

RADIATION ORDINANCE

(Chapter 303)

APPLICATION FOR IRRADIATING APPARATUS LICENCE

I ABC Company Limited
(Name of full)

of Information
(Address in full)

hereby make application for a licence (a) to sell

irradiating apparatus as described hereunder, at (b) Information

2. Description of type or types of irradiating apparatus for which licence is required :

dental X-ray machine

3. My qualifications are as follows (c) (fill in information as application)

Date this 12 day of May 20 12

Signature of Applicant.

- (a) State purpose for which licence is required, *i.e.* to possess, sell, manufacture, operate, etc.
- (b) State address at which such irradiating apparatus will be situated.
- (c) This paragraph need only be completed in the case of an application to operate irradiating apparatus.

First Application/Renewal for a Licence to Deal in or with Irradiating Apparatus

請參閱夾附的「申請須知」後，填寫本表格適用部分。

Please refer to the attached "Notes for Applicants" and complete the appropriate sections.

請在適當地方加上 Please tick as appropriate

A. 申請人資料 Particulars of the applicant

A2

公司名稱	Name of company	<u>ABC Company Limited</u>	<u>ABC 公司</u>
商業登記編號	Business Registration No.	<u>30098765-000-01-02-8</u>	
稱謂 Title	<input type="checkbox"/> 醫生 Dr <input type="checkbox"/> 博士 Dr <input type="checkbox"/> 先生 Mr <input type="checkbox"/> 女士 Mrs <input type="checkbox"/> 女士 Ms <input type="checkbox"/> 小姐 Miss		
與此申請有關的獲授權人士姓名	Name of authorized person in relation to this application	<u>安 On</u>	<u>定榮 Ting Wing</u>
		姓 (Surname)	名 (Given name)
身分證/證明文件編號.	Identity Card/Document No.	<u>G123456(7)</u>	電郵 <u>123@ghi.com.hk</u>
			E-Mail

通訊地址 Correspondence address : Information 填寫資料

稱謂 Title 醫生 Dr 博士 Dr 先生 Mr 女士 Mrs 女士 Ms 小姐 Miss

聯絡人姓名 Name of Contact Person : 李 Lee 好 Ho
 姓 (Surname) 名 (Given name)

電郵 E-Mail: Information 填寫資料 電話號碼 Tel No.: Information 填寫資料

傳真號碼 Fax No. : Information 填寫資料 手提號碼 Tel No.: Information 填寫資料

B. 目的 Purpose

B1. 續牌 Renewal of licence

輻照儀器牌照編號 Irradiating Apparatus Licence No. _____

牌照批核的儀器名單不變
 The list of approved irradiating apparatus remains unchanged
 (請到 D 部繼續填寫 Please continue from Section D)

申請加入 C 部所列輻照儀器於核准名單中
 Apply to include the irradiating apparatus in Section C to the approved list
 (請到 C 部繼續填寫，並夾附列於申請須知第 3(iv)項的有關文件)
 (Please continue from Section C, and attach the documents as listed in item 3 (iv) of Notes for Applicants)

申請從核准輻照儀器名單中刪除 C 部所列儀器
 Apply to delete the irradiating apparatus in Section C from the approved list
 (請到 C 部繼續填寫 Please continue from Section C)

只供輻射管理局填寫 FOR OFFICIAL USE ONLY 收件日期 Date received _____

申請資料不足，欠缺 Application incomplete due to lacking of _____

B2. 申請輻照儀器牌照以進行以下商業事務：

Apply for an Irradiating Apparatus Licence to carry out the following business activity:

製造 / 生產 Manufacture/Produce 在香港以外地方銷售 Sale outside Hong Kong

在香港銷售 Sale in Hong Kong 貯存 X 射線球管 Storage of X-ray Tube

C. 輻照儀器資料 (如下列空間不足填寫, 請夾附資料)

Details of the irradiating apparatus (please attach separate sheets if the space below is insufficient)

輻照儀器種類* Type of irradiating apparatus*	製造商 Manufacturer	型號 Model No.
<i>Radiography and Fluoroscopy System</i>	<i>XXX Medical Systems Co. Ltd.</i>	<i>RF 1011</i>
<i>Computed tomography (CT)</i>	<i>YYY Imaging Systems Co. Ltd.</i>	<i>CT-ABC 900</i>

*請參考<申請須知>第 4 項 Please refer to Item 4 of 'Notes for Applicants'

D. 貯存輻照儀器的樓宇(如適用) Premises for storage of irradiating apparatus (If applicable)

地址保持不變。 There is no change of address.

地址將更改如下: The address will change to :

E. 聲明 Declaration

現聲明盡本人所知, 本申請所載資料均真確無誤。

I declare that to the best of my knowledge the information in this application is true and accurate.

申請人/獲授權人簽名
Signature of Applicant/Authorized Person

授權 Authorization
公司印鑑(如適用) Company chop (if applicable)

姓名(請用正楷書寫) Name (in block letters)

日期 Date

輻射條例 (第 303 章)
RADIATION ORDINANCE (CAP 303)

新申領 / 續領 經營或處理輻照儀器牌照
First Application/Renewal for a Licence to Deal in or with Irradiating Apparatus

申請須知
Notes for Applicants

1. **申請 Application**

申請人可以使用 IA-S 表格申請牌照或續牌，以便獲准經營或處理輻照儀器。
You may use form IA-S to apply for or renew a licence that permits you to deal in or with irradiating apparatus.

在本港出售的輻照儀器，必須符合香港法例(第 303 章)輻射條例訂立的輻射安全規定。
Irradiating apparatus to be sold in Hong Kong shall comply with the requirements on radiation safety provided under the Radiation Ordinance(Cap 303) Laws of Hong Kong.

2. **遞交申請書 Submission of application :**

填妥的申請表格須送回：
This application should be submitted to:

香港西灣河太康街 28 號西灣河健康中心 3 字樓
輻射管理局牌照事務處

Radiation Board Licensing Office
3/F., Sai Wan Ho Health Centre
28 Tai Hong Street, Sai Wan Ho, Hong Kong

電話：2886 1551
傳真：2834 1224
電郵：ia@erls.gov.hk
網域：<http://www.erls.gov.hk>
Tel.: 2886 1551
Fax: 2834 1224
E-mail: ia@erls.gov.hk
Domain: <http://www.erls.gov.hk>

申請費用為 \$570。當輻射管理局收到有關申請後，會向申請人發出一般繳款單，申請人請依照一般繳款單內所列的繳款辦法繳付所需費用。
假如申請最終被否決，已繳交的款項將盡快全數退還。

The application fee is \$570. After receiving the application, the Radiation Board will issue a General Demand Note to the applicant. The applicant could make payment according to the payment instructions stated in the General Demand Note.

Should the application be unsuccessful, the paid amount will be refunded to the applicant as soon as possible.

3. **按情況需要連同申請書一併遞交的文件 Documents to be submitted with the application (where applicable)**

- (i) 首次申請輻照儀器牌照，申請人須加填表格 DH1271(S) 《輻照儀器申請表》。
For first application, applicant should also complete Form DH1271(S) "Application for Irradiating Apparatus Licence"
- (ii) A 部 - 商業登記證和獲授權人士身分證/證明文件的副本。
Section A - Copy of the Business Registration Certificate and Copy of Identity Card/Document of the authorized person.
- (iii) B 部 (續牌) - 出售輻照儀器的記錄，須詳列各購買者的姓名及持有之輻照儀器牌照編號、地址、所購買儀器及售賣日期。
Section B - Sales return including the names, address and irradiating apparatus licence number of the purchasers, the irradiating apparatus sold and the dates of sales.
- (iv) C 部 - 輻照儀器的技術規格，尤其是與輻射防護有關的規格，以及顯示遵照國際標準的測試報告。(適用於售賣在香港使用的輻照儀器。)
Section C - Technical specification of the irradiating apparatus, in particular those relating to radiological protection, and test reports showing conformance with international standards. (Applicable to irradiating apparatuses that are to be sold to users in Hong Kong).

4. 輻照儀器種類 Types of irradiating apparatus

醫療 Medical		獸醫科 Veterinary
血管造影和心臟 X 射線系統 Angiography & Cardiology X-Ray System	外周電腦斷層照相 Peripheral Computed Tomography	獸醫用電腦斷層照相 Veterinary CT
骨質密度儀 Bone Densitometer	放射照相及螢光透視系統 Radiography and Fluoroscopy System	獸醫用一般 X 射線照相機 Veterinary General X-Ray Unit
電腦斷層照相 Computed tomography (CT)	正電子連電腦斷層照相 PET-CT	獸醫用口內放射照相 Veterinary Intraoral Radiography Unit
生產放射性藥物用回旋加速器 Cyclotron for Radiopharmaceuticals	機械人放射外科治療系統 Robotic Radiosurgery System	獸醫用放射照相/螢光透視 X 射線照相機) Veterinary Radiographic/Fluoroscopic X-Ray Unit
伽瑪連電腦斷層照相機 Gamma Camera with CT Attachment	標本用放射照相系統 Specimen Radiography System	
一般診斷用 X 射線照相機 General Diagnostic X-Ray Unit	表皮 X 射線治療系統 Superficial X-Ray Therapy System	
綜合放射治療影像系統 Integrated Radiotherapy Imaging System	放射治療模擬器 Therapeutic simulator	
直線加速器 Linear accelerator	泌尿科 X 射線照相系統 Urology X-Ray System	
乳房 X 射線照相機 Mammography X-Ray unit	X 射線分析儀器 X-Ray Analyzer	
無創性立體定位放射治療裝置 Non-invasive Stereotactic Radiotherapy Device		

牙科 Dental	工業 Industrial	教學及研究 Educational/ Research
三維錐形 X 射線束牙科照相系統 3D Cone Beam Dental X-Ray System	氣溶膠中和器 Aerosol Neutralizer	教研用電腦斷層照相 CT for R&D
錐形線束電腦斷層照相 Cone Beam CT	工業放射照相機 Industrial Radiographic Unit	一般教研用 X 射線儀器 General X-ray Unit for Teaching, R&D
牙科電腦斷層照相 Dental CT	X 射線螢光鍍層厚度測量儀 Fluorescent X-ray Coating Thickness Gauge	微型電腦斷層照相 Micro-CT
口內放射照相機 Intraoral radiography Unit	液位計 Level Gauge	粒子加速器 Particle Accelerator
全牙顎斷層照相系統 Orthopantomography System	X 射線衍射儀 X-ray Diffractometer	X 射線衍射儀 X-ray Diffractometer
全景 X 射線牙科照相系統 Panoramic Dental X-Ray System	X 射線螢光光譜儀 X-Ray Florescence Spectrometer	X 射線螢光光譜儀 X-Ray Florescence Spectrometer
全景連頭顱定位側位片牙科照相機 Panoramic with Cephalometric Dental Unit	X 射線影像輔助生產系統 X-ray image assisted production System	X 射線光電子光譜儀 X-ray photoelectron spectrometer
全景電腦斷層照相系統 Panoramic with Tomography System	X 射線檢查系統 X-ray Inspection System	
全景電腦斷層連頭顱定位側位片照相系統 Panoramic, Cephalometric & Tomographic Unit	X 射線螢光分析儀器 XRF Analyzer	

保安 Security	輻照儀器配件 IA Parts
行李/包裹檢查系統 Baggage / Luggage / Parcel Inspection System	X 射線球管 X-ray tube
貨櫃/車輛 X 射線檢查系統 Cargo / Vehicle X-ray Inspection System	加速器波導管 Accelerator Waveguide

注意 Remarks :

表格中所列的所有有關牌照必須於呈交本申請書時仍為有效。有關牌照持有人請於牌照屆滿前八個星期把填妥之申請書及所需文件交到輻射管理局。否則，本局有可能在牌照屆滿前未能完成處理有關牌照的續牌申請。逾期管有、出售或以其他方式經營或處理輻照儀器乃違反輻射條例第 7(1) 條的罪行，一經定罪，可判處罰款 \$50,000 及監禁 2 年。

Any current licence mentioned in this application must remain valid on the date of submission of this application. The Licensee shall submit the duly completed application form together with the required documents to the Radiation Board 8 weeks before expiry of the licence. Otherwise, the Board may not be able to complete processing of the licence renewal application before its expiry. Possessing, selling or otherwise dealing in or with an irradiating apparatus without a valid licence is an offence to section 7(1) of the Radiation Ordinance, and shall be liable to a fine of \$50,000 and to imprisonment for 2 years.

**Radiation Board Initial Assessment Form for approving Irradiating
Apparatus to be possessed / sold / used in Hong Kong**

Radiation Board Reference:

To Radiation Board (Fax : 2834 1224 / Email: enquiry@erls.gov.hk)

Name of Licence Applicant: _____ *ABC Company*

Authorized Person: _____ *ON, Ting Wing*

(If different from Licence Applicant)

Contact Person: _____ *CHAN, Tai Man*

(If different from Authorized Person)

Contact Telephone: _____ *Information*

Mobile Phone: _____ *Information*

(If different from Contact Telephone)

Fax: _____ *Information*

Email Address: _____ *Information*

Mailing Address: _____ *Information*

Model(s) of Irradiating Apparatus to be covered in the licence:

(Please complete one questionnaire for each of the model(s) to be covered in the licence)

_____ *1) RadDiag*

_____ *2) CT-ABC 900*

Name : _____ *ON, Ting Wing*

Signature: _____

Company Chop:

Date: _____ *1 / 7 / 2012*

Radiation Board Initial Assessment Form for approving Irradiating Apparatus to be possessed / sold / used in Hong Kong

Radiation Board Reference:

To Radiation Board (Fax : 2834 1224 / Email: enquiry@erls.gov.hk)

(Please complete a separate questionnaire for each model to be assessed)

Make of apparatus: XXX Medical Systems

Model of apparatus: RF 1011

1. Is the apparatus designed to produce ionizing radiation Yes No
(If no, go to item 7)
2. What is the maximum voltage of the irradiating apparatus? 80 kV MV
(Please supply documentary proof and specify where the data can be found)
Technical specification document (p.20)
3. Is the apparatus intended to be used on human / animal? Yes No
(If yes, go to item 6)
4. What is the maximum doserate (with unit) at a distance of 5 cm from any accessible point of the surface of the apparatus? _____
(Please supply documentary proof and specify where the data can be found)

5. Is there any safety device associated with the safe operation of the apparatus?
 Yes No
(Please supply documentary proof and specify where the data can be found)

(Go to item 7)
6. What are the total filtration and tube head leakage of the irradiating apparatus?
Filtration: 2.5 mm Al (eq.) Be
Tube Head Leakage: 0.2 (mGy in one hour)
(Please supply documentary proof and specify where the data can be found)
Section 3.5 of Test Report No. 888888
7. Does the apparatus contain radioactive substance(s)? Yes No
(If yes, please supply documentary proof and specify where the data can be found)

8. This concludes our questionnaire for initial assessment of your application.
Thank you.