†

Office for Regulation of Private Healthcare Facilities

Department of Health

Guidance Notes for Application for Variation of Service / Particulars of Day Procedure Centres

1. What changes in the Day Procedure Centre (DPC) are considered as a variation of service / particulars?

The licensee of a DPC shall apply to the Director of Health (DoH) for variations of DPC services or particulars.

- (i) Variation of particulars is any change of the following
 - Change of name or contact information of
 - DPC
 - Licensee
 - Authorized Partner
 - Authorized Representative of Company or Organization
 - Chief Medical Executive (CME)
 - Change of authorized partner or authorized representative of company / organization
 - Change of CME
 - Retirement from Partnership
- (ii) Variation of service is any change of the following
 - Change in the scale or scope of services as specified in the DPC licence
 - Change in the particular medical procedures provided in the DPC premises
 - Change in the physical location where the services specified in the annex of DPC licence
 - Material change to the DPC premises, including but not limited to
 - Additions and/or alterations to the healthcare engineering systems, namely electrical installations for critical care areas, specialized ventilation systems and medical gas pipeline systems
 - Additions and/or alterations to the dental compressed air and vacuum systems

PHF(E) 26A (3/2024) Page 1 / 22

- Change in non-movable walls of clinical or clinical supporting services, e.g. renovation
- Change in water treatment and distribution system for haemodialysis

For application involving relocation of premises or change of licensee, you shall apply for a new licence using the Application Form for Day Procedure Centre Licence (PHF(E) 22A) (see <u>FAO O6</u> and <u>O7</u>).

2. Preparation before applying for variation of service / particulars

Please refer to the Private Healthcare Facilities Ordinance ("the Ordinance"), the Code of Practice for DPCs (PHF(E) 21A), and this guidance notes. These documents are available at ORPHF website.

3. Who can submit the application?

The licensee or its authorized partner / representative shall be responsible for the application for variation of DPC service / particulars.

Any change of particulars of the existing licensee or its authorized partner or representative shall also be indicated in (Section A2 / A3) in the same application. For change of authorized partner or authorized representative of company / organisation, please refer to <u>FAQ Q8</u> for the supporting documents required for submission.

4. When should I apply?

(i) Variation of particulars

You shall complete relevant parts (Sections A1 – A4) of the application form PHF 26 with the required documents (if applicable) and submit to the Office for Regulation of Private Healthcare Facilities (ORPHF) **no later than 14 days** after the change has occurred.

(ii) Variation of service

For Licensee granted with Provisional DPC Licence, please notify DH officer at least **2 months** before the intended date of service commencement for the proposed variation(s).

For Licensee granted with Full DPC Licence, you are advised to apply for variation of service at least 2 months before the intended date of service commencement for

PHF(E) 26A (3/2024) Page 2 / 22

the proposed variation(s). You shall complete and submit relevant parts (Section A5) of the application form, together with the required documents to ORPHF.

We will process your application only after the completed application form and all required documents are received, as well as the application fee (where applicable) is settled.

5. How can I apply?

You can submit the application through e-Licensing or by paper application form –

(i) e-Licensing

The licensee or its authorized partner / representative shall log in e-Licensing (*FAQ Q1*) to apply for the variation. The application can be submitted online by using <u>iAM Smart+</u> 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.

(ii) Paper application form

You can download the application form (PHF 26) and relevant documents at <u>ORPHF website</u>. The completed application form, together with the required documents, shall be submitted by post or in person, to ORPHF.

PHF(E) 26A (3/2024) Page 3 / 22

After submission of the application form and all required documents, a reference number will be sent to you later. If application fee is required, you will soon receive by email a general demand note for payment of application fee. 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 (<u>FAQ Q2</u>) is based on the type of variation and the scale of services 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 DPC. DH will arrange inspection for variation of services and you shall inform DH officer 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 documents required before site inspection specified as follows –

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

 Required documents are listed in Annex I
- (ii) Documents to be ready for on-site inspection

Required documents are listed in Annex II

Please note that failure in submitting the required documents to DH by the deadline may delay the site inspection.

PHF(E) 26A (3/2024) Page 4 / 22

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 DPC for fulfilling the licensing criteria. A deadline for such follow-up action(s) will be provided to you by DH 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, DH will normally inform you of the application result in writing within 15 working days.

If changes of 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.

10. 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 DPC. 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 if the licensee has registered an account at e-Licensing. Display of a photocopy of the certificate of licence or a printout of the electronic licence is **not** acceptable.

PHF(E) 26A (3/2024) Page 5 / 22

Flowchart for Application for Variation of Service / Particulars of DPC

1

Variation of *Particulars*

No later than 14 days after the changes have occurred

Complete relevant sections of A1 to A4 of application form (PHF 26) & submit with required documents

1

Variation of Service

At least 2 months before service commencement for the proposed variation

Licensee with <u>Provisional DPC Licence</u>, please notify DH officer direct (see <u>FAQ 13</u>)

Licensee with <u>Full Licence</u>, please complete relevant sections under A5 of application form (PHF 26) & submit with required documents

2

Payment for Application (*if applicable*)

On or before the payment due date stated on the general demand note

3

FOR VARIATION OF DPC SERVICE

Notify DH for Site Inspection

(if site inspection is required)

Date of inspection confirmed within 10 working days upon -

- Documents required submitted before site inspection
- Site ready for inspection
- On-site documents ready for inspection

4

Receipt of Letter of Approval and a New Licence (if applicable)

Letter of approval will be issued within 15 working days when compliance with the licensing requirements is met

Display the latest Certificate of Licence (including the annex) in a conspicuous place in the day procedure centre, either in its original paper form or in electronic form via electronic means

PHF(E) 26A (3/2024)

Frequently Asked Questions

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

- A1 Licensee or its authorized partner / representative shall log in e-Licensing using the User ID that is *previously* used for applying the DPC licence. Please follow the steps below to proceed 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 the licence profile before making an application, click "Licence / Exemption 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 A5) 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 sections
 - (ix) Click "Confirm Information" after final checking of data inputted

For more details, please refer to the User Guide at the login page of e-Licensing.

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

A2 The application fee is based on the variation in the scale and scope of services of the DPC and is listed as follows –

Type of DPC	Application Fee*
Variation of service by a DPC for a change in class of specialized service, or a change in total number of doctor or dentist consultation rooms, designated rooms for medical procedures and operating rooms by –	
- 0 to 5 rooms	\$ 8,860
- more than 5 rooms	\$ 11,100
Amendment of licence apart from the above	\$ 365

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

PHF(E) 26A (3/2024) Page 7 / 22

Q3 Can I have some examples of 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 DPC	\$ 365
Change of the name of the licensee who is a company or organisation	\$ 365
Appoint a new authorized partner / authorized representative of company or organization	Not required
Appoint a new CME	Not required
Change the name of DPC and change an endoscopy procedure room to an operating room	\$ 8,860
Add anaesthetic procedure as a class of specialized service without any change in the total number of rooms*	\$ 8,860
Change the total number of doctor consultation rooms from 1 to 8	\$ 11,100
Additions and/or alterations to the healthcare engineering systems, namely electrical installations for critical care areas, specialized ventilation systems and medical gas pipeline systems (for application received by ORPHF before 1 January 2028)	Not required
Additions and/or alterations of dental compressed air and vacuum systems	Not required

^{*}Total number of rooms refers to the total number of doctor or dentist consultation rooms, designated rooms for medical procedures and operating rooms

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

- A4 Application fee is required for variation of service / particulars. However, the following amendments require no application fee
 - Contact information of DPC
 - Correspondence of licensee
 - Change of authorized partner / authorized representative of licensee
 - Change of particulars of the existing authorized partner / authorized representative of licensee
 - Change of CME or particulars of existing CME

PHF(E) 26A (3/2024) Page 8 / 22

- Q5 My DPC is going to rename soon. Do I need to apply for the change? If so, how much shall I pay for the application?
- Yes, the relevant part of Section A1 of application form (PHF 26) shall be completed and submitted to DH no later than 14 days after the change has occurred. To avoid duplicating the name of other licensed private healthcare facilities (PHF), you are advised to conduct a search at the Private Healthcare Facilities Register (https://www.directory.orphf.gov.hk) to check whether the intended name of your DPC is the same as other licensed PHF.

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. You shall pay \$365 for amendment of the licence.

- Q6 I am planning to move my DPC from Building A to Building B. Should I apply for a variation of service / particulars?
- A6 Relocation of DPC premises is **not** considered as a variation of service / particulars. Applicant shall submit an application for a new DPC licence using the Application Form for Day Procedure Centre Licence (PHF 22) for relocation of DPC.
- Q7 My DPC will be operated by another company. Should I apply for a variation of service / particulars for change of name of existing licensee (Section A2 of application form)?
- No, the new operator of the DPC shall apply for a **new** DPC licence using the Application Form for Day Procedure Centre Licence (PHF 22). Please refer to the Guidance Notes for Application for DPC Licence (PHF(E) 22A) for details.
- Q8 My DPC would like to appoint a new authorized partner / authorized representative to replace the existing one. Do I need to inform DH?
- Yes. The licensee shall inform DH about the change of authorized partner / authorized representative. DH would communicate periodically with the licensee through the authorized partner / authorized representative, e.g. email reminder for licence renewal. Please complete Section A3 of the application form.

PHF(E) 26A (3/2024) Page 9 / 22

The supporting document required can be (i) a resolution or a minutes of the Board of Directors to appoint the authorized representative; or (ii) an authorization letter signed by **all** directors of the company (or by **all** partners for partnership) and an updated list of directors where necessary.

The supporting document shall include the following information –

- name of the licensee (partnership / company / body corporate other than a company, or society)
- name and the Hong Kong Identity Card / Passport Number (only for non-Hong Kong Identity Card Holder) of the authorized partner / authorized representative
- name of the day procedure centre
- the authorized representative appointed represents the licensee to handle all matters related to the DPC licence *and*
- effective date of authorization

A sample of authorization letter is available at **Annex III** for reference.

- Q9 Do I need to update the user account at e-Licensing if I want to change our authorized partner or the authorized representative of my company / organisation?
- Yes, you shall update the user account and email address of the authorized partner / authorized representative at e-Licensing as appropriate. Please read item 2.3 of the User Guide at the login page of e-Licensing (https://apps.orphf.gov.hk/Submission/) for details.
- Q10 The existing licensee of our DPC includes 3 partners. One of them will retire from the partnership. How can I inform DH and how much shall I pay for the change?
- A10 You shall complete Section A2 of the application form PHF 26. If the partner who retired from the partnership is the authorized partner, please also complete Section A3 for the change of authorized partner. The completed application form and an authorization letter shall be submitted to DH. The authorization letter shall be signed by all partners indicating the authorized partner to represent the licensee to handle all matters related to the DPC licence. A sample of authorization letter is at **Annex III** for reference.

You shall pay \$365 for amendment of the licence.

PHF(E) 26A (3/2024) Page 10 / 22

Q11 How should I inform DH if I want to change the CME?

You shall apply for a variation of particulars **no later than 14 days** after the change has occurred. The CME of DPC with medical practice must be a registered medical practitioner who has been registered for **not less than 6 years** in Hong Kong. For DPC with dental practice only, the CME must be a registered dentist who has been registered for **not less than 6 years** in Hong Kong. Also, the CME must not serve at the same time as a CME of a hospital, or as a CME for more than 2 DPCs, or more than 1 DPC and 1 clinic. The new CME shall complete the Declaration by the Chief Medical Executive of a DPC (PHF 24). Please refer to Section A4 of the application form for details.

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.

Q12 Does suspension or reshuffling of service, or replacement of equipment considered as a variation of DPC service?

- Application for variation of service is not required if the changes are of the following natures
 - (i) Temporary suspension of service
 - (ii) Reshuffling of consultation services for doctors that **does not** involve any change in the class of specialized services or the layout of DPC, or any additions and/or alterations to healthcare engineering systems
 - (iii) Provision of new equipment or replacement of equipment in existing services that **does not** affect the scale or scope of DPC services

Q13 Can I make any variation on the scale and scope of services specified on the provisional DPC licence?

A13 If you intend to vary the scale or scope of services of DPC with a provisional licence, you are required to notify DH 2 months before the intended date of service commencement for the proposed variation(s). A DPC with varied scale or scope needs to fully comply with the CoP. DH will assess the application of variation along with other requirements for the full licence.

PHF(E) 26A (3/2024) Page 11 / 22

If the variation results in an increase of the number of rooms to be counted, **additional fee** may apply.

- My DPC is going to expand the service for endoscopic procedure and increase the number of procedure rooms from 2 to 4. How should I complete the online application form?
- A14 After log in e-Licensing (<u>FAQ Q1</u>) and the application form is created, please follow the steps below to complete the application form online.
 - (i) Check "A5" for variation of DPC service
 - (ii) Under "Please list out the variation details", input the details of proposed variations
 - (iii) Indicate whether there is any change in:
 - healthcare engineering systems or installations, or water treatment and distribution system, AND
 - layout plan of clinical / clinical supporting services of the premises
 - (iv) Check on the items where variation is proposedi.e. "Change in the number of rooms" & "Change of class of specialized service or its particular medical procedures"
 - (v) A table expanded indicating the *current* scale and scope of service of the DPC is displayed
 - (vi) Under the column "Number of rooms increased or decreased", input the number of designated rooms for medical procedures to be increased, i.e. 2
 - (vii) Under the column "New" for "Endoscopic procedure", click "Yes" and check the relevant particular medical procedures under "Endoscopic procedure"
 - (viii) Click "Save and continue"
 - (ix) Click "Confirm Information" after final checking of the information inputted
 - (x) Follow the instructions to submit the application form and the supporting documents to DH

PHF(E) 26A (3/2024) Page 12 / 22

- My DPC currently provides image-guided core biopsy services under the class of specialized service "Interventional Radiology and Lithotripsy". I am planning to add the extracorporeal shock wave lithotripsy (ESWL) requiring image guidance as a new service. I note that this new service is a scheduled medical procedure under the same class of specialized service. Do I need to apply for a variation of service?
- Yes, any change in the scheduled medical procedures provided in a DPC is a change in the scope of service, no matter if the change is within the same class of specialized service specified in the licence or not. You shall apply for a variation of service for your DPC.

Q16 What information shall be indicated on the layout plan for variation of service?

- A16 Any change in the layout of clinical or clinical supporting services of the DPC shall be submitted to DH for prior approval. The layout plan shall
 - be drawn to a scale **not less than 1:100** and expressed in metric units
 - indicate non-movable walls by double lines
 - indicate the boundaries of the areas for variation of the premises by coloured lines
 - indicate the boundaries of the DPC by coloured lines (different colour as appropriate)

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

- (i) Entrance and exit
- (ii) Consultation room for doctor, consultation room for dentist, operating room, designated room for medical procedures, recovery room, room for clinical and clinical supporting services, e.g. Room for Physiotherapy
- (iii) Area for equipment reprocessing
- (iv) Hand-washing and sanitation facility
- (v) Dirty utility room
- (vi) Reconstitution facility where cytotoxic drugs are handled
- (vii) Door
- (viii) Location of major equipment required for the facility service, e.g. anaesthetic machine, biosafety cabinet or isolator, haemodialysis machine, water treatment system, imaging machine, radiotherapy equipment
- (ix) Reception and waiting area

PHF(E) 26A (3/2024) Page 13 / 22

Q17 What does it mean by critical care area in a DPC setting?

"Critical care area" means any area in a facility where failure of electrical power supply is likely to jeopardise the immediate safety or even cause major injury or death of patients or caregivers. Examples are operating room and recovery area.

Q18 Do I need to ensure the healthcare engineering systems in my DPC comply with Section 1.6 of the Code of Practice for Day Procedure Centres (PHF(E) 21A)?

A18 Requirements for the healthcare engineering systems, namely electrical installations for critical care areas, specialized ventilation systems and medical gas pipeline systems, have been included in Section 1.6 of the Code of Practice for Day Procedure Centres. As a transitional arrangement, these requirements as specified therein will take effect from 1 January 2028. You are required to ensure the compliance of requirements and complete the corresponding application process within the transitional period.

Q19 My DPC is planning to equip with the healthcare engineering systems. Is there any channel for professional opinions?

You are recommended to seek professional support from relevant service providers since early stage (e.g. competent consultant / contractor / relevant professional with healthcare engineering experience) to carry out design, installation, testing and commissioning for healthcare engineering systems and/or obtain professional opinion in compliance with the provision of relevant ordinances, codes of practice, internationally acceptable standards and guidelines as necessary. For information of healthcare engineering systems service providers in more detail, please visit our website at:

https://www.orphf.gov.hk/en/useful_information/information_of_healthcare_engineerin g_systems_service_providers_background

PHF(E) 26A (3/2024) Page 14 / 22

- Q20 My DPC is planning to install additional electrical systems for the operating room.

 What are the aspects I need to consider prior to my application for variation of service?
- **A20** The electrical installations of the DPC are designed, installed, operated and maintained to provide safe and reliable electrical supply and lighting to support the healthcare services therein.

Before the application for variation of service, please refer to the requirements set out in the Code of Practice for Day Procedure Centres (PHF(E) 21A), in particular Section 1.6 regarding the requirements for healthcare engineering systems.

In general, the design and installation of the electrical installations in critical care areas such as operating room meet internationally acceptable healthcare standards such as *Health Technical Memorandum (HTM) 06-01 (2017 edition) – Electrical services supply and distribution*, or equivalent.

- Q21 My DPC is planning to install a medical gas pipeline system (MGPS) for the provision of surgical and anaesthetic procedure. What are the aspects I need to consider prior to my application for variation of service?
- MGPS means a system comprising sources of supply, a pipeline distribution system, terminal units (to which the user connects and disconnects medical equipment), and a warning and alarm system. It applies to medical gases, medical vacuum and anaesthetic gas scavenging disposal systems.

Before the application for variation of service, please refer to the requirements set out in the Code of Practice for Day Procedure Centres (PHF(E) 21A), in particular Section 1.6, Chapter 2 and Chapter 8 regarding the requirements for healthcare engineering systems, surgical procedure and anaesthetic procedure respectively.

In general, the design and installation of the MGPS meet internationally acceptable healthcare standards such as *Health Technical Memorandum (HTM) 02-01 (2006 edition)* – *Medical gas pipeline systems*, or equivalent.

PHF(E) 26A (3/2024) Page 15 / 22

- My DPC is planning to install a specialized ventilation system for the provision of surgical and anaesthetic procedures. What are the aspects I need to consider prior to my application for the variation of service?
- "Specialized ventilation system" means the ventilation system of an operating room in a facility. The specialized ventilations are designed, installed, operated and maintained for purposes including but not limited to
 - (i) the prevention of the spread of airborne infectious disease;
 - (ii) the prevention and control of healthcare-associated infection; and
 - (iii) the dilution and removal of contaminants and fumes where used

Before the application for variation of service, please refer to the requirements set out in the Code of Practice for Day Procedure Centres (PHF(E) 21A), in particular Section 1.6, Chapter 2 and Chapter 8 regarding the requirements for healthcare engineering systems, surgical procedure and anaesthetic procedure respectively.

In general, the design and installation of the specialized ventilation systems meet internationally acceptable healthcare standards such as *ANSI/ASHRAE/ASHE Standard* 170-2021 – Ventilation of Health Care Facilities, or Health Technical Memorandum (HTM) 03-01 (2021 edition) - Specialised ventilation for healthcare premises, or equivalent.

Q23 What documents have to be ready for on-site inspection?

A23 If on-site inspection is required, relevant documents regarding the variation of service applied for have to be ready for inspection. Please see <u>Annex I</u> for the list of documents to be submitted at least 10 working days before on-site inspection and <u>Annex II</u> for the list of documents to be ready on site.

Q24 What would be the consequences if the application is incomplete?

A24 If documents required to be submitted are incomplete, the application will 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.

PHF(E) 26A (3/2024) Page 16 / 22

Q25 How long would it take for processing the application?

A25 For application involving variation of 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 applicable) will be issued to the licensee within 15 working days.

Q26 How can I display the certificate of licence properly in electronic form?

You shall display the certificate of licence (including the annex) through electronic means (e.g. using flat panel display) in a conspicuous place in the DPC. 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. If you have registered an e-Licensing account, you may log in <u>e-Licensing</u> to obtain the latest certificate of licence and conditions under "Licence / Exemption Profile".

Q27 Under what circumstances will my application for variation of service / particulars be refused?

- **A27** Under any of the following circumstance(s) the application for variation of service / particulars may be refused
 - (a) The DoH considers that it is not appropriate to approve the application
 - (b) The licensee or chief medical executive of the DPC contravenes or has contravened—
 - the Ordinance
 - a condition of the licence
 - the Code of Practice for DPCs or
 - a direction

PHF(E) 26A (3/2024) Page 17 / 22

- (c) The DoH is satisfied that the practice carried on in the DPC is a practice other than that specified in the licence
- (d) The DoH is satisfied that a medical procedure belonging to a class of specialized service other than that specified in the licence is, or has been, provided in the DPC
- (e) The DoH is satisfied that the DPC is, or has been, used in a way not serving a purpose reasonably incidental to
 - (i) the type of facility for which the licence is issued or
 - (ii) the practice or class of specialized service specified in the licence
- (f) The DoH considers that the DPC is being, or has been, operated in a way contrary to the public interest
- (g) The licensee or chief medical executive of the DPC has been convicted of an offence under the Ordinance (Cap. 633)
- (h) The licensee of the DPC—
 - if an individual—has become bankrupt or made a voluntary arrangement with the individual's creditors within the meaning of the Bankruptcy Ordinance (Cap. 6)
 - if a partnership—has been dissolved
 - 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
 - if a society—has ceased to exist
- (i) The licensee or chief medical executive of the DPC has made a false statement—
 - in the application or
 - in any report, information or document required by the Director under the Ordinance (Cap. 633)
- (j) The Director is satisfied that the licensee of the DPC is operating a type of facility other than that for which the licence is issued
- (k) The Director is satisfied that the licensee of the DPC has ceased to operate or have control over the facility
- (1) The Director is satisfied that the DPC has ceased to exist or be operated

PHF(E) 26A (3/2024)

- Q28 Do I need to ensure the dental compressed air and vacuum systems in my DPC follow the Guidelines for Dental Compressed Air and Vacuum Systems in the Code of Practice for Day Procedure Centres (PHF(E) 21A)?
- A28 The Guidelines for Dental Compressed Air and Vacuum Systems (Annex III of the Code of Practice for Day Procedure Centres) provides a general guidance on the design and installation of dental compressed air and vacuum systems in a DPC. The feasibility of implementing the Guidelines as a regulatory requirement would be reviewed as appropriate. You are encouraged to observe the requirements set out in the Guidelines in preparation for its implementation.

PHF(E) 26A (3/2024) Page 19 / 22

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 nursing staff and supporting care staff (with staff name) after variation of the service
- (b) Specialty qualification or training record of nurse

2. #For application involving additions and/or alterations to healthcare engineering systems, namely electrical installation for critical care areas, specialized ventilation systems of operating room, and medical gas pipeline systems

• Certificate(s) of compliance in prescribed form issued by a registered professional engineer of the relevant discipline certifying that the healthcare engineering systems have been designed, installed and completed in accordance with the specified internationally acceptable standard(s) and in compliance with the requirements of the Code of Practice for Day Procedure Centres. For samples of the certificate of compliance, please visit the ORPHF website (https://www.orphf.gov.hk/en/useful_information/forms).

3. For application involving haemodialysis service

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

PHF(E) 26A (3/2024) Page 20 / 22

[#]As a transitional arrangement, the requirements of the healthcare engineering systems as specified in Section 1.6 of the Code of Practice for Day Procedure Centres will take effect from <u>1 January 2028</u> (<u>FAQ Q18</u>).

List of documents to be available on-site for inspection

1. Staffing

- (a) Training records and / or training plans of relevant staff
- (b) Records of relevant drills for the service, e.g. fire, electricity, water suspension, chemical spillage, blood spillage, etc
- (c) Relevant qualifications, experience, and orientation programme records
- (d) Training records, supported by relevant testing reports as applicable, for relevant staff responsible for the reconstitution of cytotoxic drugs

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 Day Procedure Centres (PHF(E) 21A)
 - (a) Policy on staff orientation and training (e.g. staff orientation programme)
 - (b) Risk management policy and emergency response policy (e.g. contingency plan during the suspension of electricity and ventilation)

PHF(E) 26A (3/2024) Page 21 / 22

- 4. #For application involving additions and/or alterations to the healthcare engineering systems, namely electrical installation for critical care areas, specialized ventilation systems of operating room, and medical gas pipeline systems
 - A duly completed Checklist of Documents of Healthcare Engineering Systems (PHF 216) with relevant policies and documents as specified in the checklist.

- **5. Other documentary proof** of compliance of Code of Practice of Day Procedure Centres Examples are:
 - (a) Certificate(s) of fire service installations and equipment, e.g. FS251, FSI/314A
 - (b) Work completion certificate(s) of fixed electrical installation, e.g. Form WR1
 - (c) Approval document for general building plan issued by Buildings Department or other authorized parties (if applicable)
 - (d) Approved document issued by Building Department and/or other authorized parties (if there is any structure change of the premises)

6. For DPC providing haemodialysis

- (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

PHF(E) 26A (3/2024) Page 22 / 22

[#] As a transitional arrangement, the requirements of the healthcare engineering systems as specified in Section 1.6 of the Code of Practice for Day Procedure Centres will take effect from <u>1 January 2028</u> (FAQ Q18).

Authorization Letter For licensee which is a company/ organisation

To: Office for Regulation of Private Healthcare Facilities

Department of Health

Dear Sir / Madam,	
(name of the com	pany / organisation)
hereby authorizes	(Hong Kong
•	norized representative)
Identity Card / Passport number*:	, with effect from,
to represent the abovementioned comp	pany / organisation who is the licensee of
	(PHF no
(name of the day procedure	centre)
to handle all matters related to its licence	·.
Yours faithfully,	
List of all directors/officers/members/	office-bearers of the company/organisation
Signature	Signature
Name:	Name:
Signature	Signature
Name:	Name:
Signature	Signature
Name:	Name:
Signature	Signature
Name:	Name:
Date:	
*Delete as appropriate	

Authorization Letter For licensee which is a Partnership

To: Office for Regulation of Private Healthcare Facilities

Department of Health

Dear Sir / Madam,		
We hereby authorize		
(name of	authorized part	tner)
(Hong Kong Identity Card / Passport number	r*:), with effect
from,	to represe	ent the licensee of
		(PHF no)
(name of the day procedure c	entre)	
to handle all matters related to its licence.		
Yours faithfully,		
Signature	Signature	
Authorized Partner	Other Partner (Nar	ne:
	(,
Signature	Signature	
Other Partner (Name:)	Other Partner (Nar	ne:)
Signature	Signature	
Other Partner (Name:)	Other Partner (Nar	ne:)
Signature	Signature	
Other Partner (Name:)	Other Partner (Nar	ne:)
Doto		
Date:		

^{*}Delete as appropriate