



Guidance Notes for Application for Variation of Service / Particulars of Hospitals

1 What changes in the hospital are considered as a variation of service / particulars?

The licensee of a hospital shall apply to the Director of Health (DoH) for variation of hospital service or particulars.

(i) Variation of particulars is any change of the following –

- Change of name or contact information of –
 - hospital
 - licensee
 - authorized representative of licensee
 - chief medical executive (CME)
- Change of authorized representative of licensee or CME
- Change in the membership of Medical Advisory Committee (MAC)

(ii) Variation of service is any change of the following –

- Change in the scale or scope of services as specified in the hospital licence
- Change in the physical location where the services specified in the annex of the hospital licence
- Material change to the premises of the hospital, including but not limited to –
 - Addition, alteration and/or improvement to the electrical installations for critical care areas, specialized ventilation systems or medical gas pipeline systems
 - Change in non-movable walls of clinical or clinical supporting services, e.g. renovation
 - Change in water treatment and distribution system for haemodialysis

For applications regarding a change of licensee, e.g. from one company to another company, or relocation of the hospital, application for a new licence shall be made and Application form for hospital licence (PHF 14) shall be used.

For applications involving extension of a hospital block or redevelopment of an existing hospital block, please refer to Guidance Notes for Application for Hospital Licence (Cap. 633) (PHF(E) 14A) clauses 3.3 - 3.8 and contact officers of Office for Regulation of Private Healthcare Facilities (ORPHF) for application details.

2 Preparation before applying for variation of hospital service / particulars

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](#).

3 Who can submit the application?

The authorized representative of the licensee of a hospital shall be responsible for the application for variation of hospital service / particulars.

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.

4 When should I apply?

(i) **Variation of particulars** [see [Flowchart\(1\)](#) for application process]

You shall complete and submit to ORPHF relevant parts (Sections A1 - A5) of the application form (PHF 111) with the required documents (if applicable) **no later than 14 days** after the change has occurred.

(ii) **Variation of service** [see [Flowchart\(2\)](#) for application process]

(a) Letter of intent for variation of service

You are advised to submit to ORPHF a Letter of Intent for Variation of Service ([FAQ Q11](#)) **at least 3 months before** the intended date of new service or service commencement for the proposed variation. Please see [Annex I](#) for the list of information and documents to be submitted with the letter of intent. If the variations involve addition, alteration and/or improvement of healthcare engineering systems or installations, relevant documents (see PHF 112 for the document checklist) shall also be submitted with the letter of intent.

You shall then formally submit an application for variation of service for the proposed changes.

(b) Application for variation of service

At least 2 months before the intended date of service commencement for the proposed variation(s), you shall complete and submit relevant parts (Section A6) of the application form PHF 111, together with the required documents 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 (where applicable).

5 **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
6/F, Guardian House
32 Oi Kwan Road
Wan Chai, Hong Kong

After submission of the application form and all required documents, you will soon be notified by email to obtain a general demand note at e-Licensing for payment if application fee is required.

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.

6 When and how should I pay the application fee?

The amount of application fee ([FAQ Q2](#)) is based on the type of variation and the scale of service for variation. If application fee is required, 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.

7 Preparations if site inspection is required

Any variation of service may require inspection of the premises of the hospital. If site inspection is indicated, you shall prepare –

- (i) Documents to be submitted **at least 10 working days before** site inspection

Required documents as listed in [Annex II](#)

- (ii) Documents to be ready for **on-site** inspection

Required documents as listed in [Annex III](#)

- (iii) Your premises for site inspection

You shall inform ORPHF when your premises is ready for site inspection. Our officer will then confirm the date of inspection with you **within 10 working days** after receiving all required documents before site inspection.

Failure in submitting the required documents to ORPHF by the deadline may delay the site inspection.

8 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. A deadline for such follow-up action(s) will be provided to you by ORPHF officers.

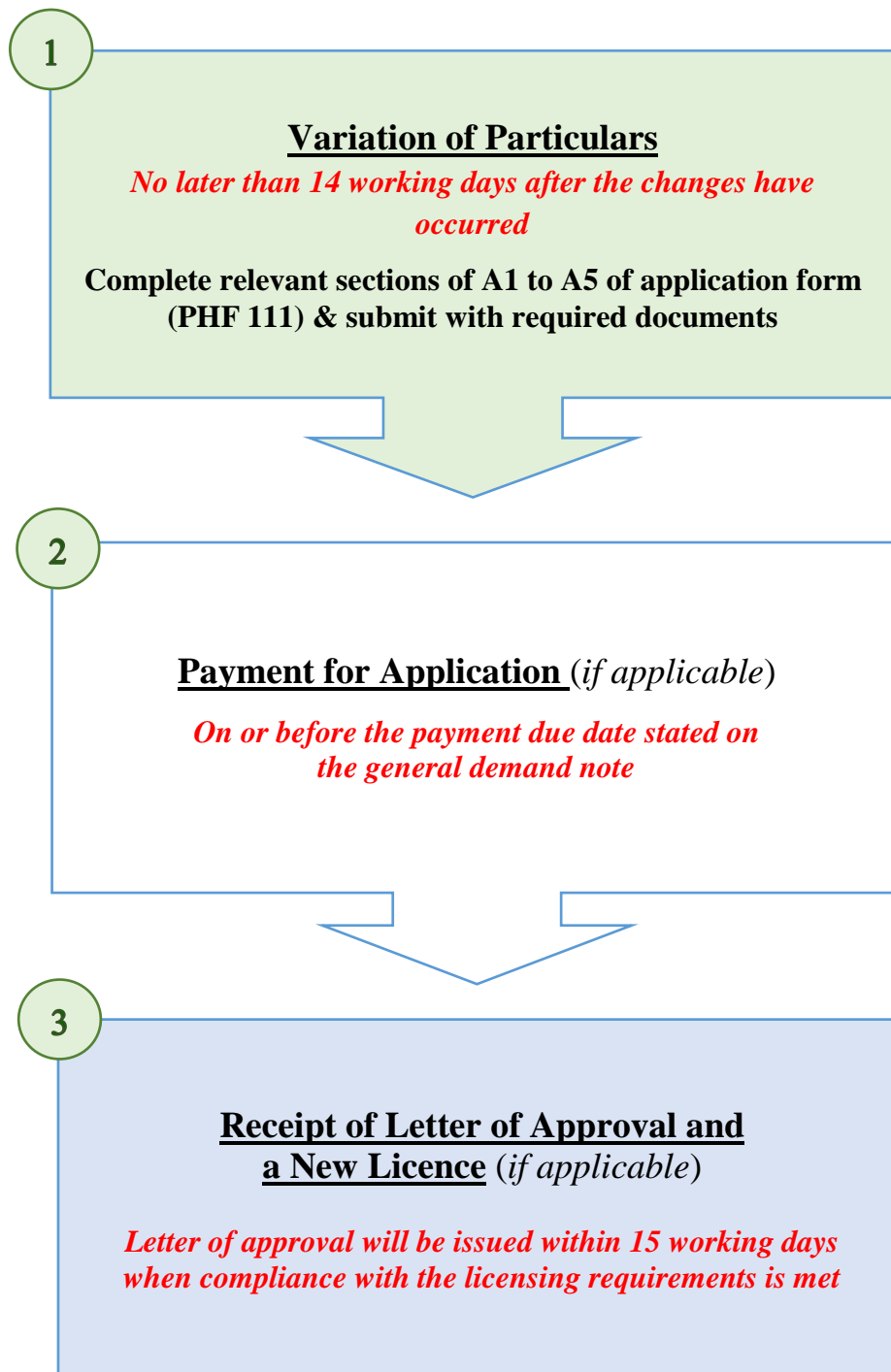
Furthermore, you may be required to prepare for additional on-site inspection(s) after completion of all required alterations and improvements to the relevant services / units.

9 When will I be notified of the application result?

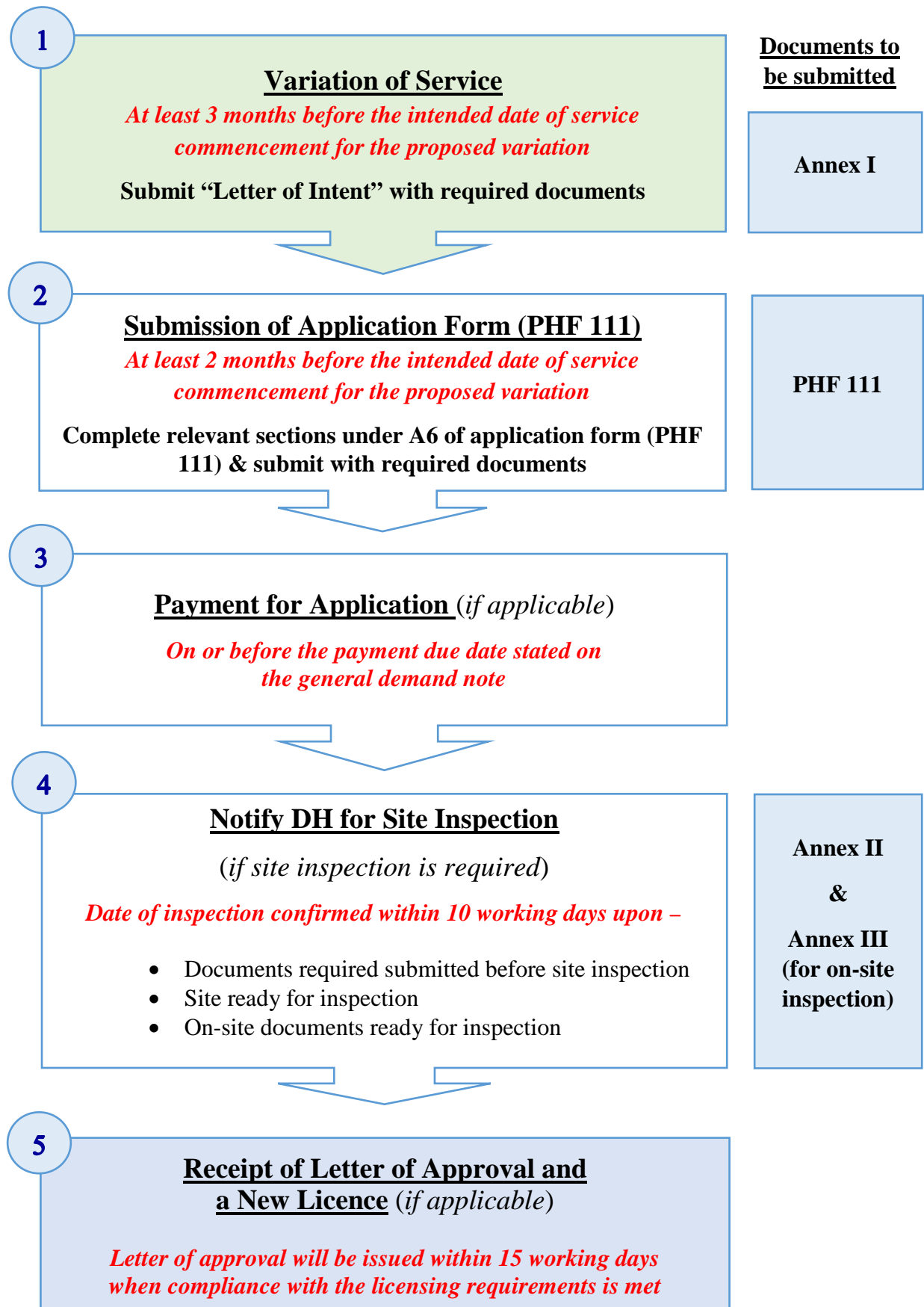
Upon completion of inspection(s), as necessary, and receipt of all documents required, normally the licensee will be informed of the application results in writing **within 15 working days**.

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.

Flowchart (1) for Application for Variation of Particulars of a Hospital



Flowchart (2) for Application for Variation of Hospital Service



Frequently Asked Questions

Q1 How can I apply for variation of service / particulars through e-Licensing?

A1 Authorized representative of the licensee shall log in e-Licensing to complete the application form. Please follow the steps below to proceed to an application for variation of service / particulars.

- (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(es) for Sections (A1 – A6) that require variations
- (vi) Input the updated information under the “New” column. Leave **blank** if there is no change in the information under the “Current” column
- (vii) Click “Save” or “Save and Continue” to save the changes
- (viii) Click “Back” to go back to previous section
- (ix) Click “Confirm Information” after final checking of data inputted

For more details, please refer to the user guide **after** log in e-Licensing.

Q2 What is the application fee for variation of service / particulars?

A2 The application fee is based on the type of variation and the scale of service for variation and is listed as follows –

Type of variation	Application Fee*
Variation of service by a hospital for a change of facility service without variation in hospital beds	\$ 20,250
Variation of service by a hospital for a change of facility service with variation in hospital beds by –	
- up to 25 beds	\$ 20,250
- 26 to 50 beds	\$ 24,750
- more than 50 beds	\$ 29,750
Amendment of licence apart from the above	\$ 365

*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 variation of service / particulars and the required fees –

Variation of Service / Particulars applied for	Fee
Change the name of hospital	\$ 365
Change particulars of existing licensee, e.g. change the name of the company/organization	\$ 365
Cessation of a clinical service, e.g. Out-patient service by Chinese medicine practitioner(s)	\$ 365
Closure of associated premises	\$ 365
Add one day bed at haemodialysis service	\$ 20,250
Reduce 2 day beds at chemotherapy service	\$ 365
Expand the paediatric service by increasing 30 in-patient beds	\$ 24,750
Change the name of hospital and expand the paediatric service by increasing 30 in-patient beds	\$ 24,750
Alteration of the electrical installations of operating room	\$ 20,250

Q4 Is application fee applied for any change in the variation of service / particulars?

A4 Application fee is required for variation of service / particulars. However, the following amendments require no application fee:

- (i) Contact information of hospital
- (ii) Correspondence of licensee
- (iii) Change of particulars of authorized representative of licensee
- (iv) Change of particulars of CME
- (v) Change in the membership of MAC

Q5 The name of my hospital and the name of existing licensee will be changed. Do I need to apply for the changes? If so, how much shall I pay for these two changes?

A5 Yes, the authorized representative of the licensee of your hospital shall complete and submit the relevant parts of Sections A1 and A2 of application form **no later than 14 days** after the change has occurred. You shall pay \$365 for the amendment of licence. 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.

Q6 My hospital is going to be operated by another company. Should I apply for a variation of service / particulars and complete Section A2 of the application form for change of name of existing licensee?

A6 No. The new operator of your hospital shall apply for a new licence using the application form PHF 14.

The change of name of existing licensee in Section A2 of the application form for variation of service / particulars refers to **no** change of the company who operates the hospital. The Certificate of Incorporation number of the company who is the licensee does not change after its name has changed.

Q7 Is relocation of the hospital or associated premises considered as an amendment of hospital address or address of associated premises in Section A1 of the application form?

A7 No. Relocation of associated premises shall apply for a variation of service. Please refer to Section A6 (item 6.6) of the application form regarding the change in the particulars or clinical services of associated premises.

Relocation of the hospital premises shall apply for a new hospital licence. Please refer to the Guidance Notes for Application for Hospital Licence (PHF(E) 14A) for details.

Q8 The Licensee of my hospital would like to appoint a new authorized representative to replace the existing one. Do I need to inform DH?

A8 Yes, the licensee shall inform ORPHF about the change of authorized representative. ORPHF would periodically communicate with the licensee, e.g. email reminder for licence renewal, through the authorized representative.

Please complete section A3 of the application form. Also, please note that a resolution in writing relating to the authorization passed by the Board of Directors of the company or body corporate shall also be submitted.

Q9 Do I need to update the user account at e-Licensing if our company wants to change the authorized representative of our hospital?

A9 Yes, the e-licensing account administrator of your hospital shall create a user account at e-licensing if the authorized representative does not have a user account. The user role “My Application” should be checked. Please read item 2.3 of the User Guide for Hospitals **after** log in e-Licensing (<https://apps.orphf.gov.hk/Submission>) for details.

Q10 How should I inform DH if I want to change the CME?

A10 You shall apply for a variation of particulars (see Section A4 of the application form) **no later than 14 days** after the change has occurred. The CME of a hospital must be a registered medical practitioner who has been registered for **not less than 15 years** in Hong Kong. Also, the CME must not serve at the same time as a CME of another private healthcare facility. The new CME shall complete the Declaration by the Chief Medical Executive of a Hospital (PHF 19).

Please also read Guidance Notes for Assessing Fitness and Properness of Applicants / Chief Medical Executives for Licence Application (PHF(E) 81A) for other requirements for CME.

Q11 Do I need to send a letter of intent to DH for any proposed variation of hospital service before submitting an application for variation?

A11 You are advised to notify ORPHF in advance by sending a letter of intent **at least 3 months before** the intended date of new service or service commencement for the proposed variation.

The letter of intent aims to facilitate both the applicant and DH to smoothen the upcoming application process. 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 and DH will not assess whether licensing requirements are met. If the variations involve any addition, alteration and/or improvement to the electrical installations for critical care area, specialized ventilation systems, or medical gas pipeline systems, additional documents are required for submission. Please refer to [Annex I](#) for the list of documents to be submitted with the letter of intent.

Q12 My hospital will have a variation of service completed by the end of Quarter 1 and another one completed by the end of Quarter 2 of this year. How should I submit the application for variation of service?

A12 You are advised to notify ORPHF in advance by sending a letter of intent **at least 3 months before** the intended date of service commencement for **each** variation of service. You should then submit an application in January or early February for variation of service to be completed in Quarter 1 and another application in April or early May for variation of service to be completed in Quarter 2.

Q13 My hospital is planning to have some changes involving clinical services of in-patient beds and day beds. Should I apply for a variation of service?

A13 Yes, variation of service of different categories specified in the licence requires prior approval by DoH. Examples are –

- (i) Conversion of an in-patient ward into a maternity ward
- (ii) Change the endoscopy procedure room to an operating room
- (iii) Change of haemodialysis day beds to chemotherapy day beds

Q14 Does suspension or reshuffling of service, or replacement of equipment consider as a variation of hospital service?

A14 Application for variation of service is not required if the changes are of the following natures –

- (i) Temporarily suspension of service
- (ii) Reshuffling of services within an approved out-patient clinic that does **not** involve any structural change in the premises or any alteration of electrical installations for critical care areas, specialized ventilation systems, or medical gas pipeline systems
- (iii) Provision of new equipment or replacement of equipment (e.g. CT scan) in an existing service that does **not** affect the scale or scope of hospital services

Q15 Which hospital services are considered as critical care areas?

A15 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.

Q16 Can I propose an alternative healthcare engineering standard / code in my hospital other than those recommended in the Code of Practice for Private Hospitals?

A16 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.

Q17 What information should be indicated on the layout plan of each clinical or clinical supporting service / unit in my application?

A17 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)

Q18 What documents have to be ready for inspection?

A18 If on-site inspection is required, relevant documents regarding the variation of service applied for have to be ready for inspection. Some documents are to be submitted **at least 10 working days before** site inspection and some documents are to be ready **on site** for inspection. Please see [Annex II](#) and [Annex III](#) for details.

For variation of service involving addition, alteration and/or improvement in the healthcare engineering systems or installations, please also refer to Checklist of Documents of Healthcare Engineering Systems and Relevant Policies to be Available on site (PHF 116) for inspection.

Q19 What would be the consequences if the application is incomplete?

A19 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.

Q20 How long would it take for processing the application?

A20 For application involving variation of hospital service, the application process normally takes around **2 months**, excluding the time taken by the applicant for submission of clarification and supplementary information, preparation of the premises and documents for site inspection, or alteration or improvement to the premises to meet the licensing requirements. If any of the above events occurs, the processing time would extend accordingly and may take more than 2 months.

Upon completion of the assessment (including inspection, if required) 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**.

Q21 Under what circumstances will my application for variation of service / particulars be refused?

A21 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

A written notification of refusal with reason(s) would be issued to the licensee **within 15 working days** from the date of last submission of documents / information from the applicant. If the licensee is aggrieved, he / she may appeal to the Administrative Appeals Board.

**Documents required to be submitted with the
“Letter of Intent for Variation of Service”**

1. Key information about the proposed variation of service to be included in the Letter of Intent

- (a) Location of new / expanded / reshuffled service(s) or alteration works
- (b) Nature of service(s) to be provided
- (c) Expected date of service commencement for the proposed variation
- (d) Outline of proposed variation(s)
- (e) Indicating whether there is / are addition, alteration and/or improvement in the healthcare engineering systems or installations i.e. electrical installations for critical care areas, specialized ventilation systems, or medical gas pipeline systems

2. Documents to prove fitness for carrying out the service in respect of accommodation

- (a) Layout plan of the premises with indication of original layout and change(s) after variation
- (b) For proposed services involving *critical care areas*[#]
 - Summary of the healthcare electrical standard(s) / code(s) by critical care areas where the key design parameters are to be complied for intended use
 - Schematic diagram(s) of the electrical installations
 - Layout plan(s) of the electrical installations
- (c) For proposed services involving *specialized ventilation areas*[#]
 - Summary of the healthcare ventilation and air-conditioning standard(s) / code(s) by specialized ventilation areas, where the key design parameters are to be compiled for intended use
 - Air-side schematic diagram(s) of the specialized ventilation systems
 - Layout plan(s) of the specialized ventilation systems

- (d) For proposed services involving *medical gas pipeline systems*[#]
- Summary of the type(s) of medical gases to be provided and the relevant healthcare engineering standard(s) / code(s) where the key design parameters are to be compiled for intended use
 - Schematic diagram(s) of the medical gas pipeline systems
 - Layout plan(s) of the medical gas pipeline systems

[#]*Note:*

For proposed services (2b) to (2d) involving the healthcare engineering systems or installations, please refer to the “Checklist of Documents of Healthcare Engineering Systems required to be submitted with the Letter of Intent for Variation of Service” (PHF 112) available at ORPHF website

https://www.orphf.gov.hk/en/useful_information/forms

3. For application involving haemodialysis service

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

**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. For application involving addition, alteration and/or improvement of 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 on management of patient safety incidents

4. For application involving addition, alteration and/or improvement in the healthcare engineering systems

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 of 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 Buildings Department or other authorised parties (where applicable)
- (d) Approved document issued by Buildings Department and/or other authorised parties and associated building plans (where there is any structure change of the premises)