



Guidance Notes for Application for Extension of a Hospital Block or Redevelopment of Existing Hospital Block

1 Preparation before applying for an extension of a hospital block or redevelopment of existing hospital block

Please refer to the Private Healthcare Facilities Ordinance (“the Ordinance”), the Code of Practice for Private Hospitals (PHF(E) 11A) and relevant standards, Guidance Notes for Assessing Fitness and Propriety of Applicants / Chief Medical Executives for Licence Application (PHF(E) 81A), and this guidance notes. These documents are available at [ORPHF website](#).

2 Who can submit the application?

The authorized representative of the licensee of a hospital shall be responsible for the application for extension / redevelopment of hospital block.

Any change of particulars of the authorized representative shall also be indicated in Section A3 in the same application. For notification of a new authorized representative of the licensee, a resolution in writing relating to the authorization passed by the Board of Directors of the company or body corporate shall also be submitted.

3 When should I apply?

(a) Letter of intent

You are advised to submit to the Office for Regulation of Private Healthcare Facilities (ORPHF) a letter of intent for application for extension / redevelopment of hospital block **no earlier than 15 months** prior to the intended commencement of operation of the new extension / hospital block. Please see [Annex I](#) for the list of information and documents to be submitted with the letter of intent.

The letter of intent and any documents submitted together with the letter of intent are not considered as a submission of application for variation of service of the hospital licence. You shall formally submit an application for extension / redevelopment of hospital block.

- (b) Application for extension / redevelopment of hospital block [*see* [Flowchart](#) for application process]

At least 9 months before the intended date of commencement of operation of the hospital extension or new hospital block, you shall complete Section A7 of the application form (PHF 111), and submit the application form together with the required documents as stated in the Checklist of Documents (PHF 122) to ORPHF.

ORPHF will then notify you by email to obtain the general demand note at e-Licensing for payment of the application fee. We will process your application **only** after the completed application form and all required documents are received, as well as the application fee is settled.

4 How can I submit the application and the relevant documents?

Authorized representative of the licensee shall log in e-Licensing ([FAQ Q1](#)) to apply for the variation. The application can be submitted online by using [iAM Smart+](#) for digital signing and by uploading all required documents through e-Licensing.

Where iAM Smart digital signing is not applied, documents that require signature shall be submitted, by post or in person, to ORPHF at the following address –

Licensing Division
Office for Regulation of Private Healthcare Facilities
Department of Health (DH)
6/F, Guardian House
32 Oi Kwan Road
Wan Chai, Hong Kong

A reference number will be generated automatically on your application form at e-Licensing. Please quote your reference number on all documents and subsequent submissions related to the application.

To facilitate the processing of your application, please follow the guidelines below on the presentation of documents for submission.

- Include a covering letter and a list of the documents submitted with the application
- Include an index of the documents with corresponding page numbers
- Paginate and index all documents and compile them as a bundle
- Highlight only the parts of the document that are relevant to the application
- For amendment or updates of previously submitted documents, state on the covering letter the parts/sections where changes have been made to the original submission and highlight the page and paragraph numbers where changes have been made

Incomplete replies or submission that do not follow the guidelines may not be entertained and will be returned to the applicant.

5 When and how should I pay the application fee?

The application fee ([FAQ Q2](#)) is based on the scale of service provided by the hospital extension or the new hospital block. You shall settle the payment on or before the due date stated on the general demand note. Payment methods are specified on the general demand note.

6 Preparations for site inspection

- (i) Documents to be submitted **at least 10 working days before** site inspection (*see [Annex II](#)*)
- (ii) Documents to be ready for **on-site** inspection (*see [Annex III](#)*)
- (iii) Notify ORPHF the date when the hospital premises have an occupation permit issued by the Building Authority and the hospital is ready for site inspection

An inspection schedule will be provided to you **within 10 working days** upon your notification of site ready for inspection, given that all required documents submitted satisfy for conducting on-site inspection. Failure in submitting the required documents to ORPHF by the deadline may delay the site inspection.

The on-site inspection will normally be conducted **within one calendar month** from the date the hospital is ready for inspection, subject to your hospital's meeting the inspection schedule issued by ORPHF.

7 Possible follow-up action(s) after site inspection

You may be required to provide additional supporting documents, to make necessary amendment(s) to the application, or to make alteration(s) or improvement(s) to the relevant services / units of the hospital for fulfilling the licensing criteria. If inspection findings reveal that follow-up action(s) by the Hospital are required, you will be informed of the issues **within 7 working days after** the completion of the on-site inspection. A deadline for such follow-up action(s) will be provided to you by ORPHF officers.

Furthermore, you may be required to prepare for additional on-site inspection(s) after completion of all required alterations and improvements to the relevant services / units.

8 When will I be notified of the application result?

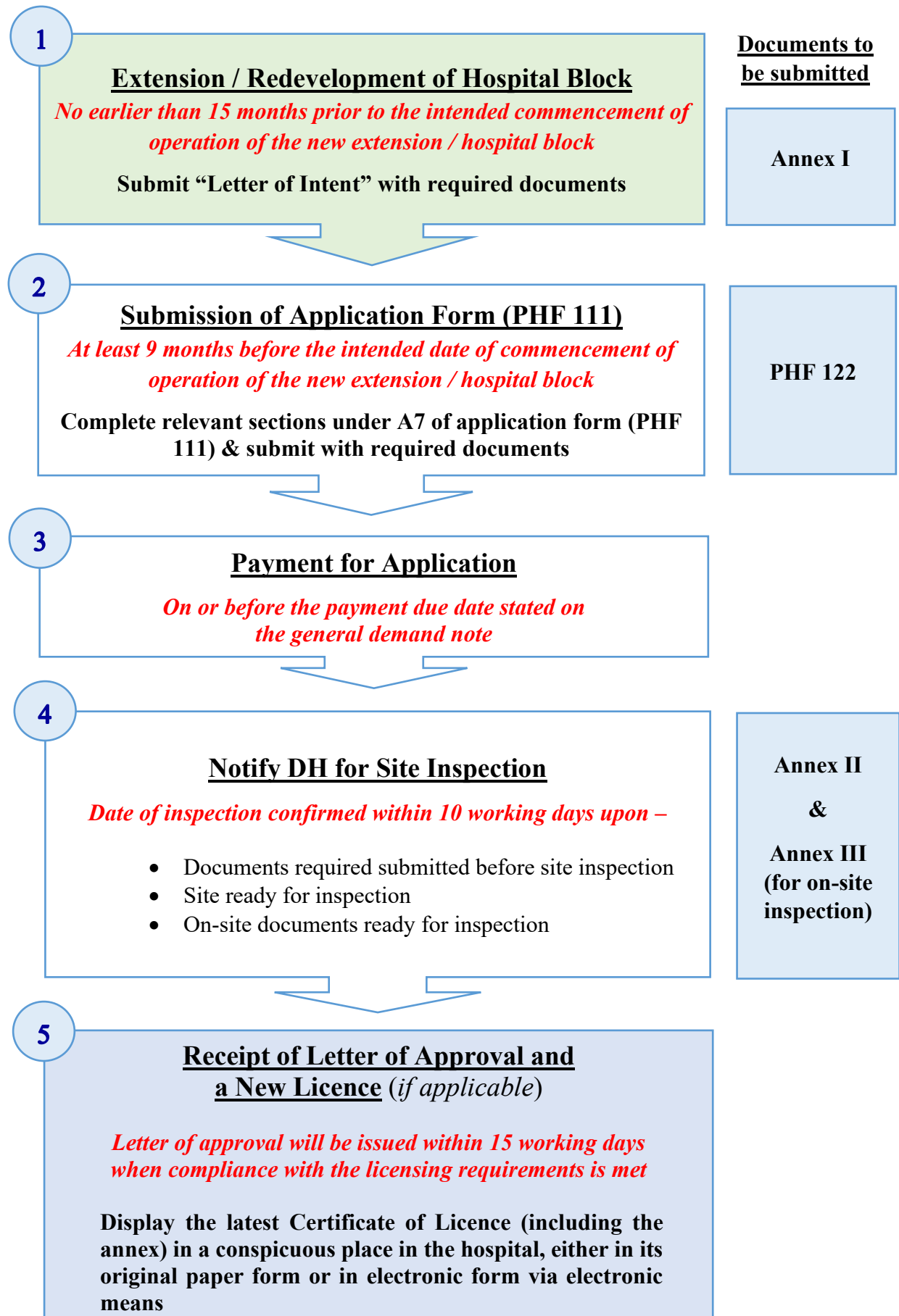
Upon completion of inspection(s), as necessary, and receipt of all documents required, normally the licensee will be informed of the application results in writing **within 15 working days**.

If changes in the particulars of the licence are involved, a new licence will be issued to the licensee subject to compliance with the licensing requirements. The end date of the new licence would be the same as specified in the existing licence.

9 Display of the certificate of licence

The licensee shall display the latest certificate of licence (including the annex) in its original paper form or in electronic form through electronic means (e.g. using flat panel display) in a conspicuous place in the hospital. The size and clarity of the electronic display should be comparable to that of the original certificate of licence in paper form. The certificate of licence and conditions in electronic form is available for download under “Licence / Exemption Profile” at [e-Licensing](#). Display of a photocopy of the certificate of licence or a printout of the electronic licence is **not** acceptable.

**Flowchart for Application for Extension of a Hospital Block /
Redevelopment of Existing Hospital Block**



Frequently Asked Questions

Q1 How can I apply for extension / redevelopment of hospital block through e-Licensing?

A1 Authorized representative of the licensee shall log in e-Licensing to complete the application form (PHF 111). Please follow the steps below to proceed to an application for extension / redevelopment of hospital block.

- (i) Log in e-Licensing (<https://apps.orphf.gov.hk/Submission>)
- (ii) Click “My Application” at the left menu bar
- (iii) To view licence profile before making an application, click “Licence Profile” at the left menu bar (*The profile of current licence will be shown*)
- (iv) Click “Apply for Variation of Service / Particulars”
- (v) Check the box for Section A7
- (vi) Similar to other variation of service, input details for each service provided at the hospital extension / new hospital block. Check “Hospital Extension / New Hospital Block” for location.
- (vii) Add new items to input details for relocation of clinical services from the existing hospital block. Check “Hospital Existing Block” for location.
- (viii) Click “Save” or “Save and Continue” to save the changes
- (ix) Click “Back” to go back to previous section
- (x) Click “Confirm Information” after final checking of data inputted

Q2 What is the application fee for extension / redevelopment of hospital block?

A2 The application fee for extension / redevelopment of hospital block is specified in Schedule 4 of the Ordinance and is listed as follows –

Type of variation	Application Fee*
Extension of a hospital block or redevelopment of existing hospital block by –	
- up to 200 beds	\$426,000
- 201 to 500 beds	\$605,300
- More than 500 beds	\$755,900

*Under Section 110 of the Ordinance, any application fee paid is not refundable.

Q3 Can I have some examples on how the application fee is calculated?

A3 Below are some examples of applications for extension / redevelopment of hospital block and the required fees –

Variation of Service applied for	Fee
Extension of a hospital block by 50 inpatient beds and 10 day beds at the time of commencement of operation of the hospital extension	\$426,000
Establishment of a new hospital block at the hospital premises, providing 20 in-patient beds at the new hospital block at its time of commencement of operation	\$426,000

Q4 Do I need to send a letter of intent to DH for extension / redevelopment of hospital block?

A4 You are advised to notify ORPHF in advance by sending a letter of intent **no earlier than 15 months before** the intended date of commencement of operation of the hospital extension / new hospital block.

The letter of intent aims to facilitate both the applicant and DH to smoothen the upcoming application process. Please see [Annex I](#) for the list of documents to be submitted with the letter of intent.

Q5 My hospital is planning to relocate the chemotherapy day centre to the new hospital extension at its time of commencement of operation. Shall I apply for this variation of service under the same application for the hospital extension?

A5 Yes, you shall indicate in Section A7 of the application form **all** clinical and clinical supporting services that would be relocated to the new hospital extension and would commence their services at the same time as the new hospital extension.

First, add an item and choose “Chemotherapy service”. Select “Hospital Extension / New Hospital Block” and input the location of the chemotherapy service to be provided at the new block. Then, input the number of day beds/chairs to be provided (e.g. +10) and variation details.

Then, add another item and choose “Chemotherapy service”. Select “Existing hospital block” and input the current location of the chemotherapy service. Then, input the number of day beds/chairs to be relocated (e.g. -10).

Q6 My hospital will relocate the pharmacy to the new hospital block 3 months after its commencement of operation. Shall I apply for this variation of service under the same application for the new hospital block?

A6 No, you shall submit a *separate* application for variation of service (under Section A6 of the application form) for relocation of services from the existing hospital block to the new hospital block if the relocation of services are made after the commencement of operation of the new hospital block. An application fee would be applied for this variation of service. Please refer to **PHF(E) 111A Guidance Notes for Application for Variation of Service / Particulars of Hospitals** for application details.

Q7 My hospital is planning to convert the surgical ward at the existing hospital block into an out-patient department when the surgical ward is relocated to the new hospital block. Shall I apply for this variation of service under the same application for the new hospital block?

A7 No, you shall submit a *separate* application for variation of service (under Section A6 of the application form) for the conversion of the surgical ward into an out-patient department at the existing hospital block. An application fee would be applied for this variation of service. Please refer to **PHF(E) 111A Guidance Notes for Application for Variation of Service / Particulars of Hospitals** for application details.

Q8 The catering department and the laundry service of our hospital are planning to be relocated to the new hospital block at the same time when the new hospital block commences its operation. Shall I apply for these variations of service under the same application for the new hospital block?

A8 For new or relocation of the catering services for *inpatients* to the new hospital block, you shall add an item under Section A7 and select “Other Clinical / Clinical Supporting Services Not Listed” as the service for variation. You shall complete **Chapter C2 Catering Service** of the Report for Application (PHF 110) and submit together with the application for variation of service for extension / redevelopment of hospital block.

Similarly, for new or relocation of the linen and laundry services to the new hospital block, you shall add another item under Section A7 for “Other Clinical / Clinical Supporting Services Not Listed”. You shall complete **Chapter C3 Linen and Laundry Services** of PHF 110 and submit together with the application.

Q9 How can I notify DH if the hospital address will be updated regarding the establishment of our hospital extension?

A9 You shall indicate the updated hospital address under Section A1 in the same application form (PHF 111) if there is an amendment of hospital address regarding the hospital extension. The updated hospital address will be displayed in the new licence when the application for extension / redevelopment of hospital block is approved.

Q10 Can I apply for other changes in the particulars of the hospital profile in the same application for extension / redevelopment of hospital block?

A10 As long as the changes in the particulars of the hospital profiles are in effect at the **same** time with the commencement of the operation of the hospital extension / new extension block, the following amendments can be made in the same application for the extension / redevelopment of hospital block:

- (i) Change of hospital particulars
- (ii) Change of particulars of the existing licensee
- (iii) Change of particulars of the authorized representative of licensee
- (iv) Change of particulars of chief medical executive
- (v) Change in the membership of Medical Advisory Committee

Q11 My hospital will have a variation of service at the existing hospital block completed at the same time with the commencement of operation of the new hospital block. Can I submit the application for variation of service in the same application for extension / redevelopment of hospital block?

A11 No, you shall submit a *separate* application (for Section A6 of the application form PHF 111) for variation of service at the existing hospital block. An application fee may be applied for this variation of service. Please refer to **PHF(E) 111A Guidance Notes for Application for Variation of Service / Particulars of Hospitals** for application details.

Q12 Which hospital services are considered as critical care areas?

A12 A “critical care area” in the hospital is an area that provides life support or complex surgery, or where failure of equipment or a system is likely to jeopardize the immediate safety or even cause major injury or death of patients or caregivers. Examples are operating theatre / room, cardiac catheterisation service, interventional angiography room, intensive care unit, high dependency unit, special care unit, cardiac care unit, labour room, and accident & emergency resuscitation bay / room, etc.

Q13 Can I propose an alternative healthcare engineering standard / code in my hospital other than those recommended in the Code of Practice for Private Hospitals?

A13 For any proposal to adopt an alternative standard / code, you are advised to consult ORPHF in advance. Justifications such as technical capability for meeting healthcare operational needs shall be submitted with substantial project reference, technical drawings and engineering calculations.

Q14 What information should be indicated on the layout plan of each clinical or clinical supporting service / unit in my application?

A14 The layout plan of each clinical or clinical supporting service / unit for variation shall –

- (i) be drawn to a scale not less than 1:100 and expressed in metric units
- (ii) indicate non-movable walls by double lines
- (iii) indicate boundaries of the area for variation by coloured lines
- (iv) indicate the actual location of the service at the premises

The following items shall be labelled on the layout plan with legends and abbreviations (where applicable) –

- in-patient bed and day bed / chair
- reception and waiting area
- nursing station
- consultation room / treatment room

- scrub up area / perioperative area / changing room / ante area (*applicable to operating rooms*)
- procedural area or operating room
- storage area for sterile items / equipment / bulk store
- area for equipment reprocessing
- handwashing and sanitation facility
- dirty utility room
- location of major equipment required for the facility service, e.g. anaesthetic machine, CT machine, resuscitation equipment, reconstitution facility etc.
- changing room, buffer area, ante area and compounding (*applicable to cleanrooms*)
- location of transfer hatches
- door (indication of interlocking where applicable)

Q15 What documents have to be ready for site inspection?

A15 Specific documents are required to be ready for site inspection. Please refer to [Annex II](#) for documents to be submitted **at least 10 working days before** site inspection and [Annex III](#) for documents to be ready **on site** for inspection.

Q16 What would be the consequences if the application is incomplete?

A16 If documents required to be submitted are incomplete, the application may be considered as deemed withdrawn after the submission deadline and reminders. The applicant will be notified to collect the documents submitted. Unclaimed documents will be disposed of in accordance with DH procedures. Applicants may submit the application again when the application form is completed and all required documents are prepared.

Q17 How long would it take for processing the application?

A17 When information necessary for conducting on-site compliance inspection has been submitted, DH will normally conduct the site inspection **within one calendar month** from the date the hospital is ready for inspection. If clarification and further information have to be sought from your Hospital, amendment to the application has to be made after submission, or alteration or improvement to the premises have to be carried out to meet the licensing requirements, the time for processing the application would be extended accordingly.

Upon completion of the assessment (including inspection(s)) and receipt of all documents required, the application results and a new licence (where appropriate) will be issued to the licensee **within 15 working days**.

Q18 How can I display the certificate of licence properly in electronic form?

A18 You shall display the latest certificate of licence (including the annex) through electronic means (e.g. using flat panel display) in a conspicuous place in the hospital. The size and clarity of the electronic display should be comparable to that of the original certificate of licence in paper form. The certificate of licence in electronic form should NOT be printed out for display.

The certificate of licence in electronic form is available for download at e-Licensing. You may log in [e-Licensing](#) to obtain the latest certificate of licence and conditions under “Licence / Exemption Profile”.

Q19 Under what circumstances will my application for variation of service / particulars be refused?

A19 Under any of the following circumstance(s) the application for variation of service / particulars may be refused –

- (i) The DoH considers that it is not appropriate to approve the application
- (ii) The licensee or chief medical executive of the hospital contravenes or has contravened –
 - the Ordinance
 - a condition of the licence

- the Code of Practice for Private Hospitals *or*
 - a direction
- (iii) The DoH is satisfied that the practice carried on in the hospital is a practice other than that specified in the licence
- (iv) The DoH is satisfied that the hospital is, or has been, used in a way not serving a purpose reasonably incidental to the type of facility for which the licence is issued
- (v) The DoH considers that the hospital is being, or has been, operated in a way contrary to the public interest
- (vi) The licensee or chief medical executive of the hospital has been convicted of an offence under the Ordinance
- (vii) The licensee of the hospital –
- if a company – has commenced to be wound up or dissolved
 - if a body corporate other than a company – has ceased to exist or carry on any business
- (viii) The licensee or chief medical executive of the hospital has made a false statement –
- in the application *or*
 - in any report, information or document required by the DoH
- (ix) The DoH is satisfied that the licensee of the hospital is operating a type of facility other than that for which the licence is issued
- (x) The DoH is satisfied that the licensee of the hospital has ceased to operate or have control over the hospital
- (xi) The DoH is satisfied that the hospital has ceased to exist or be operated

**Documents required to be submitted with the
“Letter of Intent for Extension / Redevelopment of Hospital Block”**

1. Key information about the extension / redevelopment of hospital block to be included in the Letter of Intent

- (a) Scope and scale of service(s) to be provided (e.g. bed numbers, operating hours and scope of individual service)
- (b) Layout plan of the new extension / hospital block, with a master list on the location of each specific service ([FAQ 14](#))
- (c) Summary of the healthcare electricity standard(s) / code(s) by critical care areas¹ where the key design parameters are to be complied for intended use
- (d) Summary of the healthcare ventilation and air-conditioning standard(s) / code(s) by specialized ventilation areas² where the key design parameters are to be complied for intended use
- (e) Summary of the medical gas pipeline system standard(s) / code(s) by service areas where the key design parameters are to be complied for intended use

Note:

The applicant may submit the relevant schematic diagrams and layout plans to justify the proposed systems in compliance with the standards/codes as stated.

2. For application involving haemodialysis service

- (a) Schematic diagram(s) and layout plan(s) of the proposed water treatment, distribution and piping system

¹ Critical care area means an area in a hospital that provide life support or complex surgery, or where failure of equipment or a system is likely to jeopardize the immediate safety or even cause major injury or death of patients or caregivers. Examples are operating theatre / room, cardiac catheterisation service, interventional angiography room, intensive care unit, high dependency unit, special care unit, cardiac care unit, labour room, and accident & emergency resuscitation bay / room, etc.

² Specialized ventilation area means an area in a hospital with special ventilation design for infection control and / or occupational safety. Examples are operating theatre / room, isolation room, bronchoscopy room, laboratory with biosafety risk, burns unit, labour room, aseptic preparation facilities, etc.

**List of documents required to be submitted to DH
at least 10 working days before on-site inspection**

1. Documents regarding Staffing

- (a) 2-week duty roster of medical and allied health professionals (with staff name) for each service
- (b) 2-week duty roster of nursing staff and supporting care staff (with staff name) after commencement of each service
- (c) On-call duty roster (with staff name) of medical, nursing and supporting care staff for emergency service provided after office hour

2. Documents regarding healthcare engineering systems or installations

- (a) A certificate of compliance in prescribed form issued by a Registered Professional Engineer^Δ 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 specified standard(s) and in compliance with the requirements as set out in the Code of Practice for Private Hospitals.
- (b) A certificate of compliance in prescribed form issued by a Registered Professional Engineer^Δ of the mechanical discipline or building services discipline certifying that the specialized ventilation systems for the specialized ventilation areas have been designed, installed and completed in accordance with the specified standard(s) and in compliance with the requirements as set out in the Code of Practice for Private Hospitals.
- (c) A certificate of compliance in prescribed form issued by a Registered Professional Engineer^Δ of the mechanical discipline or building services discipline certifying that the medical gas pipeline systems for the served areas have been designed, installed and completed in accordance with the specified standard(s) and in compliance with the requirements as set out in the Code of Practice for Private Hospitals.

For samples of certificate of compliance for variation of hospital services, please visit ORPHF website (https://www.orphf.gov.hk/en/useful_information/forms) for information.

^ΔNote: A Registered Professional Engineer (R.P.E.) is a professional engineer registered in a specific discipline with the Engineers Registration Board under the Engineers Registration Ordinance (Cap. 409).

3. For application involving haemodialysis service

- (a) As-fitted schematic diagram(s) and as-fitted layout plan(s) of the proposed water treatment, distribution and piping system

4. For application involving aseptic preparation of medicinal products

- (a) 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)
- (b) Microbiological testing reports showing compliance with requirements for the relevant clean room(s) in accordance with international standards (if applicable)
- (c) Microbiological testing reports showing compliance with requirements for the relevant equipment for aseptic preparation (e.g. biosafety cabinets and pharmaceutical isolators) in accordance with international standards
- (d) 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)

List of documents to be available on-site for inspection

1. Staffing

- (a) Training records and / or training plans of relevant staff for each service
- (b) Records of relevant drills for the service, e.g. code blue, fire, electricity, water suspension, chemical spillage, blood spillage, etc.
- (c) Relevant qualifications, experience, and orientation programme records

2. Medical equipment/device and other major equipment/device

- (a) Testing and commissioning or maintenance report of equipment
- (b) Valid licence(s) / certificate(s) to prove fitness for safe operation of the equipment or exemptions granted subject to conditions as appropriate by relevant authorities in operating the equipment where applicable
e.g. operating irradiating apparatus under the Radiation Ordinance (Cap. 303), autoclave and air compressor (receiver) under the Boilers and Pressure Vessels Ordinance (Cap. 56)
- (c) Maintenance schedule as advised by the manufacturer and the record of the last maintenance
- (d) Information on whether the equipment/device has means of alternative power supply other than normal power source (e.g. built-in battery)

3. Policies and procedures on relevant services as stipulated in relevant chapters in the Code of Practice for Private Hospitals PHF(E) 11A

Examples are:

- (a) Policy on staff orientation and training (e.g. Staff orientation programme and training plans for aseptic preparation service)
- (b) Policy for systematic identification of each newborn baby immediately after delivery and throughout the hospital stay for new obstetrics and nursery services

4. Healthcare engineering systems or installations

Please refer to the Checklist of Documents of Healthcare Engineering Systems and relevant policies to be available on site for inspection ([PHF 116](#)) in respect of the following:

- (a) Electrical installations
- (b) Specialized ventilation systems
- (c) Medical gas pipeline systems

5. For application involving haemodialysis service

- (a) Testing reports of the water sample obtained from the water treatment and distribution system substantiating compliance with relevant international standards
- (b) As-fitted schematic diagram(s) and as-fitted layout plan(s) of the proposed water treatment, distribution and piping system
- (c) Maintenance manual, instruction, planned preventative maintenance schedule and record of the proposed water treatment, distribution and piping system

6. Other documentary proof of compliance of Code of Practice for Private Hospitals

Examples are:

- (a) Certificate(s) of fire service installation and equipment, e.g. FS251, FSI/314A, FS172 (where applicable)
- (b) Work completion certificate(s) of fixed electrical installation, e.g. Form WR1
- (c) Approved document for general building plan issued by Building Department or other authorised parties
- (d) Approved document issued by Building Department and/or other authorised parties and associated building plans