設置 X 射線醫學診斷裝置的申請指引
Application Guideline for Installation of Medical Diagnostic X-ray Apparatus

This guideline is intended to reduce the impact on staff and patients during installation and operation of diagnostic x-ray apparatus. It applies to the installation of all medical diagnostic x-ray apparatus.

1. **Required documents for licensing application (pursuant to subsection e), section 2 of article 11 of Decree-law no. 84/90/M)**
   - 1.1 Specific location of the premise, profile of its surrounding environment (usage and purposes of the upper, lower and adjacent spaces), and general layout plan of the premise.
   - 1.2 Information of the x-ray apparatus:
     - 1.2.1 Introduction (name, purpose and main specifications and parameters);
     - 1.2.2 Copy of specification sheet, installation and operation manual;
     - 1.2.3 Original or certified true copy[Remark 1] of factory release certificate; for second-hand products, it is required to provide an original or certified true copy[Remark 1] of the certificate of inspection issued by a manufacturer-authorized service provider;
     - 1.2.4 If the above documents have been submitted in the application for import licence, the submission of such documents can be exempted by a written declaration made by the applicant, in which the application number of import licence should be specified.
   - 1.3 Protection design of the x-ray apparatus, including:
     - 1.3.1 Detailed layout of the x-ray room (showing the size), the x-ray apparatus (including direction of the main beam) and its controlled areas, the layout plan and description of the protective facilities;
     - 1.3.2 Design of protective shielding and a description of the parameters for all materials, including protective shielding for immobile facilities (e.g. doors,

windows to the outdoors, windows of the control room, ventilation ducts, walls, floors, etc.), removable protective shielding (e.g. screen panels) and the lead equivalence in relation to the thickness of various materials (e.g. lead boards, lead glasses, lead containing concrete, etc.), and indicate the source of specification standard in use. **Please refer to Annex I "Important Notes on Radiation Protection" when formulating the design**;

1.3.3 Illustration of safety installations and indicators, including operation indicator light at the entrance to the x-ray room, door safety interlock, emergency stopping device, alarm, intercom device and the position of radiation warning signs.

1.4 Information of the companies/organizations to be contracted for the protection design and/or construction, equipment installation and protection safety inspection. For installation companies/organizations, authorization from the manufacturer or qualification documents are required; for protection safety inspection companies/organizations, a certificate of competence (original/certified true copy[Remark1], or website of competent authority of the place of origin displaying such information) is required. Such documents can be submitted upon application for acceptance inspection.

1.5 Wherever applicable, the construction permit issued by the Land, Public Works and Transport Bureau in which the purpose of the construction should be specified as healthcare setting with x-ray apparatus.

1.6 Safety and Protection Management Manual **(Please refer to the sample outlines in Annex II and Important Notes on Radiation Protection in Annex I; can be submitted upon application for acceptance inspection)**.

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2. **Required documents for application for inspection of facilities (as per section 5 of article 11 of Decree-law no. 84/90/M)**

2.1 Certificate of compliance for equipment installation

2.1.1 Authorization from the manufacturer or qualification documents are required for the installation company (if not submitted upon application for installation or should be any changes after submission);

2.1.2 Declaration of the aforesaid company that the safety protection function of the apparatus has complied with safety standards and as such, what criteria are based on.

2.2 Certificate of inspection for safety protection:

2.2.1 Certificate of competency for the inspection organization (original or certified true copy [Remark1]);

2.2.2 Comprehensive test report on the radiation dose rate (unit: μGy/hr) of the apparatus, the protective facilities of the x-ray room and the surroundings. The relevant protection performance should at least fulfil the requirements stated in Annex III.

2.3 Duly completed "List of Equipment with Radioactive Sources or Radiation Apparatus for Medical Use" (Annex IV)**;**

2.4 If applicable, documentation of project completion acceptance issued by the Land, Public Works and Transport Bureau.

3. **Other remarks**

3.1 Medical diagnostic x-ray apparatus shall only be put into operation after on-site inspection and acceptance by the Health Bureau.

3.2 When applying for the annual licence renewal for the premise, reports on the calibration, maintenance and repair of the x-ray apparatus, and radiation dose

monitoring report for individual staff should be submitted[Remark 2]. Annual examination shall be arranged by the Health Bureau; the x-ray apparatus may be suspended for use in case of failure in the examination.

3.3 For change of operational status of the x-ray apparatus, notification should be made to the Health Bureau; for disposal of x-ray apparatus, notification should be made and examination will be arranged.

4. **Effective date and interim arrangements**

4.1 This edition of guideline shall apply to all new applications from 1st July 2020.

4.2 In cases where the requirements in this edition are less stringent than those of the previous one, the present edition can also apply to those pending applications.

Centre for Disease Control and Prevention of the Health Bureau

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Remarks:

1. Applicants should present originals of the documents. Meanwhile, according to provisions in article no. 5 of Decree-Law no. 62/99/M, as amended by Law no. 4/2004, the applicants may request a photocopy of the documents to be delivered to the Health Bureau.
2. According to provisions of item c) of clause 2 of article no. 5 of Decree-Law no. 84/90/M and article no. 28 of Decree-Law no. 57/82/M, employers of health service establishments should adopt measures to "protect against ionizing radiation", including "use of dosimeters by all workers".

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ANNEX I

Important Notes on Radiological Protection

Design of protective shields

1. Protection for areas where the main beam is directed must be reinforced, and the main beam must neither point at the control panel nor at doors or windows;
2. Installation of shield should be considered when the main beam is directed towards floor or ceiling occupied by people;
3. Thickness of shield: no less than 3 mm of lead equivalent for direction of the main beam; and no less than 1.5mm of lead equivalent for direction of dispersion;
4. The control panel must be installed outside the x-ray room or in a separate compartment equipped with a lead door (alternatively, a tortuous corridor can also be used to reduce dispersion entering the control panel); meanwhile, a lead window (with thickness of lead indicated) or a video system must be installed to observe situation of patients and the x-ray room;
5. For x-ray apparatus of which the control panel must be installed in the x-ray room (e.g. mammography), the protection shield of the control panel must be of a height of at least 2 metres and a sufficient width that can accommodate at least two people; and control panel must be a location where the radiation has dispersed at least two times;
6. Please pay attention that materials at joints, recesses in walls, perforations, door and door frame, observation window and window frame, etc. must be covered with sufficient protective materials:
    6.1 Ensure adequate overlapping of protective materials at joints: the width of overlapping between lead and concrete must be at least as great as the thickness of concrete. The width of overlap between lead sheets must be at least 1cm or twice the thickness of the sheet (choose the thicker one); the overlapping areas between the lead in the walls and the concrete of the floor/ceiling should not be less than the thickness of the lead;

6.2 Recesses in walls or perforations of nails or screws must be covered with protective materials to ensure that the protective shield is not impaired;

6.3 The lead equivalence of the door and door frame must be at least the same of the adjacent wall. The width of overlap of protective materials between the door and the door frame must be of at least 1.5cm; the overlapping areas between the protective lead of door frame and concrete/adobe in the wall should not be less than the thickness of the concrete/adobe in the wall; whereas the surface of door bottom must also be covered with protective lead; the distance between the door bottom and the concrete in the floor must not exceed 1.5cm;

6.4 The lead equivalence of the observation window and window frame must be at least the same of the adjacent wall. The width of overlap between lead sheets and lead glass must be of at least 1cm or equal to the thickness of the lead glass (choose the thicker one);

7. Appropriate design of protective shield must also be applied to ventilation trunks to prevent radiation leakage;
8. Protective shield on windows and window frames opening to the outside can only be exempted after due inspection, and relevant evaluation result should be submitted;
9. Avoid scattering of radiation caused by false ceiling, floor and other objects in the room.
10. All lead materials must be adequately covered to avoid lead dust pollution;
11. Safety devices and instructions must be in place, including an effective connection between operation indicator lights and doors of the room, emergency suspension device, lead windows or electronic video device for patients observation and others. It is preferable that the indicator lights are placed at eye level and should always be on during preparation and operation.

ANNEX I (Cont.)
Important Notes on Radiological Protection

Other observations (alert signals, personal and operating)

1. Radiation warning signs should be attached to all doors of the x-ray room;
2. A notice, reminding women to report their pregnancy / possible pregnancy, should be visibly placed in the waiting area and x-ray room;
3. All exposure buttons must be clearly labelled with appropriate protective measures in place to prevent access by unauthorized people. If more than one exposure button is on the panel, the equipment to which the button belongs must be clearly indicated;
4. The premise should be equipped with personal protective equipment (lead apron, thyroid shield, gonad shield, lead glasses, etc.);
5. During the operation of the equipment, the door of the room must be kept tightly closed, and workers must stay behind the protective shield, observing condition of the patient and the room through leaded glass window or video system;
6. The radiation range should be adjusted to the minimum area sufficient for clinical diagnosis;
7. During the operation of the equipment, no one should be present other than the patient. The patient's companion should put on personal protective equipment and stay as far away from the x-ray tubes as possible;
8. Mobile x-ray equipment should be carefully evaluated before use, and only used when the use of fixed equipment is not possible, and when it is clear its advantages outweigh its disadvantages. During operation, avoid directing the main beam to anyone other than the patient, and the operator should remain 2 meters away from the equipment and the patient, and put on personal protective equipment or stay behind the protective shield;
9. All operators should adopt a personal radiation dosimeter, and relevant monitoring records should be properly kept by the premise.

ANNEX II
Sample of Radiation Safety and Protection Management Manual

1. Objectives of the Manual

   The purpose of this Management Manual is to assist diagnosis and treatment units in establishing a radiation safety and protection management mechanism in order to guarantee all x-ray apparatus operate without undermining the health of staff and patients, as well as fulfilling the requirements of sanitary inspection for obtaining the permit from the Health Bureau.

2. Staff responsible for safety and protection management
   - 2.1 Designate staff for the management of safety and protection;
   - 2.2 Clearly define the duties and responsibilities of the above mentioned staff;
   - 2.3 List the duties and responsibilities of other staff in the area of radiation protection, as well as relevant training programmes.

3. Layout of the premise in relation with the surrounding environment

4. Information of apparatus
   - 4.1 Identification information and relevant parameters of the x-ray apparatus, including the serial number (SN) of x-ray bulb tube, as well as the information of the manufacturing, supplying, maintenance and inspection entities;
   - 4.2 Regular plan and record of check-up, calibration and maintenance.

5. Information of protection facilities
   - 5.1 Design of screening equipment and parameters of materials;
   - 5.2 Effective connection between operation indicator lights and doors of the room,

emergency suspension device, windows or electronic video device for patients observation and others;

5.3 List of protective equipment and personal protective articles.

6. Safety operation practices and regulations

This includes procedures for technical operation as well as regulations to reduce staff and patients' exposure to radiation (such as avoiding unnecessary examinations, reducing dose, and substituting radiograph for fluoroscopy whenever possible), and to correctly utilize time, distance and protective shield.

7. Monitoring of radiation protection

7.1 Radiation monitoring plan and record of the premise;

7.2 Radiation dose monitoring plan and report of individual staff.

8. Emergency response plan

9. Plan and record of pre-employment physical examination and annual physical examination of staff

ANNEX III
Radiation Protection Performance Indicators

Applicable Scope

All diagnostic x-ray apparatus and x-ray room facilities.

Radiation Protection Performance Indicators

1. The total filtration of useful beam emitted by an x-ray apparatus should comply with the following conditions:
   1.1 For an apparatus with a maximum voltage not exceeding 70kV: ≥ 1.5 mm thickness of aluminium;
   1.2 For an apparatus with a maximum voltage exceeding 70kV: ≥ 2.5 mm thickness of aluminium;
   1.3 For an x-ray apparatus specially designed for soft-tissue procedures such as mammography: ≥ 0.5 mm thickness of aluminium or 0.03 mm thickness of molybdenum.
2. Without prejudice to the requirements of the following paragraph, the radiation dose rate shall be less than or equal to 3μGy in one hour (≤ 3μGy/h) for any part of the outer surface of the x-ray room shielding;
3. Protective shield on windows and window frames opening to the outside can only be exempted after due inspection, and relevant evaluation report should be submitted under this situation;
4. The construction of the protective shield of an x-ray tube shall ensure that the radiation dose rate is less than or equal to 1mGy in one hour (≤1mGy/h) at a distance of 1 metre from the focal point of the x-ray tube.

List of Equipment with Radioactive Sources or Radiation Apparatus for Medical Use

☐ Update ☐ New application

I. Information of Establishment:

Permit / licence no:	
Name of establishment / doctor:	
Address of establishment:	
Contact person:	Contact phone no:

II. Equipment with Radioactive Sources or Radiation Apparatus for Medical Use (Total no: _____) ☐ Total pages of table: ____

1. Information of Apparatus / Equipment						2. Information of X-ray Tube				3. Environment of Facility Room		
S/N and status[1]	Name	Manufacturer, brand, model and S/N	Operational status[2]	Date placed in service (yy/mm/dd) / Date of last check-up / calibration / repair (yy/mm/dd)	Location / Dept/ward	S/N	Manufacturer, brand and model	Maximum voltage (kVp) / Maximum current (mA) / Range of exposure time (sec)	Total filtration (mm Al. eq)	Area [3] (m^2)	Materials used and thickness of the protective shield (walls / doors / windows) (mm)	Inspection organization for safety protection and Date of approved inspection (yy/mm/dd)
1___												
2___												

1. Information of Apparatus / Equipment						2. Information of X-ray Tube				3. Environment of Facility Room		
S/N and status[1]	Name	Manufacturer, brand, model and S/N	Operational status[2]	Date placed in service (yy/mm/dd) Date of last check-up / calibration / repair (yy/mm/dd)	Location / Dept/ward	S/N	Manufacturer, brand and model	Maximum voltage (kVp) Maximum current (mA) Range of exposure time (sec)	Total filtration (mm Al. eq)	Area [3] (m^2)	Materials used and thickness of the protective shield (walls / doors / windows) (mm)	Inspection organization for safety protection and Date of approved inspection (yy/mm/dd)
( )___												
( )___												
( )___												

(Where more space is required, please photocopy the above table)

Signature and Stamp of Responsible Person

Date: / /

1. (Update) A: Change of operational status; B: Others;
   (New Application)
   C: Replace with another x-ray apparatus or x-ray tube at the original location (If the power and specification of the new equipment / x-ray tube does not exceed the original one, the certificate of inspection for safety protection prescribed in subparagraph 2.2 of the Guideline can be exempted);
   D: Addition of facility room/ x-ray equipment;
   E: Alteration / change of location of facility room / x-ray equipment;
   F: New construction of establishment / equipment.
2. For change of operational status, notification should be made to the Health Bureau; for disposal of x-ray apparatus, notification should be made and examination will be arranged. (Operational status): o. Pending for approval; a. In use; b. Not in use (spared for possible use); c. Not in use (to be repaired); d. Not in use (unserviceable, but not planning for disposal); e. Transferred; f. Disposed; g. Unused; h. Others.
3. Facility room refers to the room equipped with x-ray tube or shielded with radiation protection materials, this does not include dressing room, or location where high voltage equipment or control panel is placed.