



設置醫用核磁共振診斷系統要求和申請流程

Requirements and Application Procedures for Magnetic Resonance Diagnosis System for Medical Use

1. General requirements:

- 1.1 Performance, installation, testing and functioning of the equipment shall comply with the requirements of the manufacturer, as well as the latest edition of Medical Electrical Equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33) issued by the International Electrotechnical Commission, IEC;
- 1.2 Installation and functioning of the equipment shall comply with the current construction, electricity, fire safety, occupational safety and health requirements in the Macao SAR, particularly in ensuring the structure of the building, as well as the safety and health of the operators, patients examined with the equipment and surrounding workers, and ensuring no nuisance like noises, vibrations or magnet will be generated that affects other users in the building outside the premise.

2. Application procedures:

- 2.1 Applicant seeks advice from Health Bureau (not compulsory): Basic information of the equipment to be installed can be submitted to the Health Bureau for preliminary advice before official application;
- 2.2 Application to Land, Public Works and Transport Bureau for construction permit, enclosed with documents prescribed in 3.1, and clearly state the utilization purpose of the premise so that the Land, Public Works and Transport Bureau may seek advice from the Health Bureau upon receipt of the application;
- 2.3 Submit to the Health Bureau documents (copies) mentioned in 3.1, application form of 3.2, and receipt of application submitted to the Land, Public Works and Transport Bureau;
- 2.4 After receiving the application letter and advice requiring letter from the Land, Public Works and Transport Bureau, the Health Bureau will scrutinize the documents and issue submission to the Land, Public Works and Transport Bureau;
- 2.5 After receiving supporting advice and analysis, the Land, Public Works and Transport Bureau will issue the construction permit;



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- 2.6 Applicant initiates relevant construction and installation process;
- 2.7 Applicant conducts testings;
- 2.8 Applicant applies to the Health Bureau for inspection and acceptance, and submit documents prescribed in 3.3;
- 2.9 Health Bureau invites the Land, Public Works and Transport Bureau, Fire Services Bureau and other relevant departments (if applicable) to conduct acceptance check together;
- 2.10 Land, Public Works and Transport Bureau issues acceptance certificate;
- 2.11 Applicant applies to the Health Bureau for permit or licence for the premise.
- 2.12 Health Bureau issues permit or license to the premise.

3. Documents required:

3.1 Application to the Land, Public Works and Transport Bureau for construction permit (decision of the Land, Public Works and Transport Bureau shall prevail):

- 3.1.1 General requirements for reconstruction/new construction project of the Land, Public Works and Transport Bureau;
- 3.1.2 The application shall explain the purpose of the reconstruction/new construction, installation requirements and manual of the equipment provided by the manufacturer, total weight of the equipment, and possible noises, vibrations, electricity, magnet or gas leakage;
- 3.1.3 Protection design and its expected standard against noises, vibrations, electricity, magnet or gas leakage.

3.2 Documents required for application to the Health Bureau

- 3.2.1 Information of natural person/juridical person of the applicant;
- 3.2.2 Construction permit issued by the Land, Public Works and Transport Bureau, including design information of construction project and installation project approved by the Land, Public Works and Transport Bureau, this includes design illustration, layout, as well as liability statement and balance sheet



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signed by the authorized designers;

3.2.3 Certification by manufacturer of the equipment (or certified true copy of the document);

3.2.4 Installation requirement and technical specifications provided by manufacturer of the equipment;

3.2.5 Information of manufacturer/organization to be assigned for the design, construction monitoring, installation and testing, including official qualification document (or certified true copy of the document by notarization of the place of origin) issued by the place of origin to the manufacturer/organization and/or technician;

3.2.6 Guarantee policy of no nuisance like noises, vibrations or magnet, or undesirable influence on health or safety will be generated that affects other users in the building outside the control area.

3.3 Upon completion of installation, the following documents should be submitted before formal functioning:

3.3.1 Qualified test report or certification accredited by the manufacturer of the equipment:

3.3.1.1 Report certifying compliance of installation requirement

3.3.1.2 Examination report on the technical performance of the equipment

3.3.1.3 Examination report on magnetic shield and radiofrequency shield

3.3.1.4 Examination report on noises

3.3.1.5 Examination report for system safety operation: including oxygen concentration alarm – activating system for emergency ventilation, fire safety alarm system, emergency shutdown system, video and audio system, etc.

3.3.2 Training certificate of operating workers, and guidelines/regulations for utilization and operation, including contingency plan in event of accident.