

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 possess

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.

Sample Form (表格樣本) IA-P1

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

申領以管有一具輻照儀器

Application for a Licence to Possess an Irradiating Apparatus

- (a) 以作安裝及調試, 準備安全運作牌照審批, 或
for its installation and testing, to prepare for application for a licence to
possess and use the irradiating apparatus in a functional state, or
(b) 於不運作狀態, 只作貯存
in a non-functional state, only for storage

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 *(Fill in either Part A1 or Part A2)*

以個人名義申請牌照, 請填寫 A1 段; 以公司名義申請牌照, 請填寫 A2 段。

Licence in the name of a person, please complete Section A1; Licence in the name of a company, please complete Section A2.

A1

稱謂 Title ☐ 醫生 Dr ☐ 博士 Dr ☒ 先生 Mr ☐ 女士 Mrs ☐ 女士 Ms ☐ 小姐 Miss
姓名
Name 陳 Chan 大文 Tai Man
姓 (Surname) 名 (Given name)
身分證 / 證明文件編號 . 電郵
Identity Card/Document No. A123456(7) E-Mail 123@abc.com.hk

或 or

A2

公司名稱 Name of company ABC Company Limited ABC 公司
商業登記編號 Business Registration No. 30098765-000-01-02-8
稱謂 Title ☐ 醫生 Dr ☐ 博士 Dr ☒ 先生 Mr ☐ 女士 Mrs ☐ 女士 Ms ☐ 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 安 On 定榮 Ting Wing
姓 (Surname) 名 (Given name)
身分證 / 證明文件編號 . 電郵
Identity Card/Document No. G123456(7) E-Mail 123@ghi.com.hk

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 手機號碼 Mobile No. : Information 填寫資料

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 _____

B. 輻照儀器來源 Origin of the irradiating apparatus **(Fill in either in Part B)**

☒ 該輻照儀器是 The irradiating apparatus is

☒ 購自(賣方) purchased from (seller)

姓名 Name **Information 填寫資料**

地址 Address **Information 填寫資料**

輻照儀器牌照編號

Irradiating Apparatus Licence No. **00000-0000-XX-0000**

電話號碼

Tel No. **2xxx xxx**

☒ 直接進口 Direct Import

i) 須申請進口證，請參閱申請須知第六項

Import licence is required, please refer to item 6 of Notes for applicants

ii) 請附上填妥的輻照儀器初步評估表格及所需的技術說明文件

Please attach the duly completed Initial Assessment Form(s) of the irradiating apparatus with the required technical specifications

或 or

☒ 本人正持有牌照管有該輻照儀器。

I am holding a licence to possess the concerned irradiating apparatus.

牌照編號為

Licence No. is **00000-0000-XX-0000**

(請到 D 項繼續填寫 Please continue from Section D)

有效期至

Valid until **7** / **1** / **2012**

日 D 月 M 年 Y

C. 輻照儀器資料 (如屬新購置輻照儀器而該儀器尚待赴運，有關資料可隨後補上)

Details of the irradiating apparatus (you may provide the required information separately if it is a new irradiating apparatus pending delivery to you)

輻照儀器種類* Type of irradiating apparatus*	製造商 Manufacturer	型號 Model No.	控制台/機身編號 Control Panel/ Machine Serial No.	X 射線球管編號 X-ray Tube Head Serial No.
Intraoral radiography Unit (refer to 'Notes for applicants', part 5, for types of irradiating apparatus) (參閱<申請須知>第五項)	XYZ Ltd.	LS012	A23561	203156

*請參考申請須知第 5 項 Please refer to Item 5 of 'Notes for Applicants'

D. 輻照儀器所在的樓宇單位 Premises where the irradiating apparatus is located

該輻照儀器將 This irradiating apparatus will be

☒ 安裝於 installed at ☐ 不作安裝而只作貯存於 stored, without installation, at

地址 Address **Information 填寫資料**

該樓宇單位是 ☐ 屬於申請人持有 owned by the applicant

This premises is

☒ 租自 rented from **XYZ company XYZ 公司**

業主姓名 Name of owner

業主地址 Address of owner **Information 填寫資料**

電話號碼 Tel No. **Information 填寫資料**

(Fill in this part if applicable)

E. 將取代的輻照儀器 Irradiating Apparatus to be replaced at the premises

(如申請中的輻照儀器並非取代任何其他輻照儀器，請到 F 項繼續填寫)

(Please continue from Section F if there is no irradiating apparatus to be replaced at premises)

1. 原有輻照儀器列載於輻照儀器牌照編號
The existing irradiating apparatus is covered
by Irradiating Apparatus Licence No.

Information 填寫資料

有效期至 Valid until 23 / 4 / 2012
日 D 月 M 年 Y

2. 該原有輻照儀器將會被
The existing irradiating apparatus will be

☒ 原址貯存 Stored at the same premises

(請為該輻照儀器填寫另一份申請表格)

(Please complete a separate application for that irradiating apparatus)

☐ 遷到本人的另一個樓宇單位 Moved to my other premises

(請為該輻照儀器填寫另一份申請表格)

(Please complete a separate application for that irradiating apparatus)

☐ 轉讓並遷離 Transferred by sale and moved away

(請夾附輻照儀器轉讓表格 IA-TRAN，承讓人須領取有效牌照，始可接收該儀器)

(Please attach transfer form IA-TRAN. The transferee must be holding a valid licence to take up the transfer)

☐ 放棄，請安排核證本人已將該輻照儀器轉為無害
Abandoned. Please arrange to certify that I have rendered it harmless

(請填寫並提交<放棄輻照儀器>表格 IA-Abandonment)

(Please submit a completed form of 'IA-Abandonment')

☐ 放棄並交由以下供應商處置
Abandoned and transferred to the following supplier for disposal

F. 聲明 Declaration

☒ 本人擬申請管有該輻照儀器，以作安裝及調試，準備安全運作牌照審批。

I intend to possess the irradiating apparatus for installation and testing purposes, to prepare for application for a licence to possess the irradiating apparatus in a functional state.

☐ 本人擬申請管有此具處於不運作狀態的輻照儀器，只作貯存。

I intend to possess the irradiating apparatus in a non-functional state, only for storage.

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)

Information 填寫資料

姓名(請用正楷書寫) Name (in block letters)

Information 填寫資料

日期 Date

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

申領以管有一具輻照儀器
Application for a Licence to Possess an Irradiating Apparatus

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for its installation and testing, to prepare for application for a licence to
possess and use the irradiating apparatus in a functional state, or
- (b) 於不運作狀態，只作貯存
in a non-functional state, only for storage

申請須知
Notes for Applicants

1. 申請 Application

- (i) 請注意，你須為每一具你管有的輻照儀器申領一個牌照。
Please note that for possession of an irradiating apparatus, you need one possession licence for each apparatus.
- (ii) 請你為擬管有而尚未領有牌照的每具輻照儀器申領牌照，每份申請只供一具儀器之用。
Please submit a separate application for each irradiating apparatus which you intend to possess but is not covered by a licence.
- (iii) 請注意，在輻射管理局發出使用輻照儀器牌照之前，申請人不得使用，或容許任何其他人士使用輻照儀器。如果申請人所申請的牌照只供貯存儀器，或有關裝置的輻射安全措施並不足夠，輻射管理局督察可能會將輻照儀器密封。
You are not permitted to use the irradiating apparatus, or to allow any other persons to use it before a licence for such purposes is issued by the Radiation Board. An Inspector of the Radiation Board may seal the irradiating apparatus if you are applying for a licence to possess the apparatus for storage only, or if the radiation safety of the installation is found to be inadequate.

2. 遞交申請書 Submission of application

填寫的申請表格須送回：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 \$410。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 \$410. 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)

用個人名義申請牌照：申請人的身分證副本/證明文件及 45x60(毫米)近照兩張。

Licence in the name of a person - Copy of Identity Card/Document of the applicant,
2 recent photographs of size 45 x 60(mm).

用公司名義申請牌照：商業登記證及獲授權人士身分證/證明文件的副本。

Licence in the name of a company - Copy of the Business Registration Certificate
Copy of Identity Card/Document of the authorized person.

4. 牌照期限 Licence period

- (i) (a) 類牌照，有效期至批出持有供使用的輻照儀器牌照為止，或為期一年，兩者以較早的日期為準。
Type (a) Licence is valid for one year, or until a licence to possess the irradiating apparatus in a functional state is granted, whichever is the earlier.
- (ii) (b) 類牌照有效期為一年。 Type (b) licence (for storage) is valid for one year.
- (iii) 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 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.

5. 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

6. 直接進口輻照儀器，必須領有按《進口(輻射)(禁止)規則》第 60K 章發出的進口證。申請進口證可遞交香港西灣河太康街 28 號西灣河健康中心三樓放射衛生科。(電話：3620 3814)

Direct import of irradiating apparatus shall be covered by an import licence issued under the Import (Radiation)(Prohibition) Regulations, Cap 60K. Application can be made to the Radiation Health Division, 3/F., Sai Wan Ho Health Centre, 28 Tai Hong Street, Sai Wan Ho, Hong Kong. (Tel: 3620 3814)

**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) RadDiaq

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.