

LEGISLATIVE COUNCIL BRIEF

Human Reproductive Technology Ordinance (Cap. 561)

HUMAN REPRODUCTIVE TECHNOLOGY (LICENSING) REGULATION

HUMAN REPRODUCTIVE TECHNOLOGY (FEES) REGULATION

INTRODUCTION

This paper briefs Members on the Human Reproductive Technology (Licensing) Regulation (*Annex A*) and the Human Reproductive Technology (Fees) Regulation (*Annex B*), made by the Council on Human Reproductive Technology and to be made by the Secretary for Financial Services and the Treasury respectively under the Human Reproductive Technology Ordinance (Cap. 561) to provide for a licensing system for regulating human reproductive technology practice and related provisions.

BACKGROUND

2. The Human Reproductive Technology Ordinance (“the Ordinance”) was enacted in 2000, *inter alia*, to establish the Council on Human Reproductive Technology (“the Council”) with a view to regulating reproductive technology procedures through a licensing system with detailed requirements to be formulated.

3. Since its establishment in 2001, the Council has, in consultation with reproductive technology practitioners including embryo researchers, academics, social workers and legal practitioners, drawn up a Code of Practice on Reproductive Technology & Embryo Research to provide guidance for practitioners in the field with a view to promoting the adoption of safe and quality practices. The Code is regularly reviewed and updated to take into

account technological advancement and the feedback from the professions and stakeholders. The Code is currently for voluntary compliance by the professions, and will take effect upon its publication in the Gazette along commencement of the Regulations. Failure to comply with the Code does not in itself result in liabilities to any proceedings, but may be taken into account when the Council grants, renews, varies, suspends or revokes a licence. In addition, the practitioners and researchers are also subject to the codes of practice and professional ethics of their respective disciplines.

4. At the same time, the Council has been formulating the detailed requirements and procedures for licensing of reproductive technology practices including treatment, storage and research. Specifically, section 45(2) of the Ordinance empowers the Council to make regulations to prescribe various matters relating to licensing including licensing conditions, qualifications of proposed persons responsible, as well as the procedures for receiving, investigating and inquiring into any complaint in relation to a licence. In 2003 and 2006, a number of members of the Council went overseas to study similar licensing systems in the United Kingdom and Australia respectively to prepare for the implementation of a licensing system in Hong Kong. After detailed and thorough deliberations, the Council has finalised the licensing requirements and procedures as set out in the Human Reproductive Technology (Licensing) Regulation (“the Licensing Regulation”) at *Annex A* and is ready for their implementation.

5. Under section 44 of the Ordinance, the Financial Secretary may, by regulation, prescribe fees to be paid to the Council in respect of any licence application and for other related services, and the Council will in turn pay all prescribed fees under the regulation into the general revenue. These are set out in the proposed Human Reproductive Technology (Fees) Regulation (“the Fees Regulation”) at *Annex B*, to be made by the Secretary for Financial Services and the Treasury (as Financial Secretary by virtue of section 3 of Interpretation and General Clauses Ordinance (Cap. 1)).

THE LICENSING REGULATION

6. The main provisions of the Licensing Regulation are highlighted as follows:

- (a) **sections 3, 4, 5 and 7** set out the requirements of a licence application including the classes of premises in which a relevant activity is proposed to be carried on and the qualifications of an individual designated to be the person responsible;
- (b) **sections 6 and 9** set out the powers of the Inspection Committee and the procedures for handling a licence application;
- (c) **section 8** provides for the procedures in handling complaints against an applicant for a licence;
- (d) **sections 10 to 15** prescribe the four classes of licences (treatment, research, storage and artificial insemination by husband (AIH) licence) which may be granted and the conditions which may be attached to all licences or each class of licences;
- (e) **sections 17 to 20** set out the procedures for handling, investigation and inquiry into a complaint against a licensee or a person responsible under a licence;
- (f) **sections 21 and 22** provide for the procedures for temporary suspension of a licence arising from a complaint; and
- (g) **section 23** provides for the effect of an appeal lodged to the Administrative Appeals Board on the relevant decisions of the Council.

THE FEES REGULATION

7. In line with the "user pays" principle, it is Government policy that costs incurred in the implementation of the licensing system would be recovered in full by means of levying of fees against licence applicants or licensees. The Fees Regulation at *Annex B* sets out a schedule of 18 items of fixed and non-refundable fees. To reflect the staff and administrative costs incurred in processing the application and carrying out of appropriate inspection, the fees for application and grant of a treatment, storage or research licence are set at \$1,200 and \$6,110 respectively, while those of an AIH licence are set at \$895 and \$3,510 respectively. The fees for an application of variation and revocation of a licence range from \$2,300 to \$5,400, depending on the class of licence in question. The schedule of fees will be reviewed and updated from time to time.

IMPLEMENTATION

8. The Council will administer the licensing system including handling of complaints, and its existing secretariat staffed by the Department of Health will provide secretarial and logistical support (including vetting of information submitted and arranging for inspection of reproductive technology centres). Actual inspection and complaint investigation will be conducted respectively by the Inspection Committee and the Investigation Committee established under the Council pursuant to Part 2 of Schedule 1 to the Ordinance, with the assistance of designated public officers as authorized persons in accordance with sections 37 and 38 of the Ordinance.

LEGISLATIVE TIMETABLE

9. The legislative timetable is as follows:

Gazettal of the Licensing Regulation	4 April 2007
Gazettal of the Fees Regulation	13 April 2007
Tabling of both Regulations in the Legislative Council	18 April 2007
Commencement of the Regulations ¹	To be appointed by the Council

10. The Secretary for Health, Welfare and Food will arrange for the commencement of the relevant parts of the Ordinance to tie in with the commencement of both Regulations to put the licensing system into operation. Separately, the Council also plans to bring the Code of Practice into force and arrange for its publication and distribution upon the commencement of the licensing system.

IMPLICATIONS OF THE PROPOSAL

Financial and Civil Service Implications

11. Administration of the licensing system will be supported by the

¹ A transitional period of 6 months after commencement of the relevant provisions is provided in section 47 of the Ordinance for reproductive technology service providers to apply for a license.

existing staffing of the Council's secretariat and the Department of Health. The administrative costs incurred in processing the application and carrying out of appropriate inspection will be recovered through licensing fees in line with the "user pays" principle. Staffing and resource required for the implementation of the licensing system will be absorbed by the existing provisions for the Council through the Department of Health.

Economic Implications

12. The licensing fees are expected to be a relatively small portion of the operating costs of reproductive technology service providers and should have minimal implications for their daily operations.

Basic Law Implications

13. The proposed Regulations are in conformity with the Basic Law, including the provisions concerning human rights.

PUBLIC CONSULTATION

14. In July 2006, the Council launched a consultation exercise on the proposed licensing system and the Code of Practice with existing reproductive technology service providers and potential applicants on the licensing system, social workers, legal practitioners, the academia and ethical groups. A total of 14 written responses were received. The Council has taken into account the comments received in preparing the proposed Licensing Regulation.

15. The Panel on Health Services of the Legislative Council was consulted on the licensing system in November 2006.

PUBLICITY

16. The Council will arrange appropriate publicity for both the public and the providers on the coming into operation of the licensing system, both before and after its commencement.

ENQUIRIES

17. Any enquiry about this paper may be directed to Mr Thomas CHAN, Principal Assistant Secretary (Health), at 2973 8111, or Mr Victor LAU, Assistant Secretary (Health), at 2973 8123.

Council on Human Reproductive Technology
Health, Welfare and Food Bureau
April 2007

HUMAN REPRODUCTIVE TECHNOLOGY (LICENSING) REGULATION

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HUMAN REPRODUCTIVE TECHNOLOGY (LICENSING) REGULATION

(Made by the Council on Human Reproductive Technology under section 45(2) of the Human Reproductive Technology Ordinance (Cap. 561))

PART 1

PRELIMINARY

1. Commencement

This Regulation shall come into operation on a day to be appointed by the Council on Human Reproductive Technology by notice published in the Gazette.

2. Interpretation

(1) In this Regulation, unless the context otherwise requires –

“AIH licence” (夫精人工授精牌照) means an artificial insemination by husband licence as described in section 10(1)(a);

“Children Register” (孩子登記冊), in relation to licensed premises, means a register that contains information, if available, on every child born in consequence of a reproductive technology procedure provided in those premises at any time on or after the commencement of Part 3;

“Donors Register” (捐贈人登記冊), in relation to licensed premises, means a register that contains information on every donor of gametes or embryos stored in those premises at any time on or after the commencement of Part 3;

“Inspection Committee” (視察委員會) means the committee established under section 6(b) of Schedule 1 to the Ordinance;

“Investigation Committee” (調查委員會) means the committee established under section 6(c) of Schedule 1 to the Ordinance;

“licensed premises” (持牌處所) means the premises specified in a licence as the premises in which the relevant activity authorized by the licence may be carried on;

“live birth event” (活產個案) means an event of the birth in Hong Kong of one or more than one live child from one single pregnancy;

“Patients Register” (病人登記冊), in relation to licensed premises, means a register that contains –

- (a) information on every person who undergoes a reproductive technology procedure in those premises at any time on or after the commencement of Part 3;
- (b) where the person is a woman, information on the person who was her husband when gametes were, or an embryo was, placed in her body pursuant to that procedure; and
- (c) where the person is a man, information on the person who was his wife when gametes were obtained from him;

“research licence” (研究牌照) means a research licence as described in section 10(1)(c);

“storage licence” (儲存牌照) means a storage licence as described in section 10(1)(d);

“treatment licence” (治療牌照) means a treatment licence as described in section 10(1)(b).

(2) In this Regulation -

- (a) a reference to a person to whom a licence applies (however expressed) is to be construed as any one of the persons prescribed in section 24(3) of the Ordinance;
- (b) except for the purposes of section 8, a reference to an application for a licence (however expressed) includes an application for the renewal of a licence; and

- (c) a reference to the grant of a licence (however expressed) includes the renewal of a licence.

PART 2

APPLICATIONS RELATING TO LICENCE

3. Application for and issue of licence

(1) An application for a licence made under section 21 of the Ordinance must be –

- (a) in a form specified for that purpose under section 42 of the Ordinance; and
 (b) accompanied by a prescribed fee.

(2) An application for variation or revocation of a licence made under section 27(4) of the Ordinance must be accompanied by a prescribed fee.

(3) The Council may do any of the following matters upon receipt of a prescribed fee –

- (a) grant a licence under section 23(1)(a) of the Ordinance;
 (b) issue an exact copy of a licence for the purposes of section 30 of the Ordinance;
 (c) issue a licence in like terms as those contained in a lost, defaced or destroyed licence under section 31 of the Ordinance.

(4) In this section, “prescribed fee” (訂明費用) means a fee prescribed by regulations made under section 44 of the Ordinance.

4. Classes of premises

Any premises specified in an application for a licence pursuant to section 21 of the Ordinance must belong to one of the following classes –

- (a) a clinic registered under the Medical Clinics Ordinance (Cap. 343);

- (b) a hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165);
- (c) a public hospital as defined in section 2(1) of the Hospital Authority Ordinance (Cap. 113);
- (d) a private consulting room that is –
 - (i) used by a registered medical practitioner in the course of his practice; and
 - (ii) not located in premises used for residential purposes;
- (e) a medical or research laboratory that is not located in premises used for residential purposes.

5. Prescribed qualifications of designated individual

For the purposes of section 23(2)(c) of the Ordinance, an individual designated in an application for a licence has the prescribed qualifications if –

- (a) he is a registered medical practitioner;
- (b) he is a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
- (c) he is a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
- (d) he holds a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
- (e) he holds other qualification in the medical, nursing, scientific or management field that is considered by the Council as acceptable for the purposes of supervising the relevant activity specified in the application.

6. Power of Inspection Committee in relation to application for licence

For the purposes of performing its functions under section 6(b) of Schedule 1 to the Ordinance, the Inspection Committee may require an applicant for a licence to –

- (a) make arrangements for any authorized person to inspect the premises specified in the application pursuant to section 21 of the Ordinance; and
- (b) provide such information, documents, assistance and facilities as are reasonably necessary to enable the Committee to make recommendations to the Council in respect of –
 - (i) the grant of the licence; or
 - (ii) any condition to which the licence may be subject.

7. Requirements for purposes of section 23(2)(e) of Ordinance

Any requirement contained in, or made pursuant to, section 3, 4 or 6 is a requirement in relation to the granting of the licence for the purposes of section 23(2)(e) of the Ordinance.

8. Complaint about applicant for licence

(1) Any person may lodge a complaint with the Inspection Committee against an applicant for a licence.

(2) On receiving such a complaint, the Inspection Committee may require the complainant to do all or any of the following –

- (a) set out the specific allegations in writing;
- (b) provide any further evidence or information about the complaint;
- (c) make one or more statutory declarations to support any allegation in the complaint.

(3) 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.

9. Determination of application for licence

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 section 8(3); and
- (c) any other information or documents that the Council or the Committee considers relevant to the application.

PART 3

CLASSES OF LICENCES AND LICENCE CONDITIONS

10. Classes of licences

(1) Subject to subsections (2), (3), (4), (5) and (6), the Council may only grant a licence that belongs to one of the following classes –

- (a) an artificial insemination by husband licence, which authorizes –
 - (i) a procedure under which a man's sperm are introduced into the vagina or uterus of his wife otherwise than by sexual intercourse; and
 - (ii) if necessary for and incidental to such procedure, the storage of sperm used or intended to be used in the procedure;
- (b) a treatment licence, which authorizes –
 - (i) the carrying on of one or more than one type of reproductive technology procedure; and

- (ii) the storage of gametes or embryos used or intended to be used in such procedure;
 - (c) a research licence, which authorizes –
 - (i) the conduct of one project of embryo research; and
 - (ii) the storage of gametes or embryos used or intended to be used in such research;
 - (d) a storage licence, which authorizes the storage of gametes or embryos used or intended to be used in a reproductive technology procedure or embryo research.
- (2) The Council shall not grant a licence in contravention of section 19 of the Ordinance or any regulation made under section 45(1)(c) of the Ordinance.
- (3) Every AIH licence is granted subject to –
 - (a) all general conditions specified in section 11;
 - (b) all specific conditions specified in section 12; and
 - (c) any other conditions specified in the licence.
- (4) Every treatment licence is granted subject to –
 - (a) all general conditions specified in section 11;
 - (b) all specific conditions specified in sections 13 and 15; and
 - (c) any other conditions specified in the licence.
- (5) Every research licence is granted subject to –
 - (a) all general conditions specified in section 11;
 - (b) all specific conditions specified in section 14; and
 - (c) any other conditions specified in the licence.
- (6) Every storage licence is granted subject to –
 - (a) all general conditions specified in section 11;
 - (b) all specific conditions specified in section 15; and
 - (c) any other conditions specified in the licence.

11. General conditions of every licence

For the purposes of section 10(3)(a), (4)(a), (5)(a) and (6)(a), the following are the general conditions specified in relation to every licence –

- (a) only the relevant activity specified in the licence may be carried on pursuant to the licence;
- (b) any such activity shall not be carried on in contravention of any provision of the Ordinance or any other enactment;
- (c) any such activity may be carried on only in the licensed premises and under the supervision of the person responsible;
- (d) without prejudice to other conditions applicable to the licence, the proper conduct of any such activity, and the proper discharge of the functions of any person to whom the licence applies, shall at all time be secured, taking account of any relevant provision of the code;
- (e) any such activity may be carried on for a person only if a consent form has been signed in relation to that person in accordance with the code;
- (f) the registers and records in relation to any consent or information as required by the code to be obtained and kept shall be properly maintained in, or readily accessible from, the licensed premises;
- (g) the licensee shall provide to the Council the information required to be contained in Register A in such form as specified in the code; and
- (h) a notice of a change in any information provided in relation to the licence, or the application for the licence, shall be given to the Council within 28 days after the occurrence of the change.

12. Specific conditions of AIH licence

For the purposes of section 10(3)(b), the following are the specific conditions specified in relation to every AIH licence –

- (a) any reproductive technology procedure specified in the licence may be provided only to persons who are the parties to a marriage, except where the procedure is continued to be provided to persons who were the parties to a marriage when sperm were placed in the body of the wife pursuant to the procedure;
- (b) proper practices and procedures shall be adopted to identify and record –
 - (i) the identity of each individual who undergoes a reproductive technology procedure in the licensed premises; and
 - (ii) any sperm used at the time of insemination in each case; and
- (c) a Patients Register and a Children Register shall be properly kept and maintained in, or readily accessible from, the licensed premises.

13. Specific conditions of treatment licence

For the purposes of section 10(4)(b), the following are the specific conditions specified in relation to every treatment licence –

- (a) any reproductive technology procedure specified in the licence may be provided only to persons who are the parties to a marriage, except where the procedure is –
 - (i) provided to a surrogate mother pursuant to a surrogacy arrangement;
 - (ii) continued to be provided to persons who were the parties to a marriage when gametes were, or an

- embryo was, placed in the body of a woman pursuant to the procedure; or
- (iii) for obtaining gametes;
- (b) a reproductive technology procedure shall not be provided to a person unless account has been taken of the welfare of any child who may be born in consequence of the procedure;
- (c) if any surrogacy arrangement is authorized by the licence -
- (i) a reproductive technology procedure may be provided pursuant to such arrangement only if –
 - (A) the gametes used in the procedure are those of the parties to a marriage; and
 - (B) the wife in that marriage is unable to carry a pregnancy to term and no other treatment option is practicable for her; and
 - (ii) the arrangement shall be reported to the Council within 3 months after the completion of the procedure for each treatment cycle;
- (d) if sex selection is authorized by the licence –
- (i) it may be conducted only for the purpose of avoiding a sex-linked genetic disease specified in Schedule 2 to the Ordinance which may prejudice the health of the embryo; and
 - (ii) each case of sex selection achieved through a reproductive technology procedure shall be reported to the Council within 3 months after the procedure has taken place;
- (e) prior approval of the Council shall be obtained for carrying on any reproductive technology procedure

involving tissue typing in conjunction with preimplantation genetic diagnosis in the licensed premises;

- (f) close liaison with –
- (i) any donor of gametes or embryos stored in the licensed premises;
 - (ii) any recipient of the donated gametes or embryos and her husband;
 - (iii) if other gametes or embryos of the donor are stored in the licensed premises under another licence, a person to whom that licence applies; and
 - (iv) if other gametes or embryos of the donor are donated in any other premises, the person in charge of those premises,

shall be established for the purpose of ensuring that no more than 3 live birth events are brought about by the gametes or embryos donated by any single donor;

- (g) a system shall be established and maintained so as to ensure that proper practices and procedures are adopted and followed in the licensed premises;

- (h) proper practices and procedures shall be adopted to identify and record –

- (i) the identity of each individual who undergoes a reproductive technology procedure in the licensed premises;
- (ii) any sperm and egg used in each reproductive technology procedure;
- (iii) any embryo used in each case and the patient undergoing the reproductive technology procedure at the time of embryo transfer; and

- (iv) any gamete or embryo involved at the time of cryopreservation and thawing; and
- (i) a Patients Register and a Children Register shall be properly kept and maintained in, or readily accessible from, the licensed premises.

14. Specific conditions of research licence

For the purposes of section 10(5)(b), the following are the specific conditions specified in relation to every research licence –

- (a) a person shall not do any of the following in the licensed premises –
 - (i) for the purposes of embryo research –
 - (A) bring about the creation of an embryo; or
 - (B) combine human and non-human gametes or embryos or any part of them such as to give rise to a 2 cell zygote;
 - (ii) keep or use an embryo after the appearance of the primitive streak;
 - (iii) place any non-human gamete or embryo or any part of it in any human;
 - (iv) place any human gamete or embryo or any part of it in any animal;
 - (v) replace the nucleus of a cell of an embryo with a nucleus taken from any other cell; or
 - (vi) clone any embryo;
- (b) an embryo the creation of which was brought about in vitro may be stored in the licensed premises only if acquired from a person to whom another licence applies or imported in accordance with the code; and

- (c) a notice with a copy of the report of the outcome of the research project authorized by the licence attached to it shall be given to the Council within 3 months after the completion of the project.

15. Specific conditions relating to storage

(1) For the purposes of section 10(4)(b) and (6)(b), the following are the specific conditions specified in relation to every treatment licence or storage licence –

- (a) embryos may be stored in the licensed premises only for and on behalf of the parties to a marriage;
- (b) in the case of a treatment licence, an embryo the creation of which was brought about in vitro otherwise than pursuant to the licence may be stored in the licensed premises only if acquired from a person to whom another licence applies or imported in accordance with the code;
- (c) in the case of a storage licence, an embryo the creation of which was brought about in vitro may be stored in the licensed premises only if acquired from a person to whom another licence applies or imported in accordance with the code;
- (d) a person shall not be allowed to collect his or her own gametes or embryos from the licensed premises except in circumstances specified in the code;
- (e) except as provided in subsection (3) –
 - (i) a gamete or embryo shall not be stored in the licensed premises beyond the period as provided in subsection (2); and
 - (ii) the gamete or embryo shall, upon the expiry of that period, be disposed of according to the

instructions given in the consent form required by the code to be signed by the person entitled to the gamete or embryo; and

- (f) a Donors Register shall be properly kept and maintained in, or readily accessible from, the licensed premises.

(2) For the purposes of subsection (1)(e), regardless of whether any gamete or embryo has been stored in any premises before or since the commencement of this section, it shall not be stored in the licensed premises beyond the following period starting from the day on which the gamete or embryo begins to be stored –

- (a) in the case of an anonymous donation, the shorter of the following –
 - (i) 10 years; or
 - (ii) the period up to the time when the donated gametes or embryos have brought about 3 live birth events, or such other number of live birth events as specified by the donor, whichever is smaller;
- (b) in the case of a person whose gametes or embryos are stored for use in a reproductive technology procedure to be provided to the person, 10 years;
- (c) except as otherwise provided by the code, in the case of a donation made by the donor to a recipient designated by the donor in the circumstances permitted under the code, 2 years;
- (d) in the case of a cancer patient, or any other patient, who may be rendered infertile as a result of chemotherapy, radiotherapy, surgery or other medical treatment –
 - (i) for gametes, the longer of the following –
 - (A) 10 years; or

(B) the period up to the time when the patient reaches the age of 55 years; and

(ii) for embryos, 10 years.

(3) Subject to subsections (4) and (5), subsection (1)(e) does not apply to any gamete or embryo if –

(a) it has been stored in any premises before the commencement of this section; and

(b) the Council is satisfied that the person responsible under the licence has used his best endeavours but failed to obtain the consent of the person entitled to the gamete or embryo to dispose of it.

(4) If the gametes or embryos donated by any single donor fall within the description in subsection (3) and no proper record is kept of any live birth event brought about by them, those gametes or embryos shall not be used in any reproductive technology procedure –

(a) after they have brought about 3 live birth events since the commencement of this section; or

(b) after the expiry of 2 years from the commencement of this section,

whichever is earlier.

(5) If the gametes or embryos donated by any single donor fall within the description in subsection (3) and proper record is kept of any live birth event brought about by them, but there is no proper record of the day from which they have been stored, those gametes or embryos shall not be used in any reproductive technology procedure –

(a) after they have brought about 3 live birth events, or such other number of live birth events as specified by the donor, whichever is smaller; or

(b) after the expiry of 2 years from the commencement of this section,

whichever is earlier.

PART 4

COMPLAINT AGAINST PERSON RESPONSIBLE OR LICENSEE

16. Interpretation and application of Part 4

(1) In this Part –

“Committee Chairperson” (委員會主席) means the Chairperson of the Investigation Committee;

“complaint” (申訴) means a complaint lodged under section 17(1);

“complaint subject” (申訴對象) means a person against whom a complaint is lodged.

(2) If the Council renews a licence while a complaint relating to the licence is being dealt with under this Part, the renewal does not –

(a) affect the operation of this Part; or

(b) prevent the renewed licence from being revoked, varied or suspended as a result of the complaint.

17. Lodging and preliminary processing of complaint

(1) Any person may lodge a complaint with the Council against the person responsible under a licence or the licensee.

(2) The Secretary to the Council shall refer a complaint to the Investigation Committee for further processing.

(3) The Committee Chairperson may require the complainant to do all or any of the following –

(a) set out the specific allegations in writing;

(b) provide any further evidence or information about the complaint;

(c) make one or more statutory declarations to support any allegation in the complaint.

(4) Without prejudice to the generality of sections 37 and 38 of the Ordinance, the Committee Chairperson may direct an authorized person to –

- (a) enter and inspect any licensed premises under the licence related to the complaint for the purposes of investigating the complaint; and
- (b) make a report on the findings for consideration by the Investigation Committee.

18. Frivolous or groundless complaint

(1) If the Investigation Committee, having regard to any recommendation made by the Committee Chairperson and any report made under section 17(4), determines that a complaint is frivolous or groundless and should not proceed further, it shall –

- (a) dismiss the complaint; and
 - (b) give the complainant a notice of the decision with reasons.
- (2) Any matter for determination under subsection (1) may be –
- (a) considered by the Investigation Committee by the circulation of papers; and
 - (b) decided by a resolution approved in writing by a majority of the members of the Committee who are for the time being present in Hong Kong.

19. Inquiry into complaint

(1) Unless the Investigation Committee dismisses a complaint under section 18(1), the Committee Chairperson shall fix the date, time and place of a meeting for the Committee to consider the complaint.

(2) The Committee Chairperson shall ensure that the complaint subject is given notice of the following at least 28 days before the date of the meeting –

- (a) the receipt of the complaint;

- (b) any matter or allegation that may form the basis for the exercise of the Council's power under section 27(1), (2) or (3) of the Ordinance; and
 - (c) the date, time and place of the meeting.
- (3) The notice must be accompanied by –
 - (a) a copy of the complaint if it is lodged in writing;
 - (b) a copy of any statutory declaration made by the complainant;
 - (c) an invitation to the complaint subject to submit in writing any explanation for any matter or allegation mentioned in subsection (2)(b) or any representations within 14 days after the date of the notice; and
 - (d) an invitation to the complaint subject to attend the meeting to make oral representations.

(4) If the Committee Chairperson considers that in the circumstances of a particular case, it is desirable not to disclose to the complaint subject the identity of any person contained in any document mentioned in subsection (3)(a) or (b), the Chairperson may arrange for such necessary obliteration or other editorial modification of the document so that the identity of such person will not be disclosed.

(5) The Investigation Committee shall hold any meeting for considering a complaint in private subject to the direction of the Committee Chairperson to permit any person to be present as the Chairperson considers appropriate.

(6) If the Investigation Committee considers that any matter or allegation mentioned in subsection (2)(b) should be amended, it may direct the Secretary to the Investigation Committee to –

- (a) make the amendment;
- (b) advise the complaint subject of the amendment; and

- (c) invite the complaint subject to submit any further explanation or representations.

(7) The Investigation Committee may arrange any such investigation into the complaint to be made and obtain such additional advice or assistance as the Committee considers necessary.

(8) After considering the complaint, the Investigation Committee shall submit a written report on the complaint to the Council setting out –

- (a) any matter or allegation that may form the basis for the exercise of the Council's power under section 27(1), (2) or (3) of the Ordinance;
- (b) the representations made by the complaint subject in relation to those allegations;
- (c) the findings of the Committee; and
- (d) recommendations made by the Committee as to whether the Council should exercise its power under section 27(1), (2) or (3) of the Ordinance and the reasons for making the recommendations.

20. Consideration of complaint by Council

(1) The Council may refer a complaint back to the Investigation Committee for further investigation if the Council considers necessary.

(2) If the Council decides not to vary or revoke a licence related to a complaint, it shall –

- (a) give the complaint subject a notice of the decision; and
- (b) give the complainant a notice of the decision with reasons.

(3) If the Council proposes or determines to vary or revoke a licence related to a complaint, it shall act in accordance with section 28 of the Ordinance.

(4) The Council may propose to vary or revoke a licence related to a complaint by a resolution approved in writing by a majority of its members who are for the time being present in Hong Kong.

(5) The Council may make a determination to vary or revoke a licence related to a complaint only at a meeting of the Council by a majority of votes of its members present and voting.

(6) The Secretary to the Council shall publish a notice in the Gazette announcing the Council's decision to vary or revoke a licence related to a complaint and any condition to which the decision is subject after the decision has taken effect according to section 23(4).

(7) When considering a record of conviction of the person responsible under a licence or the licensee for the purposes of this Part –

- (a) the Council shall not be required to inquire into the question as to whether the person responsible or the licensee was properly convicted; and
- (b) the Council may consider any record of the case in which such conviction was recorded and any other evidence that may be available and is relevant as showing the nature and gravity of the offence.

21. Suspension of licence

(1) The Investigation Committee shall, for the purposes of performing any function delegated to it by the Council pursuant to section 10(1) of the Ordinance in relation to the suspension of a licence related to a complaint, act in accordance with section 29(1) and (2) of the Ordinance, this section and section 22.

(2) Except as provided in subsection (3), any matter for determination by the Investigation Committee under section 29(1) of the Ordinance may be –

- (a) considered by the Committee by the circulation of papers; and
- (b) decided by a resolution approved in writing by a majority of the members of the Committee who are for the time being present in Hong Kong.

(3) If any member of the Investigation Committee requests a meeting to be held for the purpose of considering any matter for determination under section 29(1) of the Ordinance, the matter may be decided only at a meeting of the Committee by a majority of votes of its members present and voting.

(4) If the Investigation Committee decides that a licence related to a complaint shall be suspended under section 29(1) of the Ordinance, it shall give the person responsible under the licence and the licensee a notice of the following –

- (a) the decision of the suspension of the licence with reasons;
- (b) the period of the suspension of the licence; and
- (c) any conditions that the Committee considers appropriate to impose in relation to the suspension of the licence.

(5) The person responsible under a licence or the licensee who has received a notice under subsection (4) may at any time make a written representation to the Council for the purposes of –

- (a) raising his objection to the suspension of the licence; and
- (b) setting out any ground on which he seeks a revocation of that notice.

(6) On receipt of any representation made under subsection (5), the Chairperson of the Council shall direct the Secretary to the Council to –

- (a) fix the date, time and place for the purpose of determining whether the notice of suspension should be revoked under section 29(4) of the Ordinance; and
- (b) invite the person responsible or the licensee concerned to make oral representations at the hearing, whether by himself or by a person acting on his behalf.

22. Renewal notice for suspension of licence

(1) If the Investigation Committee decides to renew a notice given under section 21(4) for a further period, it shall give the person responsible under the licence and the licensee a notice of the following –

- (a) the decision of the renewal with reasons;
- (b) the period of the further suspension of the licence; and
- (c) any change to the conditions that the Committee considers appropriate to impose in relation to the suspension of the licence.

(2) Section 21(5) and (6) applies in relation to a notice given under subsection (1) of this section as if it were a notice given under section 21(4).

PART 5

APPEAL TO ADMINISTRATIVE APPEALS BOARD AGAINST DECISIONS OF COUNCIL

23. Appeal to Administrative Appeals Board

(1) This section applies to an appeal made against a decision of the Council mentioned in section 41 of the Ordinance to the Administrative Appeals Board (“the Board”).

(2) If the Board reverses such a decision, the Council shall take the necessary action to give effect to that reversal.

- (3) If an appeal is made against a decision of the Council to –
- (a) refuse to grant a licence;
 - (b) grant a licence in respect of part only of the premises or relevant activity specified in the application concerned;
 - (c) grant a licence subject to conditions;
 - (d) refuse to vary a licence so as to designate another individual in place of the person responsible;

- (e) refuse to vary or revoke a licence on an application by the person responsible or the licensee; or
- (f) suspend a licence for a certain period of time,

the appeal does not affect the operation of the decision pending appeal, unless the Council decides otherwise and the notice of the decision contains a statement to that effect.

(4) If the Council makes a decision to vary or revoke a licence otherwise than on an application by the person responsible or the licensee, the decision takes effect –

- (a) upon the expiry of the time within which a notice of appeal may be lodged under section 9 of the Administrative Appeals Board Ordinance (Cap. 442); or
- (b) in the case of a notice of appeal having in fact been lodged under section 9 of that Ordinance, upon the disposal of the appeal,

unless the Council decides otherwise and the notice of the decision contains a statement to that effect.

Chairperson,
Council on Human Reproductive
Technology

Explanatory Note

This Regulation provides for the requirements relating to the implementation of the licensing system laid down by the Human Reproductive Technology Ordinance (Cap. 561) (“the Ordinance”) for regulating human reproductive technology procedures, embryo research and related activities (“relevant activities”).

Part 1 – Preliminary

2. Part 1 contains the commencement and interpretation provisions for this Regulation (sections 1 and 2).

Part 2 – Applications relating to licence

3. Part 2 deals with applications made to the Council on Human Reproductive Technology (“the Council”) relating to a licence to carry on a relevant activity.

4. Section 3 requires an application for such a licence to be submitted in a specified form together with a fee prescribed by regulations made under section 44 of the Ordinance. It further provides that a prescribed fee is payable in respect of other matters such as an application for variation or revocation of a licence, the grant of a licence and the issue of a duplicate or replacement copy of a licence.

5. Any premises proposed to be the licensed premises in which the relevant activity may be carried on must belong to one of the classes of premises specified in section 4.

6. The application must also designate an individual possessing the qualifications prescribed in section 5 as the person under whose supervision the relevant activity is to be carried on.

7. Under section 6, the Inspection Committee established under the Council may require an applicant to make arrangements for the inspection of the proposed licensed premises and to provide further information and assistance.

8. The Council shall not grant a licence unless it is satisfied that the above requirements, among others, are satisfied (section 7).

9. Section 8 provides for the receipt by the Inspection Committee of any complaint about an applicant for a licence and the procedures for handling the complaint.

10. Section 9 requires the Inspection Committee to present its recommendations in respect of an application and any other relevant representation and information to the Council to facilitate the latter's determination of the application.

Part 3 – Classes of licences and licence conditions

11. Part 3 sets out the different classes of licences that the Council may grant and the conditions to which those licences are subject.

12. For the purposes of authorizing different types of relevant activities, the Council may grant 4 classes of licences, namely, artificial insemination by husband (AIH) licences, treatment licences, research licences and storage licences (section 10) .

13. While all licences are granted subject to the general conditions specified in section 11, specific conditions are also attached to every licence belonging to each class of licence as respectively specified in sections 12, 13, 14 and 15.

Part 4 – Complaint against person responsible or licensee

14. Part 4 provides for the procedures for handling a complaint made against the person responsible under a licence or the licensee. Section 16 contains the interpretation and application provisions for this Part.

15. Section 17 provides for the receipt by the Council of such a complaint and the preliminary investigation into the complaint by the Investigation Committee established under the Council.

16. The Investigation Committee may dismiss a complaint if it is frivolous or groundless (section 18). Otherwise, the Committee shall conduct an inquiry into

the complaint and submit a report to the Council according to the procedures set out in section 19.

17. Section 20 provides for the procedures to be followed when the Council considers a complaint and makes any determination concerning the variation or revocation of a licence related to the complaint.

18. Where the Investigation Committee has been delegated any function of the Council under section 29 of the Ordinance to suspend a licence, the procedures set out in sections 21 and 22 are applicable.

Part 5 – Appeal to Administrative Appeals Board against decisions of Council

19. Part 5 makes supplementary provisions concerning an appeal made to the Administrative Appeals Board against a decision of the Council under the Ordinance and the operation of the decision pending appeal (section 23).

HUMAN REPRODUCTIVE TECHNOLOGY (FEES) REGULATION

(Made by the Secretary for Financial Services and the Treasury under
section 44 of the Human Reproductive Technology Ordinance
(Cap. 561))

1. Commencement

This Regulation shall come into operation on the day appointed for the commencement of section 3 of the Human Reproductive Technology (Licensing) Regulation (L.N. of 2007).

2. Interpretation

In this Regulation, “AIH licence” (夫精人工授精牌照), “research licence” (研究牌照), “storage licence” (儲存牌照) and “treatment licence” (治療牌照) have the same meanings as in the Human Reproductive Technology (Licensing) Regulation (L.N. of 2007).

3. Prescribed fees

A fee prescribed in column 3 of the Schedule shall be paid to the Council in respect of the matter described, opposite the fee, in column 2 of the Schedule.

SCHEDULE

[s. 3]

PRESCRIBED FEES

Item	Matter	Fee
1.	Application for, or application for the renewal of, the following under section 21 of the Ordinance –	
	(a) an AIH licence	\$895
	(b) a treatment licence	\$1,200
	(c) a research licence	\$1,200
	(d) a storage licence	\$1,200

2.	Grant or renewal of the following under section 23(1)(a) of the Ordinance –	
	(a) an AIH licence	\$3,510
	(b) a treatment licence	\$6,110
	(c) a research licence	\$6,110
	(d) a storage licence	\$6,110
3.	Application for variation of the following under section 27(4) of the Ordinance –	
	(a) an AIH licence	\$3,470
	(b) a treatment licence	\$5,400
	(c) a research licence	\$5,400
	(d) a storage licence	\$5,400
4.	Application for revocation of the following under section 27(4) of the Ordinance –	
	(a) an AIH licence	\$2,300
	(b) a treatment licence	\$3,730
	(c) a research licence	\$3,730
	(d) a storage licence	\$3,730
5.	Issue of an exact copy of a licence for the purposes of section 30 of the Ordinance	\$555
6.	Issue of a licence in like terms as those contained in a lost, defaced or destroyed licence under section 31 of the Ordinance	\$555

Secretary for Financial Services and
the Treasury

2007

Explanatory Note

This Regulation prescribes the fees payable to the Council on Human Reproductive Technology in respect of applications relating to, and other services connected with, licences granted under the Human Reproductive Technology Ordinance (Cap. 561).