

MINISTRY OF HEALTH MALAYSIA

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



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MINISTRY OF HEALTH MALAYSIA
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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 LICENCE APPLICATIONS

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, dental or veterinary 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,
Lembaga Perlesenan Tenaga Atom (LPTA),
Kementerian Sains Teknologi dan Alam Sekitar,
Tingkat 2 & 13, Plaza Pekeliling,
No.2, Jalan Tun Razak, 50400 Kuala Lumpur.**

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

- i. **RM15.00 application fee ;**
(The payment of the processing fee shall be made payable to the **Ketua Pengarah, LPTA** in the form 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 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 form of **money order/postal order/ crossed cheque**.

Note : The **pre-approval letter** to **buy and store** the apparatus shall then be issued to the applicant when the licence fee is paid. This is to help the applicant to install the apparatus faster before the actual licence is issued.

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 The following shall then be submitted together with the original licence certificate :

- i. **Certificate and summary of performance and safety tests** of the apparatus and the associated facilities certified by an accredited consultant. Performance and safety testing shall be in accordance with the regulatory requirements and relevant code of practice as spelt out in **Appendix 2**.

Note : Calibration reports for dental and veterinary xray machines do not need to be certified by an accredited consultant. Reports from suppliers are accepted

- ii. Medical report of the operator(s) using **Borang LPTA/BM/5**.
- iii. Proof of personnel dose monitoring such as film badge, thermoluminescence dosimeters or other approved monitoring devices has been provided to the operator(s)

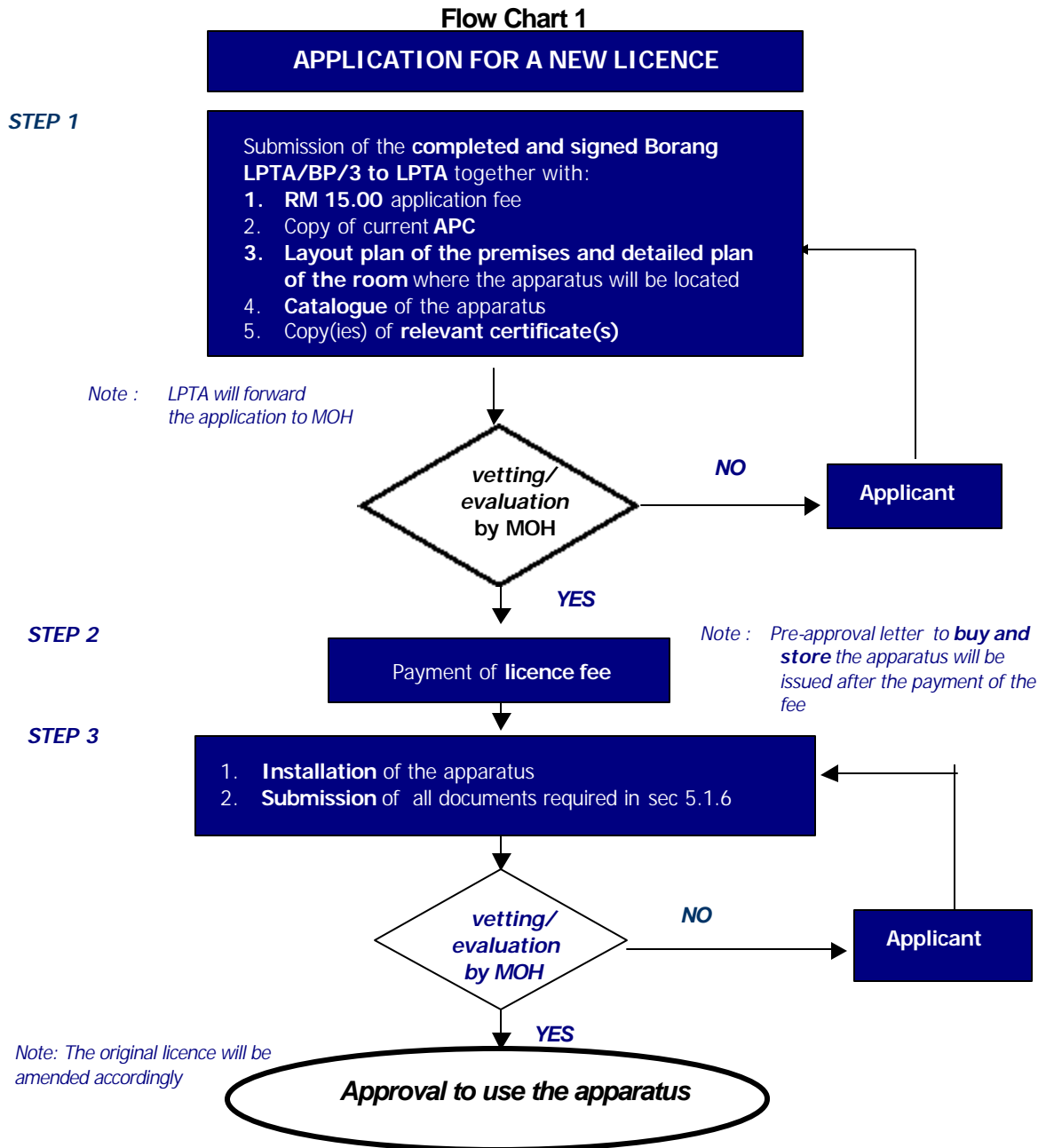
iv. *Continuous Medical Education*

For GP's Clinic, a copy of certificate of attendance of related courses approved by appropriate authority (both for licensee and newly employed operators).

The course contents are specified in **Appendix 4**

5.1.7 The **approval to use** the apparatus shall be given only if all the conditions in **5.1.6** are fulfilled. 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 **Flow Chart 1**.



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.**

The forms shall be accompanied by the following ;

- i. **RM15.00 application fee and licence fee** (The amount is subjected to the number and type of apparatus) made payable to the **Ministry of Health Malaysia** in the form of **money order/postal order/ crossed cheque**,
The amount of licence fee shall be in accordance with the **schedule in Appendix 1**.
- ii. **A copy of the current Annual Practising Certificate (APC)**
- iii. **Certificate and summary of performance and safety tests** of the apparatus and the associated facilities certified by an accredited consultant.
Note : Calibration reports for dental and veterinary x-ray machines do not need to be certified by an accredited consultant. Reports from suppliers are acceptable.
- iv. **Medical report of the radiation worker(s) using Borang LPTA/BM/5.**
- v. **A report on monitoring and analysis of film reject rate- for both GP's clinic and radiological clinic/hospital**
- vi. **A report on audit of x-ray radiograph (refer note(b)) - only for GP's clinic. Quality audit performed by FEMOMA is acceptable**
- vii. **A copy of continuous medical education (CME) certificate for all doctors and operators (refer note(c)) - for both GP's clinic and radiological clinic/hospital**
- viii. **Proof of personnel dose monitoring such as film badge, thermoluminescence dosimeters or other approved monitoring devices which has been provided to the operator(s)**

Note :

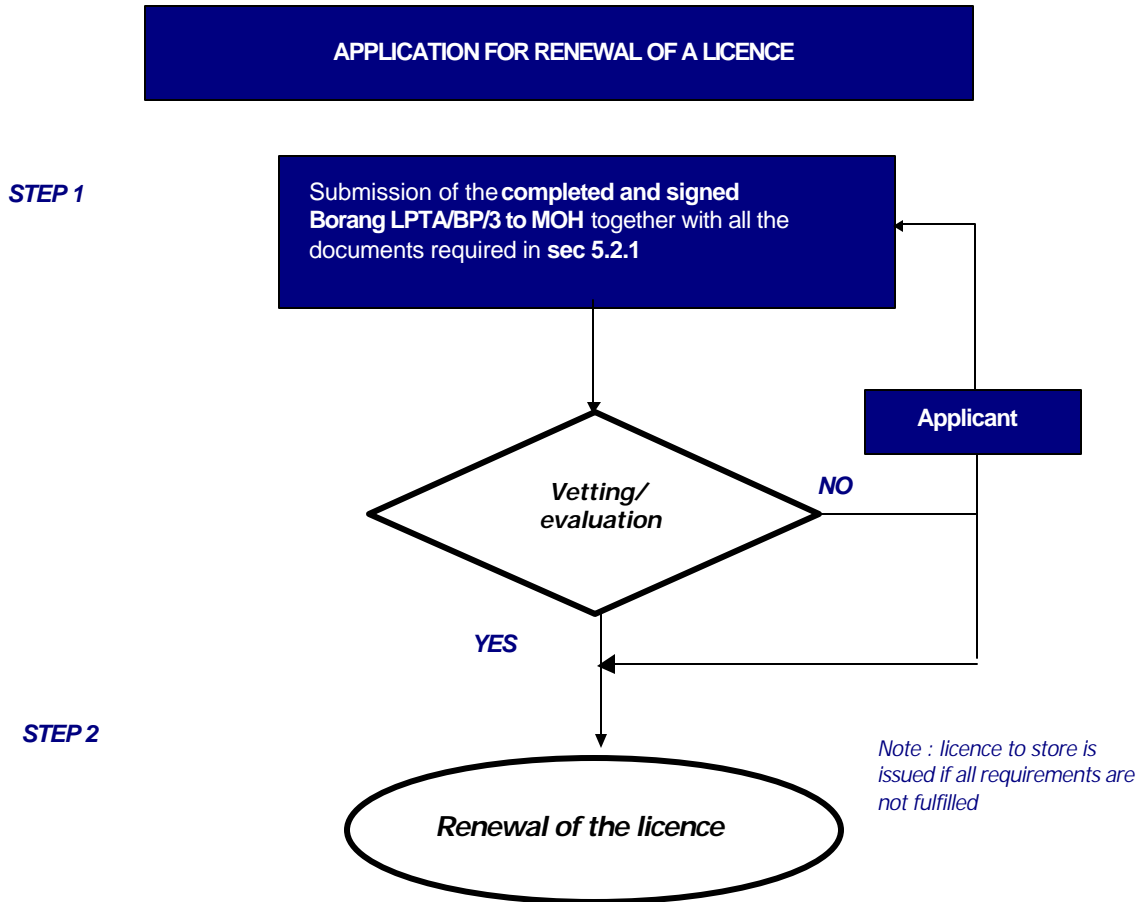
- a. Borang LPTA/BP/3 must be submitted with **at least** items **(i) & (ii)** before application can be processed otherwise; the application will be rejected.
- b. Criteria and standard for the purpose of **Audit of X-ray Radiographs** is listed in **Appendix 3**.
- c. Licenced doctors and trained operators are required to undergo continuous medical education to update their knowledge on yearly basis. The training syllabus are as in **Appendix 4**.
- d. Requirements **(v), (vi) & (vii)** are not applicable for dental clinics

Step 2

- 5.2.2 Upon processing and when the requirements are partly fulfilled, licence will be issued **to store** only. The licensee is not permitted to use the apparatus until all the requirements are fulfilled.

The flowchart of the procedures to apply for renewal of a licence is as shown in **Flow Chart 2**.

Flow Chart 2



5.3 APPLICATION FOR AMENDMENT OF A LICENCE

There are 3 categories of amendment of a licence :

- a) Change of address which involve the transfer of the location of the apparatus;
- b) Purchase of new/additional apparatus ; and
- c) Selling of apparatus already licensed

Documents required for application of amendment are listed below :

Type of Amendment	Documents Required
Change of address	<ol style="list-style-type: none"> 1. <i>Intention letter</i> 2. <i>a copy of current Annual Practising Certificate (APC) which specifies the address of the new premises;</i> 3. <i>Layout plan of the new premises and detailed plan of the new room in which the apparatus will be located.</i> 4. <i>RM 200.00 of transfer fee</i> 5. <i>Original licence certificate and Lampiran A.</i>
Purchase of new/ additional apparatus	<ol style="list-style-type: none"> 1. <i>Borang LPTA/BP/3</i> 2. <i>RM15.00 application fee</i> 3. <i>Catalogue of the new/additional apparatus to be purchased.</i> 4. <i>layout plan of the new premises and detailed plan of the new room in which the apparatus will be located.</i> 5. <i>Additional licence fee - depends on the number and category of apparatus to be purchased (see Appendix 1)</i> 6. <i>Original licence certificate and Lampiran A.</i>
Selling of apparatus	<ol style="list-style-type: none"> 1. <i>Borang LPTA/BP/3</i> 2. <i>RM15.00 application fee</i> 3. <i>RM200.00 fee to sell the apparatus</i> 4. <i>Original licence certificate and Lampiran A.</i>

Note : All the payments should be made payable to the **Ministry of Health Malaysia** in the form of *money order/postal order/crossed cheque*

Step 1

5.3.1 An application to amend a licence shall be made by submitting **all the above documents** (or come personally) to;

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

Step 2

- 5.3.2 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**.

Or

If the licensee/designated person comes personally to the office, the application will be evaluated and vetted by the duty officer immediately. If all the requirements are fulfilled, the applicant will be asked for the additional licence fee which is payable by money order/postal order/crossed cheque.

Note :

- i. An application for change of address :

*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**.*

- ii. An application for the purchase of new/ additional apparatus

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

- iii. An application for selling an apparatus

*The licensee shall also ensure that the **buyer has already obtained a valid licence to buy the apparatus**. The original licence certificate shall then be amended accordingly (Step 3 does no need to follow).*

The licensee is permitted to sell his/her licenced apparatus within the period of one year.

Step 3

- 5.3.3 **A certificate and summary of 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**.

Note : Calibration reports for dental and veterinary x-ray machines do not need to be certified by an accredited consultant. Reports from suppliers are acceptable.

- 5.3.4 The original licence certificate shall then be amended accordingly.

*The flow-chart of the procedures to apply for the amendment of licensed apparatus is as shown in **Flow Chart 3**.*

Flow Chart 3

