./ Accession No.	Age and Gender Distribution		DAP Indicator			DRL Exceeded	
			Male/Female	Age (Years)	Scan Length (cm)	CTDI <sub>w</sub>	DLP (mGy.cm)	Y	N
01	11/11/19	8801	FEMALE	50	14cm	56.10	1049.50	✓	
02	11/11/19	8803	FEMALE	79	13.5cm	56.10	965.20	✓	
03	11/11/19	8814	MALE	70	13.5cm	56.10	993.40	✓	
04	11/11/19	8815	FEMALE	73	13.5cm	56.10	993.40	✓	
05	11/11/19	8828	MALE	76	13.5cm	56.10	853	✓	
06	10/11/19	8837	FEMALE	61	13.5cm	56.10	904.7	✓	
07	10/11/19	8838	MALE	71	13.5cm	56.10	1021.40	✓	
08	14/11/19	8847	FEMALE	11	13.5cm	56.10	931	✓	
09	15/11/19	8852	FEMALE	55	13.5cm	56.10	909.20	✓	
10	17/11/19	8858	FEMALE	53	13.5cm	56.10	1021.40	✓	
11	18/11/19	8859	MALE	70	13.5cm	56.10	1049.50	✓	
12	20/11/19	8867	MALE	50	13.5cm	56.10	937.20	✓	
13	23/11/19	8874	FEMALE	58	13.5cm	56.10	881.10	✓	
14	24/11/19	8881	MALE	73	13.5cm	56.10	993.40	✓	
15	29/11/19	8895	MALE	45	13.5cm	56.10	934.90	✓	
16	29/11/19	8900	MALE	64	13.5cm	56.10	993.40	✓	
17	30/11/19	8904	FEMALE	40	13.5cm	56.10	1021.40	✓	

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

Number of Adult Plain CT Brain examinations that exceed the DRL value in a month: 0

Reported by: [REDACTED] Date: 06 JAN 2020  
 Verified by: [REDACTED] Date: 06 JAN 2020

L13

LAMPIRAN 4B

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

Facility: CT-SCAN  
 Department: Radiology Department  
 Machine Model: [REDACTED]  
 Year: [REDACTED]

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.	13	1	7.6
Feb.	9	1	11.1
Mar.	7	1	14.3
Apr.	8	0	0
May	5	0	0
June	3	0	0
July	7	1	14.3
Aug.	10	0	0
Sept.	6	0	0
Oct.	14	2	14.3
Nov.	4	0	0
Dec.	4	1	25
<b>TOTAL</b>	<b>90</b>	<b>8</b>	<b>8.8</b>
	(D)	(N)	

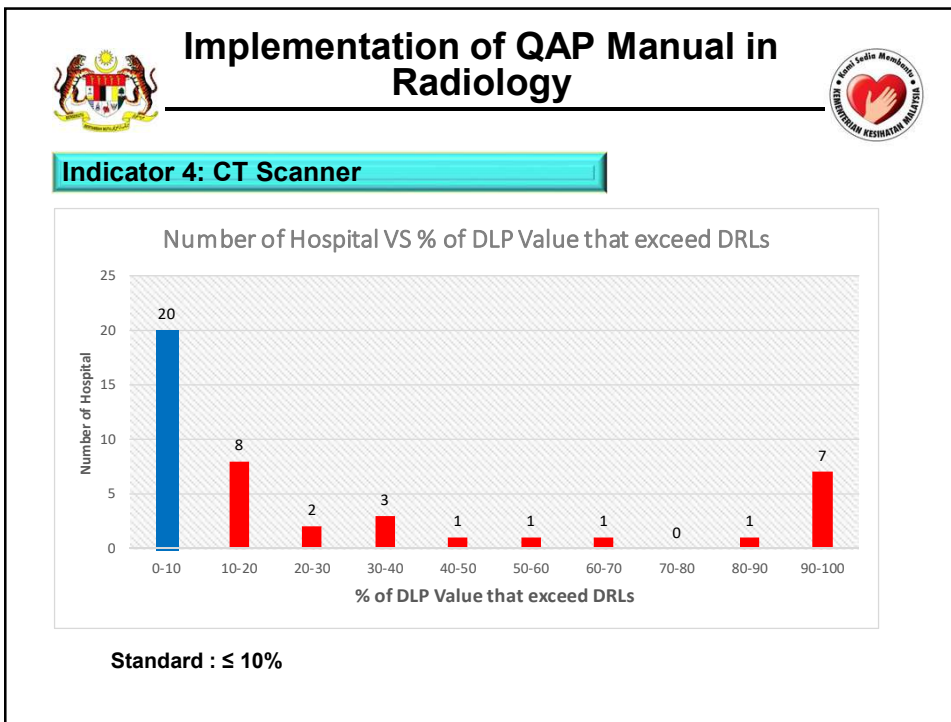
% of DLP for Adult Plain CT Brain Examination that exceed DRL: (N/D x 100) = 8.8 %

**SHORTFALL IN QUALITY**



Causes: \_\_\_\_\_  
 Corrective Action: \_\_\_\_\_

Reported by: [REDACTED] Date: [REDACTED]  
 Verified by: [REDACTED] Date: 23 JAN 2020

L14



## Implementation of QAP Manual in Radiology

LAMPIRAN 5A

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

FACILITY : \_\_\_\_\_

MACHINE MODEL : \_\_\_\_\_

YEAR OF INSTALLATION : \_\_\_\_\_

IMAGE PROCESSOR TYPE / MODEL : \_\_\_\_\_

STANDARD : ≤ 3%

**Indicator 5:  
Mammography –  
Conventional  
(Montly)**

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


Remarks: \_\_\_\_\_

Corrective Action: \_\_\_\_\_


Data Analyzed by: \_\_\_\_\_ Verified by: \_\_\_\_\_

Name: \_\_\_\_\_ Position: Senior Radiographer/ Radiologist

Date: \_\_\_\_\_ Date: \_\_\_\_\_



## Implementation of QAP Manual in Radiology



### Indicator 5: Mammography – Conventional (Yearly)

LAMPIRAN 5C

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

FACILITY : \_\_\_\_\_  
 MACHINE MODEL : \_\_\_\_\_  
 IMAGE PROCESSOR TYPE/MODEL : \_\_\_\_\_

REASON FOR REJECT	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															
EQUIPMENT	6. Patient Motion															
	7. Patient Related Artifact															
	8. Mechanical Fault															
OTHER REASONS	9. Aborted AEC															
	10. Film Artifacts															
	11. Cassette / Film															
	12. Darkroom Processing															
	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: Senior Radiographer


Date: \_\_\_\_\_

Verified by:


.....

Name: Radiologist

Date: \_\_\_\_\_



## Implementation of QAP Manual in Radiology



### Indicator 5: Mammography – FFDM/ CR (Montly)

LAMPIRAN 5B

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

FACILITY : \_\_\_\_\_  
 MACHINE MODEL / YEAR OF MACHINE : \_\_\_\_\_  
 YEAR OF INSTALLATION : \_\_\_\_\_  
 CASSETTE READER : \_\_\_\_\_  
 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							
EQUIPMENT	6. Patient Motion							
	7. Patient Related Artifact							
	8. CR Image Reader Fault							
OTHER REASONS	9. Mechanical Fault							
	10. Blank Image							
	11. Aborted AEC							
	12. Software Failure							
	13. Detector / Imaging Plate							
	14. Artifacts							
	15. Other Reasons. Please specify: _____							
Total number of error								
Total number of images rechecked (A)								
Total number of images used (B)								
Percentage of images rechecked (A/B) x 100%								

REMARKS : \_\_\_\_\_  
 Corrective Action : \_\_\_\_\_

Data Analyzed by:

.....

Name: Senior Radiographer

Date: \_\_\_\_\_

Verified by:

.....

Name: Radiologist

Date: \_\_\_\_\_



# Implementation of QAP Manual in Radiology



## Indicator 5: Mammography – FFDM/ CR (Yearly)

LAMPIRAN 5D

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.			
<b>HUMAN FAULTS</b>															
1. Incorrect Patient ID															
2. Wrong Patient															
3. Marker															
4. Positioning Technique															
5. Exposure Faults															
6. Patient Motion															
7. Patient Related Artifact															
8. CR Image Reader Fault															
<b>EQUIPMENT</b>															
9. Mechanical Fault															
10. Blank Image															
11. Aborted AEC															
12. Software Failure															
13. Detector / Imaging Plate															
14. Artifacts															
<b>OTHERS</b>															
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: Senior Radiographer  
 Date: \_\_\_\_\_

Verified by:  
 Name: \_\_\_\_\_  
 Position: Radiologist  
 Date: \_\_\_\_\_

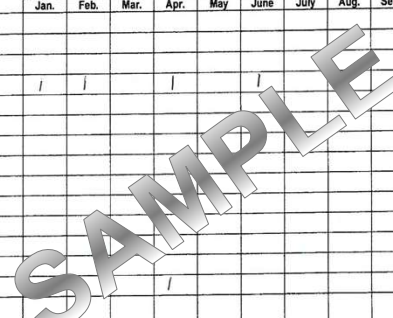




LAMPIRAN 5D



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

FACILITY : Mammography  
 MACHINE MODEL : MCU 100 (Technica)  
 CASSETTE READER TYPE/MODEL : Alpha CR 85 X Developer  
 LASER PRINTER TYPE/MODEL : Chestrom Aquileo printer 5950 / Epson pp-1100 II CB / DVD publisher.

REASON FOR RETAKE	MONTHS												TOTAL	PERCENTAGE	
	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.			
<b>HUMAN FAULTS</b>															
1. Incorrect Patient ID															
2. Wrong Patient															
3. Marker															
4. Positioning Technique	1	1		1		1								4	20%
5. Exposure Faults															
6. Patient Motion															
7. Patient Related Artifact															
8. CR Image Reader Fault															
<b>EQUIPMENT</b>															
9. Mechanical Fault															
10. Blank Image															
11. Aborted AEC															
12. Software Failure															
13. Detector / Imaging Plate														1	20%
14. Artifacts				1											
<b>OTHERS</b>															
15. Other Reasons. Please specify.....															
Total number of error	1	1	-	2	-	1	-	-	-	-	-	-	-	2	
Total number of images rejected (A)	1	1	-	2	-	1	-	-	-	-	-	-	-	5	
Total number of images used (B)	115	40	118	554	565	431	339	329	276	64	75	96		2882	
Percentage of images rejected (A÷B) x 100%	0.87	2.5	-	0.36	-	0.24	-	-	-	-	-	-	-	0.17	



 <b>Latest Implementation of QAP Manual in Radiology</b> 		
NEW INDICATORS		
INDICATORS	STANDARD	FORMS SUBMIT TO JKN EVERY YEAR
Percentage of radiographs rejected	$\leq 2.5\%$	Lampiran 1A
Proportion of retakes for digital images	$\leq 2.5\%$	Lampiran 2A
Percentage of fluoroscopic procedures where patient dose exceed the Malaysian diagnostic reference level (DRL)	$\leq 20\%$	Lampiran 3A dan 3B
Percentage of dose length product (DLP) for adult CT brain examination that exceed the Malaysian DRL	$\leq 10\%$ exceed Malaysian DRL values (The DLP value for CT brain examination is 1050 mGy.cm)	Lampiran 4A dan 4B
Percentage of rejected mammography films/images	$< 3\%$	Lampiran 5C Lampiran 5D

 <b>Latest Implementation of QAP Manual in Radiology</b> 	
<b>Element 2: Quality Control (QC)</b>	
<b>When?</b>	
<ul style="list-style-type: none"> <li>✓ <b>Acceptance testing (New equipment)</b> <ul style="list-style-type: none"> <li>✓ Conformance to manufacture's specifications/criteria &amp; regulatory requirements.</li> </ul> </li> <li>✓ <b>Routine performance evaluations</b> <ul style="list-style-type: none"> <li>✓ Specific tests performed at regular intervals</li> <li>✓ Evaluate malfunctioning or out-of-spec equipment</li> <li>✓ To check the deviation of the current performance</li> </ul> </li> <li>✓ <b>Change in major component(s)</b></li> <li>✓ Maintenance/calibration and associated checks shall be done every year.</li> <li>✓ Performance test and safety must be undertaken by an accredited Class H Medical Physicist Consultant (QC report).</li> </ul>	





## Latest Implementation of QAP Manual in Radiology



### Element 2: Quality Control (QC)

#### Why?

- ✓ All irradiating apparatus and related facilities should undergo QC tests to ensure compliance with the performance standards and requirements of radiation safety.
- ✓ In addition to ensure that the performance of the equipment meets the specified specifications, the commissioning should be done to obtain baseline data.




## Latest Implementation of QAP Manual in Radiology




### Element 2: Quality Control (QC)

- ✓ **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.



## Latest Implementation of QAP Manual in Radiology




**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	L23
Table 1.b	: Performance and Safety Standards for Digital System Associated Facilities	L26
Table 2	: Performance and Safety Standards for General/ Mobile X-ray Equipment	L28
Table 2.a	: Additional Performance and Safety Standards for Computed Radiography (CR) System	L31
Table 2.b	: Additional Performance and Safety Standards of Digital Radiography (DR) System	L35
Table 3	: Performance and Safety Standards for Fluoroscopy Systems	L38
Table 4	: Performance and Safety Standards for Computed Tomography (CT) Scanner	L45
Table 5.a	: Performance and Safety Standards for Screen Films and Computed Radiography Mammography System	L50
Table 5.b	: Performance and Safety Standards for Full Field Digital Mammography System	L54
Table 6	: Performance and Safety Standards for Bone Mineral Densitometry (BMD) System	L61

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



## Latest Implementation of QAP Manual in Radiology




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


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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




## Latest Implementation of QAP Manual in Radiology







• QC CERTIFICATE




• QC TEST SUMMARY



• QC FULL REPORT







## Latest Implementation of QAP Manual in Radiology




**List of Class H Medical Physicist Consultant**


Bil	Nama Syarikat	Alamat Syarikat	No. Telefon
1	AGENSI NUKLEAR MALAYSIA	BANGI, 43000 KAJANG, SELANGOR	03-8911 2000 / 03-8911 1518
2	GAMEDIX SDN. BHD.	CT-01-10, CORPORATE TOWER, SUBANG SQUARE, JALAN SS 15/4G, 47500 SUBANG JAYA, SELANGOR	03-5638 4331
3	ALPHA CENTENNIAL (M) SDN. BHD.	LOT 706B, TINGKAT 2, KOMPLEKS DIAMOND, BANGI BUSINESS PARK, 43650 BANDAR BARU BANGI, SELANGOR	03-8927 4891
4	SINARAN CONSULTANCY SDN. BHD.	CT-01-09, FIRST FLOOR, CORPORATE TOWER SUBANG SQUARE, JALAN SS15/4G 47500 SUBANG JAYA, SELANGOR	03-5631 9658 / 012-294 2998
5	BIOENGINEERING SDN. BHD.	NO. 23B, JALAN PJS 1/33, PETALING UTAMA 12, PETALING UTAMA BATU 7, 46000 PETALING JAYA, SELANGOR	03-7772 8587 / 012-364 6467
6	ALYPZ SDN. BHD.	NO. 14, JALAN INDUSTRI USJ 1/1, TAMAN PERINDUSTRIAN USJ 1, 47600 SUBANG JAYA, SELANGOR	03-8023 9200
7	TECHNOSOL RESOURCES SDN. BHD.	NO D2A, PUSAT PERDAGANGAN ALAM JAYA, JALAN PPAJ 2/5, BANDAR PUNCAK ALAM, 42300, SHAH ALAM, SELANGOR	013-2191393
8	MEDICAL PHYSICS SERVICES SDN. BHD.	L2-13A, TIMES 89 BUSINESS PLAZA, JALAN 8A/133, TAMAN SRI SENTOSA, JALAN KLANG LAMA, 58000 KUALA LUMPUR, WILAYAH PERSEKUTUAN	1700 817 662
9	EDGENTA HEALTHTRONICS SDN. BHD.	LEVEL 17, MENARA UEM, TOWER 1, THE HORIZON, BANGSAR SOUTH CITY, NO. 8, JALAN KERINCHI, 59200 KUALA LUMPUR, WILAYAH PERSEKUTUAN	03-2725 7821

 <b>Latest Implementation of QAP Manual in Radiology</b> 			
<b>Element 3: Audit Radiograf (1) – General Radiography</b> <b>Audit on the Quality of Radiographs</b>			
<b>Number of Radiographs / Images Audited</b>			
Type of Examination	Private Medical Practitioner / Clinics	Health Clinics	All Hospital / Medical Institutions
Adult Chest	10	10	15
Adult Extremity / Lumbar		10	15
Neonatal Chest / Abdomen	-	-	10
<b>Total</b>	<b>10</b>	<b>20</b>	<b>40</b>

 <b>Latest Implementation of QAP Manual in Radiology</b> 				
<b>Element 3: Audit Radiograf (1) – General Radiography</b> <b>Audit on the Quality of Radiographs</b>				
<b>Standard Percentage</b>	<b>:</b> 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	



## Latest Implementation of QAP Manual in Radiology



**Element 3: Audit Radiograf (1) – General Radiography  
Audit on the Quality of Radiographs**


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



## Latest Implementation of QAP Manual in Radiology



**Element 3: Audit Radiograf (1) – General Radiography  
Audit on the Quality of Radiographs**

LAMPIRAN 7A

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
<b>PART 1.0 - IMAGE ANNOTATION</b>																
1.1	Patient identification															
1.2	Date of Examination															
1.3	Name of Clinic/Hospital															
1.4	Primary anatomical marker															
<b>PART 2.0 - PATIENT POSITIONING</b>																
2.1	Symmetrical positioning of thorax <i>Sternoclavicular joints should be equidistant</i>															
2.2	Medial border of the scapulae to be outside of the lung fields.															
<b>PART 3.0 - IMAGE COLLIMATION</b>																
3.1	Collimation of image a) The upper border should include both apices and the lower border to include the diaphragm. b) The lateral border to include the rib cage and part of shoulder joints.															
<b>PART 4.0 - IMAGE QUALITY ASSESSMENT</b>																
4.1	Contrast and exposure are adequate a) retro cardiac area can be visualized															



# Latest Implementation of QAP Manual in Radiology



## Element 3: Audit Radiograf (1) – General Radiography Audit on the Quality of Radiographs

LAMPIRAN 7A

**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
4.2	b) Linear and reticular details out to the lung periphery.															
	c) Enough to visualize vertebral body T1 to T4.															
	The lungs are well inflated It should be possible to visualize either six ribs anteriorly or ten ribs posteriorly.															
4.3	Sharp visualization of normal chest anatomy Visually sharp:															
	a) The trachea and proximal bronchi															
	b) The borders of the heart and aorta															
	c) The diaphragm and costo-phrenic angles															
<b>TOTAL MARKS / 15</b>																
*For each radiograph, minimum 12 score to pass audit																
<b>SCORING</b>																
		PERCENTAGE = %														

\*\*Adapted from European 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:

Verified by:

Name:  
Position:  
Date:

Name of Radiologist:  
Date:

LAMPIRAN 7A

**AUDIT FORM A  
IMAGE QUALITY ASSESSMENT : CHEST RADIOGRAPH FOR ADULT**

FACILITY : \_\_\_\_\_

TYPE OF MACHINE / YEAR OF MACHINE : SHIMADZU FLEXA VISION / 2018

TYPE OF IMAGE PROCESSOR : Conventional Processor  CR System  DR System

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

NUM.	CRITERIA	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
<b>PART 1.0 - IMAGE ANNOTATION</b>																
1.1	Patient identification	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
1.2	Date of examination	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
1.3	Name of Clinic / Hospital	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
1.4	Primary anatomical marker	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
<b>PART 2.0 - PATIENT POSITIONING</b>																
2.1	Symmetrical positioning of thorax Sternoclavicular joints should be equidistant.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2.2	Medial border of the scapulae to be outside of the lung fields.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
<b>PART 3.0 - IMAGE COLLIMATION</b>																
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.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
<b>PART 4.0 - IMAGE QUALITY ASSESSMENT</b>																
4.1	Contrast and exposure are adequate	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	a) Able to visualize retro cardiac area.															
	b) Linear and reticular details seen out to the lung periphery.															
	c) 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.															
	Sharp visualization of normal chest anatomy Visually sharp:															
	a) Trachea and proximal bronchi															
	b) Borders of the heart and aorta															
	c) Diaphragm and costo-phrenic angles															
<b>TOTAL MARKS</b>																
*For each radiograph, minimum 12 score to pass audit																
<b>SCORING ( / 10)</b>																
		PERCENTAGE = %														

\*\*Adapted from European 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: \_\_\_\_\_ Verified by: \_\_\_\_\_


Name: \_\_\_\_\_ Position: \_\_\_\_\_ Date: 06 JAN 2020

Name of Radiologist: \_\_\_\_\_ Date: 06 JAN 2020

L69 - L69 (Manual Pelaksanaan Program Jaminan Kualiti (GAP) dalam Perkhidmatan Radiologi (Pindaan: Januari 2019))



## Latest Implementation of QAP Manual in Radiology



**Element 3: Audit Radiograf (2) – Mammography  
PGMI Classification of Mammogram Films / Images**

**SCORING METHOD**


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

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


PGMI categorization / classification of mammogram images

Criteria	Standard	Reference
Images with P, G, M categories	> 97%	Appendix 8 Appendix 8A
Images with P, and G categories	>50% (75% desirable)	
Images with I (Inadequate)	<3%	

Each case shall satisfy the above standards



## Latest Implementation of QAP Manual in Radiology



**Element 3: Audit Radiograf (2) – Mammography  
PGMI Classification of Mammogram Films / Images**

<b>Standard Percentage</b>	<p>The acceptable quality standards are as follow :</p> <p>i. Images with P, G, M categories shall be &gt; 97%</p> $\frac{\text{Total number of cases in P,G and M categories}}{\text{Total number of randomly selected 50 mammogram cases}} \times 100\%$ <p>ii. Images with P and G categories shall be &gt; 50% (75% desirable)</p> $\frac{\text{Total number of cases in P, and G categories}}{\text{Total number of randomly selected 50 mammogram cases}} \times 100\%$ <p>iii. Images with I (Inadequate) category shall be &lt; 3%</p> $\frac{\text{Total number of cases in I categories}}{\text{Total number of randomly selected 50 mammogram cases}} \times 100\%$
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## Latest Implementation of QAP Manual in Radiology



### ELEMENT 4: CONTINUOUS MEDICAL EDUCATION (CME)

- CME courses of at least 4 hours per year are compulsory for all workers.
- All CME courses must be approved by Medical Radiation Surveillance Division, MOH.
- Online CME maximum of 2 hours per year can be accepted.
- Seminars, workshops or meetings which include the topics listed are accepted.
- Courses organized by the MOH, Universities, Institutions and recognized Professional Bodies may be accepted.
- 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 MOH.




## Latest Implementation of QAP Manual in Radiology




### ELEMENT 4: CONTINUOUS MEDICAL EDUCATION (CME)

CME courses should cover any of the following topics:

- i. Legislation and Regulation of Act 304
- ii. Radiation Safety Awareness
- iii. Quality Assurance Program Management
- iv. X - Ray Equipment and Associated Facilities
- v. Clinical Practices and Radiologic Correlation
- vi. Requirements & Criteria for Image Quality
- vii. Interpretation of Clinical Images
- viii. Current Developments of Imaging Modalities & Radiation Protection



## Latest Implementation of QAP Manual in Radiology



### MONITORING OF QAP IMPLEMENTATION

When should we submit the relevant documents?

- ✓ Indicator and audit radiographs reports should be submitted to the JKN before 31 January each year.
- ✓ Other requirements (QC & CME) – subject to their expiry date).

# https://radia.moh.gov.my




Laman Web Rasmi  
**BAHAGIAN KAWALSELIA RADIASI PERUBATAN**  
Kementerian Kesihatan Malaysia

[Laman Utama](#) [Mengetahui Kami](#) [Sistem Online](#) [Perundangan](#) [Muat Turun](#) [Soalan Lazim](#) [Hubungi Kami](#) [EKSA](#)

## Permohonan Pelupusan Radas Penyinaran

Tatacara Pelupusan Radas Penyinaran dan Peranti yang Menggunakan Bahan Radioaktif Selaras dengan Ketetapan di Bawah Akta Perlesenan Tenaga Atom 1984 (AKTA 304) telah mula dilaksanakan. Pemohon perlu melengkapkan borang A dan B bagi menggantikan penggunaan 'reply slip' sedia ada untuk permohonan proses pelupusan.  
Mohon rujuk KKM-153(13/239)(11)JLD.2 bertarikh 03/08/2018.

Sistem Online

  
**Penggunaan Pejabat**

  
**Pendaftaran Kerajaan**

  
**Pelesenan Swasta**

  
**Class H (Lawatan)**

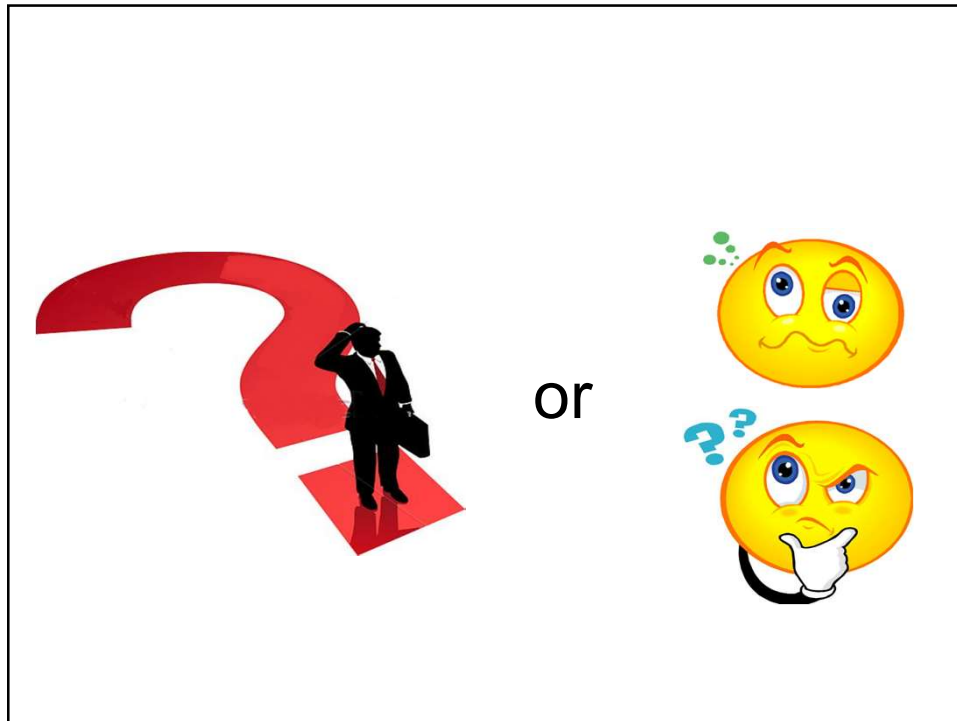
Berita dan Pengumuman

27-Aug-2018  
Inovasi bantu pesakit kanser - Sm-153  
EDTMP

Muat Turun

Tahun 2018 - Pekeliling Keperluan Regulatori Di Bawah Akta Perlesenan Tenaga Atom 1984 (Akta 304) Rasi E26888

Carian



 *Thank you*  

**MEDICAL RADIATION SURVEILLANCE DIVISION  
MINISTRY OF HEALTH  
LEVEL 4, BLOCK E3, COMPLEX E, PRECINCT 1  
FEDERAL GOVERNMENT ADMINISTRATIVE CENTRE  
62590 PUTRAJAYA**

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Website : <https://radia.moh.gov.my>

