



《私營醫療機構條例》(第 633 章) 醫院更改服務/資料申請
Application for Variation of Service / Particulars of Hospital
under the Private Healthcare Facilities Ordinance (Cap. 633)

擴建/重建醫院大樓文件清單

Checklist of Documents for Extension / Redevelopment of Hospital Block

請在適當的方格內填上 ☒ 號並提供相關的文件

Please tick as appropriate and provide the relevant documents

A. 醫院擴建大樓/新醫院大樓的文件	Documents for the Hospital Extension / New Hospital Block
<input type="checkbox"/> 醫院處所平面佈置圖 (i) 每層圖則以不小於 1:200 比例繪製; 及 (ii) 每個服務/單位圖則(包括所有臨牀 及輔助服務/單位) 以不小於 1:100 比例繪製	Layout plans of the premises of the hospital (i) Layout plan of each floor of the premises of the hospital drawn to the scale of not less than 1:200; and (ii) Layout plan of each service/unit (including all clinical and supporting services/units) of the premises of the hospital drawn to the scale of not less than 1:100
<input type="checkbox"/> 採用 Portable Document Format (PDF) 格式的醫院處所平面佈置圖的電子副 本	Electronic copy of the layout plan of the hospital premises in Portable Document Format (PDF).
<input type="checkbox"/> 屋宇署或其他獲授權的機構發出的批 核文件以證明一般建築圖則已獲批准	Approval document for general building plan issued by the Buildings Department or other authorized parties
<input type="checkbox"/> 建築事務監督發出同意展開及開始進 行建築工程的文件	Consent for commencement and carrying out of Building Works issued by the Building Authority
<input type="checkbox"/> 有關醫療工程系統的文件清單 (PHF 112) 的最新資料	Checklist of documents of healthcare engineering systems (PHF 112) with the latest information
電力裝置	Electrical Installation
<input type="checkbox"/> 由電機界別或屋宇裝備界別的註冊專 業工程師以訂明表格簽發的設計證明 書, 證明醫院關鍵醫護區的電力裝置乃 根據相關的國際認可標準及私家醫院 實務守則的要求而設計	A certificate of design in prescribed form issued by a Registered Professional Engineer of the electrical discipline or building services discipline certifying that the electrical installations for critical care areas of the hospital have been designed in accordance with the relevant internationally acceptable healthcare engineering standard(s) and the requirements of the Code of Practice for Private Hospitals

A. 醫院擴建大樓/新醫院大樓的文件（續）	Documents for the Hospital Extension / New Hospital Block (Cont.)
<input type="checkbox"/> 主電力系統配電示意圖	Schematic diagram(s) of the main electrical system
<input type="checkbox"/> 關鍵醫護區的電力裝置配電示意圖	Schematic diagram(s) of the electrical installations for critical care area(s)
<input type="checkbox"/> 主電力設備平面圖	Layout plan(s) of the main electrical equipment
<input type="checkbox"/> 關鍵醫護區的電力裝置平面圖	Layout plan(s) of the electrical installations for critical care area(s)
<u>特殊通風系統</u>	<u>Specialized Ventilation System</u>
<input type="checkbox"/> 由機械界別或屋宇裝備界別的註冊專業工程師以訂明表格簽發的設計證明書，證明醫院的特殊通風系統乃根據相關的國際認可標準及私家醫院實務守則的要求而設計	A certificate of design in prescribed form issued by a Registered Professional Engineer of the mechanical discipline or building services discipline certifying that the specialized ventilation systems of the hospital have been designed in accordance with the relevant internationally acceptable healthcare engineering standard(s) and the requirements of the Code of Practice for Private Hospitals
<input type="checkbox"/> 主通風及空調系統空氣側及水側示意圖	Air-side and water-side schematic diagram(s) of the main ventilation and air-conditioning system
<input type="checkbox"/> 特殊通風系統空氣側示意圖	Air-side schematic diagram(s) of the specialized ventilation systems
<input type="checkbox"/> 主通風及空調設備平面圖	Layout plan(s) of the main ventilation and air-conditioning equipment
<input type="checkbox"/> 特殊通風系統平面圖	Layout plan(s) of the specialized ventilation systems
<u>醫療氣體管道系統</u>	<u>Medical Gas Pipeline System</u>
<input type="checkbox"/> 由機械界別或屋宇裝備界別的註冊專業工程師以訂明表格簽發的設計證明書，證明醫院的醫療氣體管道系統乃根據相關的國際認可標準及私家醫院實務守則的要求設計	A certificate of design in prescribed form issued by a Registered Professional Engineer of the mechanical discipline or building services discipline certifying that the medical gas pipeline systems of the hospital have been designed in accordance with the relevant internationally acceptable healthcare engineering standard(s) and the requirements of the Code of Practice for Private Hospitals
<input type="checkbox"/> 醫療氣體管道系統的主系統示意圖	Main schematic diagram(s) of the medical gas pipeline systems

A. 醫院擴建大樓/新醫院大樓的文件（續）	Documents for the Hospital Extension / New Hospital Block (Cont.)
<input type="checkbox"/> 醫療氣體管道系統示意圖 <input type="checkbox"/> 醫療氣體管道系統的主設備平面圖 <input type="checkbox"/> 醫療氣體管道系統平面圖	<p>Schematic diagram(s) of the medical gas pipeline systems</p> <p>Layout plan(s) of the main equipment for medical gas pipeline systems</p> <p>Layout plan(s) of the medical gas pipeline systems</p>
<p><u>如有提交申請意向書</u></p> <input type="checkbox"/> 任何衛生署發出的相關指定文件	<p><u>If a Letter of Intent was submitted</u></p> <p>Any other relevant document(s) stated in the specified list of document issued by DH</p>
<p><u>於實地視察至少 10 個工作天前提交的文件</u></p> <input type="checkbox"/> 由電機界別或屋宇裝備界別的註冊專業工程師以訂明表格簽發的符合規格證明書，證明醫院關鍵醫護區的電力裝置乃根據相關的國際認可標準設計、安裝及完成，符合私家醫院實務守則的規定 <input type="checkbox"/> 由機械界別或屋宇裝備界別的註冊專業工程師以訂明表格簽發的符合規格證明書，證明醫院的特殊通風系統乃根據相關的國際認可標準設計、安裝及完成，符合私家醫院實務守則的規定 <input type="checkbox"/> 由機械界別或屋宇裝備界別的註冊專業工程師以訂明表格簽發的符合規格證明書，證明醫院的醫療氣體管道系統乃根據相關的國際認可標準設計、安裝及完成，符合私家醫院實務守則的規定	<p><u>Documents to be submitted at least 10 working days before site inspection</u></p> <p>A certificate of compliance in prescribed form issued by a Registered Professional Engineer of the electrical discipline or building services discipline certifying that the electrical installations for the critical care areas of the hospital have been designed, installed and completed in accordance with the relevant internationally acceptable healthcare engineering standard(s) and comply with the requirements of the Code of Practice for Private Hospitals</p> <p>A certificate of compliance in prescribed form issued by a Registered Professional Engineer of the mechanical discipline or building services discipline certifying that the specialized ventilation systems of the hospital have been designed, installed and completed in accordance with the relevant internationally acceptable healthcare engineering standard(s) and comply with the requirements of the Code of Practice for Private Hospitals</p> <p>A certificate of compliance in prescribed form issued by a Registered Professional Engineer of the mechanical discipline or building services discipline certifying that the medical gas pipeline systems of the hospital have been designed, installed and completed in accordance with the relevant internationally acceptable healthcare engineering standard(s) and comply with the requirements of the Code of Practice for Private Hospitals</p>

B. 醫院牌照申請報告 (PHF 110) 的相關章節	Relevant Chapters in Report for Application for Hospital Licence (PHF 110)
<input type="checkbox"/> B1 服務提供及護理程序	B1 Service Delivery and Care Process
<input type="checkbox"/> B4 無菌製劑配製服務	B4 Aseptic Preparation Service
<input type="checkbox"/> B5 心導管插入術服務	B5 Cardiac Catheterisation Service
<input type="checkbox"/> B8 牙科服務	B8 Dental Service
<input type="checkbox"/>

C. 醫護人手安排的文件*	Documents regarding staffing of healthcare workers*
<input type="checkbox"/> 醫生及專職醫療人員兩星期輪值表 (包含員工姓名)	2-week duty roster of medical and allied health professionals (with staff name) for each service
<input type="checkbox"/> 護士及護理支援人員兩星期輪值表 (包含員工姓名)	2-week duty roster of nursing staff and supporting care staff (with staff name) after commencement of each service
<input type="checkbox"/> 於非辦公時間負責提供緊急服務的醫護專業人員隨時候召輪值表 (包括員工姓名)	On-call duty roster (with staff name) of healthcare professionals for emergency service provided after office hour

*於實地視察至少 10 個工作天前提交 Submission at least 10 working days before site inspection

D. 如所提供的服務涉及 <u>注射製品的無菌注射製劑配製服務</u> *	If services provided involve <u>aseptic preparation service for injectable products</u> *
<input type="checkbox"/> 國際認可第三方無塵房潔淨驗收報告，以證明符合相關的無塵房標準(例如符合歐盟GMP A級或 ISO 5級環境空氣潔淨度(以微塵粒子計算))	Cleanroom certification report issued by an internationally recognized third party (e.g. meeting European Union GMP grade A environment or ISO Class 5 of air cleanliness by particle concentration)
<input type="checkbox"/> 無塵房的微生物檢測報告，以證明符合國際認可的無塵房相關標準	Microbial testing reports showing compliance with requirements for the relevant clean room(s) in accordance with international standards
<input type="checkbox"/> 無菌製劑配製設備設施(例如生物安全櫃、製藥用隔離器)測試報告，以證明符合國際認可相關的無菌製劑儀器標準(例如符合歐盟GMP A級或 ISO 5級環境空氣潔淨度(以微塵粒子計算))	Acceptance reports for equipment for aseptic preparation (e.g. biosafety cabinets and pharmaceutical isolators) showing compliance with internationally acceptable standards (e.g. meeting European Union GMP grade A environment or ISO Class 5 of air cleanliness by particle concentration)
<input type="checkbox"/> 無菌製劑配製設備的微生物檢測報告，以證明符合國際認可的無菌製劑配製設備相關標準，例如：生物安全櫃和藥品隔離器	Microbial testing reports showing compliance with the relevant requirements for equipment for aseptic preparation (e.g. biosafety cabinets and pharmaceutical isolators) in accordance with international standards

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E. 如提供 <u>血液透析服務</u>	If <u>haemodialysis service</u> is provided
<input type="checkbox"/> 預期用水處理及輸送系統與其相連的喉管及管道系統的示意圖及平面圖	Schematic diagram(s) and layout plan(s) of the proposed water treatment, distribution and piping system
<input type="checkbox"/> *用水處理及輸送系統與其相連的喉管及管道系統的示意圖及裝配竣工平面佈置圖	*As-fitted schematic diagram(s) and as-fitted layout plan(s) of the proposed water treatment, distribution and piping system

*於實地視察至少 10 個工作天前提交 Submission at least 10 working days before site inspection