

SECTION 2 - LICENCE APPLICATION PROCEDURES

The following procedures apply to all applications for the grant, renewal, variation or revocation of a licence.

1. Application for Licence and Licence Renewal

1.1 Subject to section 4 of the HRT (Licensing) Regulation, a person may make an application to the Council for the grant or renewal of a licence to carry on a relevant activity in premises specified in the application. (*Section 21 of the Ordinance*)

1.2 Under normal circumstances, the Council will make a decision to grant a licence; a proposal to refuse to grant a licence; or a proposal to grant a licence subject to special conditions (including the grant of a licence in respect of part only of the premises or relevant activity specified in the application concerned) in approximately 6 months on receipt of all necessary documents and information from the applicant.

1.3 Applications should be made on the Council's standard licence application form, together with a crossed cheque in the amount of the application fee under the HRT (Fees) Regulation (see Section 3) made payable to "the Government of the Hong Kong Special Administrative Region" or "the Government of the HKSAR". The application should contain all items of information requested in the form, and should be accompanied by such additional information or material as may be specified in the application form or in any notes which accompany the application form.

1.4 The Council's standard licence application forms are attached as Annexes 1, 3, 5 and 7 of this Manual for first-time applications and as Annexes 2, 4, 6 and 8 for licence renewals.

1.5 Completed applications should be submitted in person or by post together with the application fee to —

Council on Human Reproductive Technology
Room 58, 17/F, Wu Chung House
213 Queen's Road East
Wanchai, Hong Kong

1.6 When a completed licence application form is received by the Council, an acknowledgement will be sent and the Secretariat will conduct an initial check for any omissions. If there are any omissions from the information required for consideration of a licence application by the Council, the Secretariat will request for additional information before the Council commences to consider the application. Despite the said initial check, the Council may ask for further information from time to time in the course of processing the application.

2. Inspection

2.1 The Secretariat will arrange for an inspection team to visit the premises in which it is proposed that the relevant activity will take place.

2.2 A report of the inspection will be prepared by the inspection team for consideration by the Inspection Committee.

Treatment or Storage Licence

2.3 For the purposes of considering whether to grant a treatment or storage licence, inspection(s) will normally be carried out by an inspection team which is composed of a member of the Council, a member of the Ethics Committee, a registered medical practitioner from the Department of Health, a scientist nominated by the Inspection Committee, a representative from the Hong Kong College of Obstetricians and Gynaecologists (HKCOG) and a lay person. The inspection team may also include not more than three other experts who have expertise in carrying out inspection of the premises under application.

Research Licence

2.4 For the purposes of considering whether to grant a research licence, inspection(s) will normally be carried out by an inspection team consisting of a member of the Ethics Committee, a registered medical practitioner from the Department of Health, a scientist nominated by the Inspection Committee, and a

lay person.

AIH Licence

2.5 For the purposes of considering whether to grant an AIH licence, inspection(s) will normally be carried out by an inspection team consisting of the Chairperson or a member of the Inspection Committee, a registered medical practitioner from the Department of Health or a scientist, and a lay person.

General

2.6 Inspections will normally include the following elements –

- (a) general consideration of the application for the licence and how the inspection is to be structured. For this purpose the centre should provide a private room for the inspection team during inspection;
- (b) a meeting with the senior members of staff. This will normally include the person responsible, licensee, embryologist in charge, accredited specialist, counsellor in charge and nurse co-ordinator;
- (c) a tour of the centre to inspect the premises. During this part of the visit the team may wish to speak to other staff, such as the clinical, laboratory, nursing and counselling staff; and
- (d) a meeting with patients nominated by the centre. This will be conducted without the presence of any representative of the centre.

2.7 Inspection will normally last between half a day and a full day depending on the size of the centre and the nature of the activities to be licensed. During the inspection, the inspection team will be looking to ensure that the centre is complying with the requirements of the Ordinance, regulations/guidelines, and that its practices are in line with the Code and the Supplementary Code. The inspection team will cover the area outlined in the checklist enclosed at Annex 11.

2.8 If other centres, clinics or practitioners are allowed to use the centre's facilities or services, the applicants may be requested to make arrangements for the inspections of these other centres, clinics or premises of these practitioners.

2.9 Inspections will normally be arranged with the centre in advance. The inspection team may, however, make unannounced inspections from time to time.

2.10 The Council, or a person or committee delegated by the Council under section 10(1) of the Ordinance, has powers under sections 27 and 29 of the Ordinance to revoke, vary or suspend a licence irrespective of whether any inspection has been conducted prior to the revocation, variation or suspension. The circumstances and procedures for revocation, variation and suspension are set out in detail in Parts 8 and 9 of Section 1 of this Manual.

3. Examination by Inspection Committee

3.1 The Inspection Committee is responsible for —

- (a) conducting inspections of premises for the purposes of ascertaining whether the premises in respect of which the licence is to be granted are suitable for the relevant activity; and
- (b) making recommendations to the Council in respect of —
 - (i) the grant of licences;
 - (ii) any conditions to which any licence, or class of licence, may be subject.

(Section 6(b) of Schedule 1 to the Ordinance)

3.2 The Inspection Committee may meet regularly or on ad hoc basis.

3.3 For the purposes of performing its functions as mentioned in paragraph 3.1 above, the Inspection Committee may require an applicant for a licence to provide such information, documents, assistance and facilities as are reasonably necessary to enable the Committee to make recommendations to the Council in respect of the grant of a licence or any condition to which the licence may be subject.

3.4 If a complaint is received against an applicant for a licence (other than an applicant for renewal of a licence), the Inspection Committee shall give the applicant under complaint a notice inviting him to submit a written representation in respect of the complaint within 14 days after the date of the notice. An authorized person may enter and inspect any premises to which a licence relates pursuant to section 37 of the Ordinance, and produce a report on

the findings for consideration by the Inspection Committee.

3.5 Where the application is for the renewal of a licence, and there is an outstanding complaint against the licensee, the application will be processed by the Inspection Committee, but without prejudice to the outstanding complaint being handled in accordance with Part 4 of the HRT (Licensing) Regulation.

3.6 For the purposes of facilitating the determination of an application for a licence, the Inspection Committee shall present to the Council —

- (a) the Committee's recommendations in respect of the application;
- (b) any representation submitted under paragraph 3.4; and
- (c) any other information or documents that the Council or the Committee considers relevant to the application.

4. Consideration by Council

4.1 Upon receipt of the recommendations made by the Inspection Committee and other relevant information as detailed in paragraph 3.6 (b) and (c) above, and subject to the procedure as set out in paragraphs 4.8 to 4.12 hereof, the Council shall, as soon as is practicable, by notice given to the applicant —

- (a) grant a licence to the applicant —
 - (i) to carry on in the premises specified in the application (or such part of those premises as may be specified in the licence) the relevant activity specified in the application (or such part of that activity as may be specified in the licence); and
 - (ii) subject to such conditions, if any, as are specified in the licence;or
- (b) refuse to grant a licence to the applicant.

(Section 23(1) of the Ordinance)

4.2 A licence granted by the Council will be subject to the conditions to be attached to —

- (a) every licence; or
- (b) every licence belonging to a class of licence specified in the HRT (Licensing) Regulation.

(Section 45(2)(a) of the Ordinance)

4.3 For the purposes of determining whether a licence should be granted or refused, the Council may require the attendance before it of an applicant who is an individual or, in the case of an applicant which is company, a representative of the company who is an individual authorized by the company to so attend, and may examine any individual who so attends. (*Section 22(2) of the Ordinance*)

4.4 The Council may ask for such further information or report(s) as it considers desirable or necessary, and may give directions as to the manner in which, and the person(s) by whom such information or report(s) are to be furnished.

4.5 If the Council considers that the information available to it is insufficient for it to be able to determine a licence application, it will inform the applicant through the Secretariat. The Council will not consider the application until the applicant provides such additional information as it may require.

Grant or Renewal of Licence

4.6 The Council shall, in the case of a determination to grant or renew a licence, give notice of the determination to the licensee and the person responsible. (*Sections 28(5)(a)*)

4.7 Upon receipt of the prescribed fee in respect of the grant or renewal of a licence under the HRT (Fees) Regulation, the Council shall issue the appropriate licence. Each licence shall specify the relevant activity that may be carried on in the premises specified in the application. Payment of the prescribed fee should be made by a crossed cheque made payable to “the Government of the Hong Kong Special Administrative Region” or “the Government of the HKSAR”. The cheque should be submitted in person or by post to —

Council on Human Reproductive Technology
Room 58, 17/F, Wu Chung House
213 Queen’s Road East
Wanchai, Hong Kong

Refusal to Grant a Licence, Grant of Licence subject to Special Conditions, etc.

4.8 Where the Council proposes to —

- (a) refuse to grant a licence;
- (b) grant a licence in respect of part only of the premises or part only of the relevant activity specified in the application concerned; or
- (c) grant a licence subject to special conditions,

the Council shall give notice of the proposal, the reasons for it, and the effect of section 28(3) of the Ordinance to the applicant. *(Section 28(1)(a), (b)&(c) of the Ordinance)*

4.9 If, within the period of 28 days beginning with the day on which notice of the proposal is given, any person to whom notice was given under section 28(1) of the Ordinance gives notice to the Council of a wish to make to the Council representations about the proposal in any way referred to in section 28(4) of the Ordinance, the Council shall, before making its determination, give the person an opportunity to make representations. *(Section 28(3) of the Ordinance)*

4.10 Such representations may be —

- (a) oral representations made by the person, or another person acting on behalf of the person, at a meeting of the Council;
- (b) written representations made by the person.

(Section 28(4) of the Ordinance)

4.11 The Council shall, in the case of a determination to —

- (a) refuse to grant a licence;
- (b) grant a licence in respect of part only of the premises or part only of the relevant activity specified in the application concerned; or
- (c) grant a licence subject to special conditions,

give notice of the determination to the applicant, and the person responsible as appropriate. The Council shall also give in the notice the reasons for its decision. *(Sections 28(5)(a)&(b) and (6)(a),(b)&(c) of the Ordinance)*

4.12 An applicant who is aggrieved by the Council's decision may appeal to the Administrative Appeals Board. *(Section 41 of the Ordinance)*

5. Application for Revocation and Variation of Licence

5.1 Applications for variation or revocation of licence should be made to the Council in written form, stating the reasons for variation or revocation and any proposed measures or arrangements consequential upon the variation or revocation, and accompanied by the prescribed fee in relation to the application for variation or revocation of a licence under the HRT (Fees) Regulation (see Section 3 and paragraphs 8.9 to 8.11 of Section 1)

5.2 An applicant for variation or revocation of a licence should state in his/her application the address at which any notice, order or other document may be served on him/her.

5.3 When an application is received by the Council, an acknowledgement will be sent by the Secretariat. If the Council considers that the information available to it is insufficient for it to be able to determine the application, it will request for additional information through the Secretariat. The Council will not further process the application until the applicant has provided such additional information as it may require.

Inspection

5.4 Depending on the circumstance of individual applications, the Council may request for an inspection to all relevant premises for the purpose of consideration of the application.

Revocation or Variation of Licence

5.5 The Council shall, in the case of a determination to vary or revoke a licence, give notice of the determination to the licensee and the person responsible. (*Section 28(5)(c) of the Ordinance*)

5.6 The revocation of a licence may be subject to the conditions specified in the notice effecting the revocation. A person who contravenes any such condition commits an offence under section 39(1) of the Ordinance.

5.7 In the case of variation of licence, the original licence before variation should be returned to the Secretariat. Upon receipt of the original licence, the Council shall issue a new licence. The new licence shall incorporate the variation approved by the Council and shall specify the relevant activity that may be carried on in the premises specified in the application.

5.8 The expiry date of the new licence shall remain the same as the original licence.

Refusal to Vary a Licence so as to Designate Another Individual in place of the Person Responsible

5.9 Where the Council proposes to refuse to vary a licence so as to designate another individual in place of the person responsible, the Council shall, in giving notice of the proposal, also give in the notice the reasons for it, and the effect of section 28(3) of the Ordinance, to the applicant. *(Section 28(1)(d) of the Ordinance)*

5.10 If, within the period of 28 days beginning with the day on which notice of the proposal is given, any person to whom notice was given under section 28(1) of the Ordinance gives notice to the Council of a wish to make to the Council representations about the proposal in any way referred to in section 28(4) of the Ordinance, the Council shall, before making its determination, give the person an opportunity to make representations. *(Section 28(3) of the Ordinance)*

5.11 Such representations may be –

- (a) oral representations made by the person, or another person acting on behalf of the person at a meeting of the Council;
- (b) written representations made by the person.

(Section 28(4) of the Ordinance)

5.12 The Council shall, in the case of a determination to refuse to vary a licence so as to designate another individual in place of the person responsible, give notice of the determination to the applicant. The Council shall also give in the notice the reasons for its decision. *(Sections 28(5)(b) & (6)(d) of the Ordinance)*

5.13 Any person aggrieved by the Council's decision may appeal to the Administrative Appeals Board against that decision made by the Council. *(Section 41 of the Ordinance)*

6. Withdrawal of Application

6.1 Any application for a licence or application for variation or revocation of a licence may be withdrawn at any time by giving notice in writing to the Council.