

**GUIDELINES TO OBTAIN CLASS C LICENCE
UNDER THE ATOMIC ENERGY LICENSING ACT 1984
(ACT 304)
FROM THE MINISTRY OF HEALTH MALAYSIA**



*ENGINEERING SERVICES DIVISION
MINISTRY OF HEALTH MALAYSIA
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Class C Licence Under The
Atomic Energy Licensing Act
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1 SCOPE

- 1.1 This document is prepared to provide guidelines for obtaining **Class C licence** under the **Atomic Energy Licensing Act 1984 (Act 304) for medical and dental purposes from the Ministry of Health Malaysia.**
- 1.2 A Class C licence issued by the Director General of Health Malaysia is for the purpose of purchasing, storing, using or transferring (selling) irradiating apparatus such as X-ray machines for medical imaging.

2 OBJECTIVE

- 2.1 The objective of this document is to disseminate information on;
- 2.1.1 **procedures to apply for a Class C licence** under the Atomic Energy Licensing Act 1984 (Act 304) from the Ministry of Health Malaysia ;
- 2.1.2 **licensing conditions and requirements.**

3 INTRODUCTION

- 3.1 Under the provision of regulation 6(1), Radiation Protection (Licensing) Regulations 1986, Class C licence is defined as a licence to manufacture, trade in, produce, process, purchase, own, possess, use, transfer, handle, sell or store irradiating apparatus.
- 3.2 Under the provision of subsection 12(1)(b), Atomic Energy Licensing Act 1984 (Act 304), no person shall deal in, possess or dispose of any radioactive material, nuclear material, prescribed substance or irradiating apparatus, unless he is the holder of a valid licence issued under section 16(5) by the appropriate authority for such purpose and as specified in the licence.
- 3.3 Section 15(2) Atomic Energy Licensing Act 1984 (Act 304) says that the Board shall grant a general licence to the Director General of Health to issue a separate licences on behalf of the Board to any person applying for a licence to undertake any of the activities referred to in the classification of licences under this Act where such activities are in respect of medical purposes.
- 3.4 Therefore, **any person who intends to deal in, possess or dispose of any irradiating apparatus for medical and dental purposes shall possess a valid licence issued by the Director General of Health Malaysia.**

4 CATEGORIES OF APPLICATION FOR A LICENCE

- 4.1 There are **three categories** of application, i.e. application for a **new licence**, application for **renewal of a licence** and application for **amendment of a licence**.

4.1.1 Application for a new licence

An application made by a qualified person (as described in paragraph 6.2) who intends to use an irradiating apparatus for medical or dental purpose.

4.1.2 Application for renewal of a licence

An application made by a licence holder who wishes to renew his/her licence. The application shall be done at least one month before the expiry date of the previous licence.

4.1.3 Application for amendment of a licence

An application made by a licence holder to amend any particulars in the original licence or the apparatus already licensed. There are three categories of amendment i.e.,

- i. Change of address which will involve the transfer of the location of the apparatus ;
- ii. Purchase of new/additional apparatus ; or
- iii. Selling of apparatus already licensed

Approval from the Director General of Health Malaysia shall be obtained prior to any of the above amendments. For any other amendment, a written notification should be submitted to the Ministry of Health Malaysia.

Note: Application for amendments as described in paragraph 4.1.3 **shall not include** amendments concerning **ownership and change of licence holder**.

5 PROCEDURES TO APPLY FOR A LICENCE

5.1 APPLICATION FOR A NEW LICENCE

Step 1

- 5.1.1 An application for a new licence shall be made using the application forms (**Borang LPTA/BP/3**) which can be obtained from the following address ;

**Ketua Pengarah,
Ibu Pejabat Lembaga Perlesenan Tenaga Atom (LPTA),
Kementerian Sains Teknologi dan Alam Sekitar,
Batu 24, Jalan Dengkil,
43800 Dengkil,
Selangor Darul Ehsan.**

5.1.2 The forms shall be completed, signed and **returned to the above address** accompanied by the following ;

- i. **RM15.00** application fee ;
- ii. a copy of current Annual Practising Certificate (**APC**) ;
- iii. **layout plan of the premises** and **detailed plan of the room** in which the apparatus will be located ;
- iv. **catalogue** of the apparatus to be licensed ;
- v. copy(ies) of **relevant certificate(s)**.

Note : *LPTA shall then forward the application to the Director General of Health Malaysia for the purpose of processing.*

Step 2

5.1.3 Upon processing and when all the requirements are fulfilled, the applicant shall be required to **pay a licence fee**, the amount of which shall be in accordance with the **schedule in Appendix 1**.

5.1.4 The payment of the licence fee shall be made payable to the **Ministry of Health Malaysia** in the forms of **money order/postal order/crossed cheque**.

Note : *The licence to **buy and store** the apparatus shall then be issued to the applicant when the licence fee is paid.*

Step 3

5.1.5 The licensee shall then proceed to **purchase and install the apparatus in the approved premises**. However, he/she is **not permitted to use it**.

5.1.6 **A report of the installation including performance and safety tests of the apparatus and the associated facilities** duly completed and signed by **an accredited consultant** shall then be submitted together with the **original licence certificate**.

5.1.7 The **approval to use** the apparatus shall be given only if the report indicates that the apparatus and associated facilities fulfill all the requirements. The original licence certificate to **buy and store** will then be amended to **store and use**.

The flow-chart of the procedures to apply for a new licence is shown in Appendix 2.

5.2 APPLICATION FOR RENEWAL OF A LICENCE

Step 1

5.2.1 An application to renew a licence shall be made by submitting the completed and signed application forms (**Borang LPTA/BP/3**) directly to;

**Director of Engineering Services
Engineering Services Division,
Ministry of Health Malaysia,
4th & 6th Floor, Wisma Sime Darby,
Jalan Raja Laut, 50590 Kuala Lumpur.
(att. : Radiation Safety Unit)**

The forms shall be accompanied by the following ;

- i. **RM15.00** application fee made payable to the **Ministry of Health Malaysia** in the forms of **money order/postal order/crossed cheque** ;
- ii. a copy of current Annual Practising Certificate (**APC**) ;
- iii. **performance and calibration report** of the apparatus duly completed and signed by an **accredited consultant** ;
- iv. medical report of the radiation worker(s) (**Borang LPTA/BP/5**).

Step 2

5.2.2 Upon processing and when all the requirements are fulfilled, the applicant shall be required to **pay a licence fee**, the amount of which shall be in accordance with the **schedule in Appendix 1**.

5.2.3 The payment of the licence fee shall be made payable to the **Ministry of Health Malaysia** in the forms of **money order/postal order/crossed cheque**.

Note : *The licence shall then be **renewed when all the requirements are fulfilled and the licence fee is paid**. The flow-chart of the procedures to apply for renewal of a licence is shown in Appendix 3.*

5.3 APPLICATION FOR AMENDMENT OF A LICENCE

5.3.1 Application to transfer licensed apparatus to a new premises

Step 1

5.3.1.1 An application to transfer a licensed apparatus to a new premises shall be made by submitting an **intention letter** to;

**Director of Engineering Services
Engineering Services Division,
Ministry of Health Malaysia,
4th & 6th Floor, Wisma Sime Darby,
Jalan Raja Laut, 50590 Kuala Lumpur.
(att. : Radiation Safety Unit)**

The letter shall be accompanied by the following ;

- i. a copy of current Annual Practising Certificate (**APC**) which **specifies the address of the new premises** ;
- ii. **layout plan of the new premises** and **detailed plan of the new room** in which the apparatus will be located.

Step 2

5.3.1.2 Upon processing and when all the requirements are fulfilled, the applicant shall be required to **pay a licence fee**, the amount of which shall be in accordance with the **schedule in Appendix 1**.

5.3.1.3 The payment of the licence fee shall be made payable to the **Ministry of Health Malaysia** in the forms of **money order/postal order/crossed cheque**. The **original licence certificate** shall also be submitted for the purpose of amendment.

Note : *The apparatus shall then be **transferred and installed in the new premises after the licence is amended**. However, the licensee is **not permitted to use the apparatus**.*

Step 3

5.3.1.4 **A report of the installation including performance and safety tests of the apparatus and the associated facilities** duly completed and signed by an **accredited consultant** shall then be submitted together with the **original licence certificate**.

5.3.1.5 **The approval to use** the apparatus shall be given only if the report indicates that the apparatus and associated facilities fulfill all the requirements.

5.3.1.6 The original licence certificate shall then be amended accordingly.

The flowchart of the procedures to apply for the transfer of licensed apparatus is shown in Appendix 4.

5.3.2 Application to purchase new/additional apparatus

Step 1

5.3.2.1 An application to purchase new/additional apparatus shall be made by submitting the completed and signed application forms (**Borang LPTA/BP/3**) directly to ;

**Director of Engineering Services
Engineering Services Division,
Ministry of Health Malaysia,
4th & 6th Floor, Wisma Sime Darby,
Jalan Raja Laut, 50590 Kuala Lumpur.**

The forms shall be accompanied by the following ;

- i. **RM15.00** application fee made payable to the **Ministry of Health Malaysia** in the forms of **money order/postal order/crossed cheque** ;
- ii. a copy of current Annual Practising Certificate (**APC**) ;
- iii. **layout plan of the premises** and **detailed plan of the room** in which the apparatus will be located ;
- iv. **catalogue** of the new/additional apparatus to be purchased.

Step 2

5.3.2.2 Upon processing and when all the requirements are fulfilled, the applicant shall be required to **pay a licence fee**, the amount of which shall be in accordance with the **schedule in Appendix 1**.

5.3.2.3 The payment of the licence fee shall be made payable to the **Ministry of Health Malaysia** in the forms of **money order/postal order/crossed cheque**. The **original licence certificate** shall also be submitted for the purpose of amendment.

Note : *The licensee shall then **install the new/additional apparatus in the approved room**. However, he/she is **not permitted to use it**.*

Step 3

5.3.2.4 **A report of the installation including performance and safety tests of the apparatus and the associated facilities** duly completed and signed by **an accredited consultant** shall then be submitted together with the **original licence certificate**.

5.3.2.5 The **approval to use** the new apparatus will be given only if the report indicates that the apparatus and associated facilities fulfill all the requirements. The original licence certificate shall then be amended accordingly.

The flow-chart for the procedures to apply for the purchase of new/additional apparatus is shown in Appendix 5.

5.3.3 Application to sell licensed apparatus

Step 1

5.3.3.1 An application to sell a licensed apparatus shall be made by submitting a completed and signed application forms (**Borang LPTA/BP/3**) directly to ;

**Director of Engineering Services,
Engineering Services Division,
Ministry of Health Malaysia,
4th & 6th Floor, Wisma Sime Darby,
Jalan Raja Laut, 50590 Kuala Lumpur.
(att. : Radiation Safety Unit)**

The forms shall be accompanied by the following ;

- i. **RM15.00** application fee made payable to the **Ministry of Health Malaysia** in the forms of **money order/postal order/crossed cheque** ;
- ii. **RM200.00** fee to sell the apparatus made payable to the **Ministry of Health Malaysia** in the forms of **money order/postal order/crossed cheque** ;
- iii. **original licence certificate**.

5.3.3.2 The licence shall then be amended accordingly and the licensee is permitted to sell his/her licenced apparatus within the period of one year.

Note : *The licensee shall also ensure that the **buyer has already obtained a valid licence to buy the apparatus**. The flow-chart of the procedures to apply for the sale of licensed apparatus is shown in Appendix 6.*

6 LICENSING REQUIREMENTS AND CRITERIA - MINISTRY OF HEALTH MALAYSIA

6.1 Documents Of Reference

The licensing requirements and criteria are based on the following documents ;

- i. Law of Malaysia : Atomic Energy Licensing Act 1984 (Act 304) ;
- ii. Atomic Energy Licensing Act 1984 (Act 304) : Radiation Protection (Licensing) Regulations 1986 ;
- iii. Atomic Energy Licensing Act 1984 (Act 304) : Radiation Protection (Basic Safety Standards) Regulations 1988 ;
- iv. Malaysian Standards (MS 838) : Code Of Practice For Radiation Protection (Medical X-Ray Diagnosis)

6.2 Person Responsible For The Licence

The person shall ;

- i. be a **registered medical or dental practitioner** ;
- ii. possess a current Annual Practising Certificate (APC). The address of practice specified in his/her current APC should be the same as the address where the apparatus is to be used or stored.

6.3 Person Who Supervises The Use Of The Apparatus

The person shall ;

- i. be a **registered medical or dental practitioner** ;
- ii. possess a current Annual Practising Certificate (APC). If the person who supervises the apparatus is not the same as the person responsible for the licence, the address of practice specified in his/her APC should be the same as the address of where the apparatus is to be used or stored;
- iii. be able to supervise directly the usage of the apparatus in the premises.

6.4 Person Who Operates The Apparatus

The person shall be ;

- i. a **qualified radiographer**, full-time or part-time ; or
- ii. an **X-ray operator** currently employed in the clinics and has been **trained in the Orientation Programme conducted by the College of General**

Practitioners Society of Malaysia. He/she shall be **restricted to the procedures he/she has been trained to do** ; or

- iii. a **worker trained in the programmes approved by the licensing authority** (inclusive of training already carried out). The training syllabus and facilities would be vetted before approval is given ; or
- iv. a medical or dental practitioner.

6.5 Personnel Monitoring And Radiation Protection Programme

- 6.5.1 The licensee shall provide personnel monitoring devices for the person(s) who operate(s) the irradiating apparatus
- 6.5.2 The personnel monitoring devices shall be film badges, thermoluminescence dosimeters or other approved monitoring devices.
- 6.5.3 The personnel monitoring devices shall be obtained from ;

**Director General,
Malaysian Institute for Nuclear Technology Research (MINT),
Ministry of Science, Technology and Environment,
Bangi, 43000 Kajang.**

6.6 Irradiating Apparatus

- 6.6.1 The irradiating apparatus used shall be of the **approved type**.
- 6.6.2 In an institution in which there is only one irradiating apparatus, the apparatus has **to be/of 11 kW power (100 mA at 110 kV)**. With a high power apparatus the quality of radiographs will be upgraded and radiation hazards will be reduced.
- 6.6.3 The **performance and safety standard** of the apparatus and associated facilities shall meet the requirements as contained in **Malaysian Standard (MS 838 : 1985) : Code Of Practice For Radiation Protection (Medical X-Ray Diagnosis)**.

6.7 Description Of The Room Where The Apparatus Will Be Installed And Other Associated Facilities

- 6.7.1 The detailed layout plan submitted for evaluation shall clearly specify the following information ;
 - i. **location and dimension** of the room ;
 - ii. **material used and thickness** of the **wall, ceiling and floor** ;

- iii. **position, size and material used** for the **windows, doors** and **other openings** ;
- iv. **position of the apparatus** in the room and the **position of the operating console** ;
- v. **use of spaces/rooms adjoining to the room** including those above and below ;
- vi. **warning light/sign** at the door of the room ;
- vii. position and dimension of the **dark room**.

6.7.2 All plans shall be in **technical drawings** and the scale shall be in **metric (S.I.) unit**.

6.7.3 All dimensions shall meet minimum standard specified in **Malaysian Standard (MS 838 : 1985) : Code Of Practice For Radiation Protection (Medical X-Ray Diagnosis)**. The dimensions of the room where the apparatus will be installed and other associated facilities are summarized in **Appendix 7**.

***Note** : The applicant is advised not to initiate the construction of the room where the irradiating apparatus will be installed until the plan submitted for evaluation is approved.*

6.8 Installation And Radiation Safety Report

6.8.1 The report of the **installation including performance and safety tests of the apparatus and associated facilities** shall be completed and duly signed by an **accredited consultant**.

6.8.2 The report shall include the following informations ;

- i. Particulars of the accredited consultant
- ii. Particulars of the licence holder
- iii. Particulars of the irradiating apparatus installed/tested
- iv. Type/model
- v. Type and serial number of the components of the apparatus
- vi. Result of the tests conducted

6.8.3 The tests to be conducted are as follows ;

- i. **Performance criteria**
 - ?? Accuracy of the technique factors
 - Accuracy of kVp, mAs
 - Accuracy of exposure time

- ?? Radiation output
 - *Exposure reproducibility*
 - *Exposure linearity*
- ii. **X-ray beam limitation**
 - ?? Beam collimation
 - ?? Beam perpendicularity
- iii. **Leakage and scattered radiation**
- iv. **X-ray beam filtration**
- v. **Image quality**
 - ?? Resolution
 - ?? Contrast
- vi. **Processing conditions**
 - ?? Condition of the darkroom
 - ?? Condition of all the cassettes
 - ?? Sensitometry

6.8.4 The **performance and safety standards and criteria of the apparatus and other associated facilities** should conform with the requirements outlined in the **MS 838** document. **Appendices 8 and 9** show the summary of the performance and safety standards and criteria.

6.9 Accredited Consultant

An accredited consultant shall possess a **valid Class H licence** issued by the Director General of Health Malaysia.

LICENCE FEE FOR THE IRRADIATING APPARATUS

i) Licence fee according to categories

Category	Type of irradiating apparatus	Licence fee per year
1	Dental X-ray units, mobile and fixed medical X-ray units, mobile veterinary X-ray units, X-ray gauges, other irradiating apparatus not specified in this table	RM100.00 for the first apparatus RM20.00 for every additional apparatus
2	Industrial radiography X-ray units, X-ray analysis units, chiropractic X-ray units, X-ray therapy units not operable above 500 peak kilovolt	RM300.00 for the first apparatus RM60.00 for every additional apparatus
3	Computerised tomography units, accelerators, neutron generators, X-ray therapy units operable above 500 peak kilovolt	RM1000.00 for the first apparatus RM200.00 for every additional apparatus

ii) Licence fee for the sale or transfer of the irradiating apparatus

Licence fee in respect of the sale or transfer of irradiating apparatus shall be **RM200.00 (Ringgit Malaysia two hundred only) per year** for each licence **irrespective of the number or category** of apparatus to be sold or transferred.

iii) Payment of licence fee

Payment of the licence fee shall be made payable to the **Ministry of Health Malaysia in the form of money order/postal order/crossed cheque.**

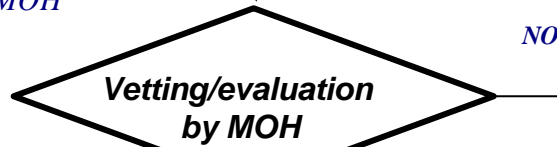
APPLICATION FOR A NEW LICENCE

STEP 1

Submission of the **completed and signed Borang LPTA/BP/3** to LPTA together with:

1. **RM 15.00** application fee
2. Copy of current **APC**
3. **Layout plan of the premises and detailed plan of the room** where the apparatus will be located
4. **Catalogue** of the apparatus
5. Copy(ies) of **relevant certificate(s)**

Note : LPTA will forward the application to MOH



Applicant

STEP 2

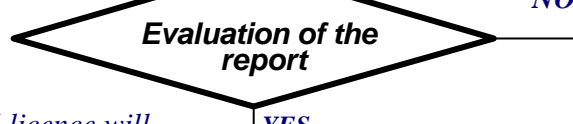
Payment of licence fee

Note : Licence to buy and store the apparatus will be issued after the payment of the fee

STEP 3

1. **Installation** of the apparatus
2. Submission of ;
 - i. **installation including performance and safety tests report**
 - ii. **original licence certificate**

Note : The original licence will be amended accordingly



Applicant

Approval to use the apparatus

APPLICATION FOR RENEWAL OF A LICENCE

STEP 1

Submission of the **completed and signed Borang LPTA/BP/3** to MOH together with ;
1. **RM15.00** application fee
2. **performance and calibration report**
3. **copy(ies) of medical report (page 16 of Borang LPTA/BM/5)**

Applicant

Vetting/evaluation

NO

YES

STEP 2

Payment of licence fee

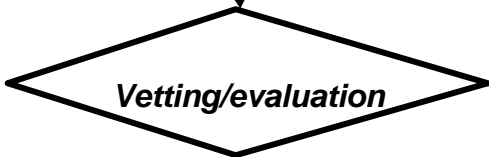
Renewal of the licence

APPLICATION TO TRANSFER A LICENSED APPARATUS TO A NEW PREMISES

STEP 1

Submission of **intention letter to MOH** together with ;
 1. copy of current **APC**
 2. **layout plan of the premises and detailed plan of the room** where the apparatus will be located

Applicant



STEP 2

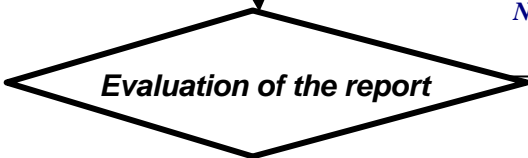
1. Payment of **licence fee**
 2. Submission of **original licence certificate**

Note : The original licence will be amended and the apparatus can be transferred and installed in the new approved premises

STEP 3

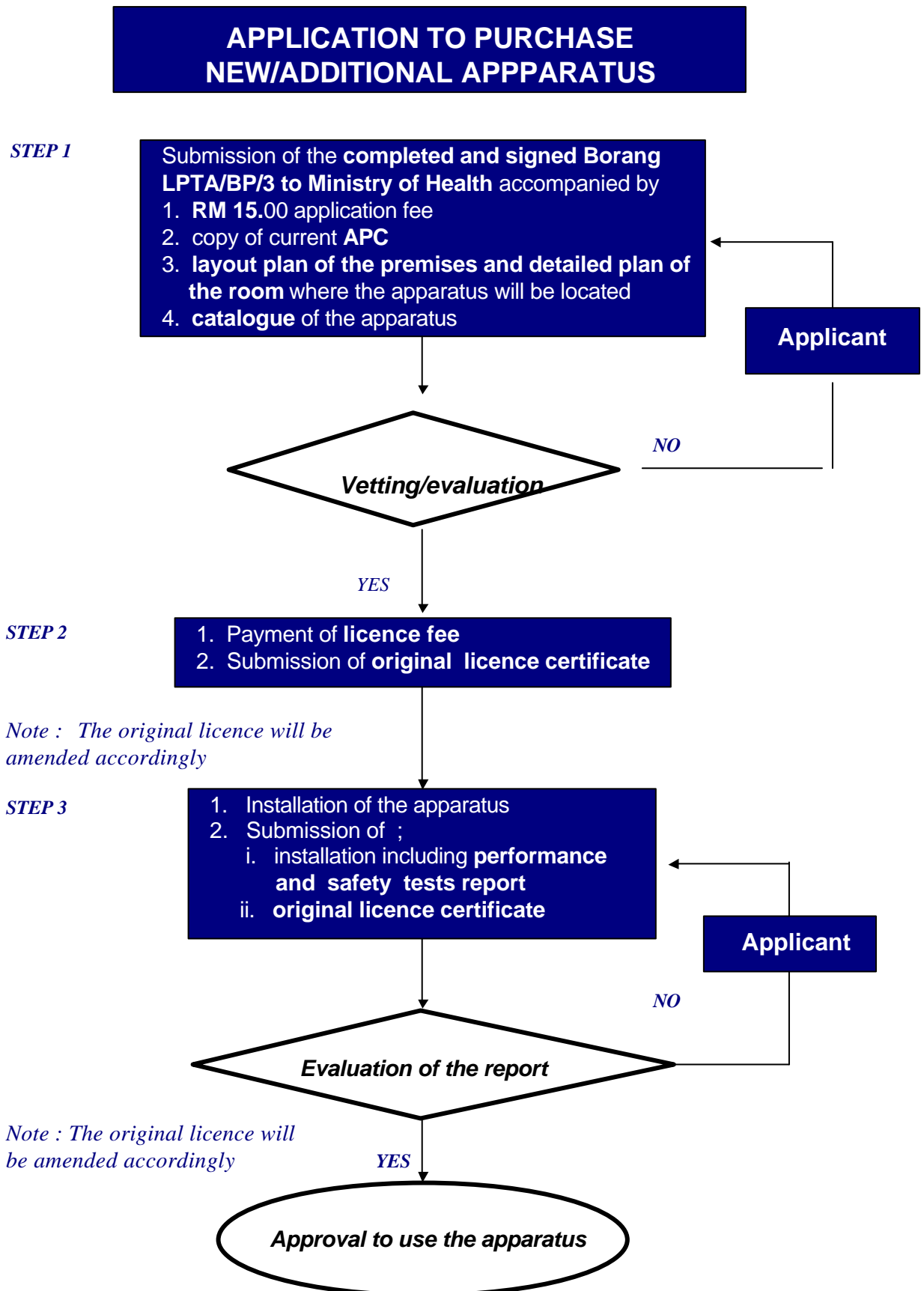
Submission of ;
 1. **installation including performance and safety tests report**
 2. **original licence certificate**

Applicant



Note : The original licence will be amended accordingly

Approval to use the apparatus



APPLICATION TO SELL A LICENSED APPARATUS

STEP 1

Submission of the **completed and signed Borang LPTA/BP/3 to MOH** together with ;

1. **RM15.00** application fee
2. **RM200.00** fee to sell the apparatus
3. **original licence certificate**

Applicant

Vetting/evaluation

NO

YES

Note : The licence will be amended accordingly

Approval to sell the apparatus

DIMENSION OF THE ROOM WHERE THE APPARATUS WILL BE LOCATED AND OTHER ASSOCIATED FACILITIES						
Type of irradiating apparatus	Dimension of the room (internal)	Dimension of the darkroom (internal)	Thickness of shielding at the door and wall	Dimension and thickness of lead at the wall (behind chest stand)	Dimension of lead glass window (thickness 2.0mm Pb equivalent)	Dimension and thickness of lead at the floor (if the premises is at the upper floor)
General X-ray (control panel inside - without table)	2.5m x 4.0m	1.5m x 2.0m	2.0mm *Pb eq (*lead equivalent)	1.2m x 1.2m x 2.0mm Pb eq.	> 100kVp; 35cm x 30cm < 100kVp; 25cm x 20cm	1.2m x 2.5m x 2.0mm
General X-ray (control panel inside - with table)	3.0m x 5.0m	1.5m x 2.0m	2.0mm Pb eq	1.2m x 1.2m x 2.0mm Pb eq.	> 100kVp; 35cm x 30cm < 100kVp; 25cm x 20cm	1.2m x 2.5m x 2.0mm
General X-ray (control panel outside - without table)	2.5m x 3.5m	1.5m x 2.0m	2.0mm Pb eq	1.2m x 1.2m x 2.0mm Pb eq.	> 100kVp; 35cm x 30cm < 100kVp; 25cm x 20cm	1.2m x 2.5m x 2.0mm
General X-ray (control panel outside - with table)	2.5m x 4.0m	1.5m x 2.0m	2.0mm Pb eq	1.2m x 1.2m x 2.0mm Pb eq.	> 100kVp; 35cm x 30cm < 100kVp; 25cm x 20cm	1.2m x 2.5m x 2.0mm
Dental X-ray	2.0m x 3.0m	not applicable	1.0mm Pb eq	not applicable	not applicable	not applicable
X-ray OPG	2.5m x 3.5m	not applicable	1.5mmPb eq.	not applicable	not applicable	not applicable
Flourosocopy	6.0m x 4.0m	1.5m x 2.0m	2.0mm Pb eq	not applicable	100cm x 50cm	1.2m x 2.5m x 2.0mm
Mammography	2.5m x 3.5m	1.5m x 2.0m	1.0mm Pb eq	not applicable	35cm x 30)cm	not applicable
Angiography	6.5m x 4.5m	1.5m x 2.0m	2.0mm Pb eq	not applicable	100cm x 50cm	1.2m x 2.5m x 2.0mm
C.T. Scanner	5.5m x 4.0m	1.5m x 2.0m	2.0mm Pb eq	not applicable	100cm x 50cm	1.2m x 2.5m x 2.0mm

USEFUL BEAM FILTRATION REQUIREMENT	
Normal operational kVp of the apparatus	Minimum total filtration in the useful beam
Below 70kVp	1.5 mm aluminium equivalent
70kVp to 100kVp	2.0 mm aluminium equivalent
Above 100kVp	2.5 mm aluminium equivalent

HALF VALUE LAYER (HVL)		
Tube voltage	Measured operating potential	Minimum HVL (mm Al)
Designed operating range		
Below 50kVp	30	0.3
	40	0.4
	49	0.5
50kVp to 70kVp	50	1.2
	60	1.3
	70	1.5
Above 70kVp	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1