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Assisted Human Reproduction Implementation Office

Consultation Background Paper
Licensing Under the *Assisted Human Reproduction Act*

Administration of Licensing for Controlled Activities and Premises

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Consultation Background Paper

Licensing Under the *Assisted Human Reproduction Act*

Administration of Licensing for Controlled Activities and Premises

1.0 Issue

The administration of licensing for undertaking controlled activities and for premises where controlled activities may be undertaken under the *Assisted Human Reproduction Act* (AHR Act).

2.0 Purpose

The purpose of this paper is to seek stakeholder feedback on the design of the proposed licensing administration process. The licensing administration process is one component of the licensing framework. Other components include the licensing requirements for controlled activities and for premises. The overarching objective of the licensing framework is to mitigate health and safety risks by ensuring that:

- persons undertaking controlled activities are qualified to do so;
- premises are suitable for the controlled activities that will be undertaken;
- general management issues are respected in the conduct of controlled activities; and
- licensees are compliant with the Act and regulations as well as the terms and conditions of their licence.

The objective of the licensing administration process is to support this overarching objective by upholding certain principles which are discussed in section 3.2.

3.0 Introduction

This paper will focus on the following steps in the licensing administration process:

- applying for a licence;
- reviewing and assessing a licence application, approving or refusing to approve an application, and issuing a licence for an approved application;
- renewing a licence;
- amending a licence; and
- relinquishing a licence.

The remaining steps in the licensing administration process (amending, suspending or revoking a licence for cause, and restoring a suspended licence) will be the subject of future consultations on compliance and enforcement.

3.1 Authority under the *Assisted Human Reproduction Act*

The AHR Act provides the authority for Assisted Human Reproduction Canada (the Agency) to administer a dual licensing regime (for undertaking controlled activities and for premises). A premises licence will ensure that the physical features of the premises (location, building design, and building conditions) are suitable to undertake controlled activities. An applicant for a premises licence could be the owner or operator of a premises. An applicant for a controlled activity licence could be any person who intends to undertake a controlled activity. This could include an incorporated entity or an individual. In the case of an incorporated entity, a "Responsible Person" will need to be designated for the purposes of ensuring compliance with the Act and regulations.

Persons undertaking controlled activities must operate in an environment where requirements for general management issues (e.g., personnel, equipment and sanitation) are respected. One option could be for the premises licensee or designated person to be responsible for ensuring that requirements for general management issues are met within the premises.

The Agency has the power to issue a licence, as well as to attach terms and conditions to a licence at the time of issuance or at any time thereafter. In addition, the Agency may amend or renew a licence. Finally, although beyond the scope of this paper, the Agency may amend a licence for cause, suspend a licence, or revoke a licence where there is a:

- contravention of the Act or regulations;
- contravention of the terms and conditions of a licence; or
- failure to comply with any measures ordered to be taken under the AHR Act (e.g., according to section 44(1), the Agency may take, or order any person to take, all reasonable measures to prevent, reduce or mitigate health or safety risks that result, or may result, from a controlled activity).

The Agency may also prescribe conditions for restoring a suspended licence.

3.2 Overview of the Licensing Administration Process

Principles

Several principles are important to guide the development of the licensing administration process, including:

Fair Process

In order to demonstrate fair, consistent and evidence-based decision making, the process should:

- be clear and accessible to applicants;
- allow applicants reasonable opportunity to provide all necessary information or documentation, and to respond to other information or documentation being relied upon by the Agency; and
- include the provision of reasons for the Board's decisions.

Transparency

Section 19 of the AHR Act provides for public inspection of a broad range of information pertaining to the Agency's licensing and enforcement activities which will support public accountability, and help to ensure that the Agency operates in an open and transparent manner. Options, which are being developed for the purpose of section 19, will be the subject of future consultations.

Privacy

The process must also ensure that privacy rights are respected, in accordance with the requirements of the Act.¹

Accountability

The Agency will be responsible for managing the licensing administration process in a manner that respects government legislation, regulations, policies and processes. Within the Agency, the Agency will be accountable for ensuring that the Board of Directors (the Board) has the required information to make decisions regarding all aspects of licensing. The Board will be accountable for making objective decisions about licensing.

¹See the AHRA, sections 14 to 19.

The applicant will be responsible for providing complete and accurate information in licence applications. Once licensed, the licensee will be responsible to abide by the terms and conditions of the licence, if applicable, in addition to the Act and regulations.

Accessibility, Clarity and Responsiveness

The process should be user-friendly. The applicant should be provided with clear information about licensing requirements, and have reasonable access to the Agency to seek clarification about requirements and the administrative process while not placing undue burden on the Agency's resources.

Efficiency

The process should strike a balance between inputs and outputs (between the information or documentation required to make informed decisions, and the timeliness of those decisions). For the Agency, this will include ensuring that the process is manageable and resources are allocated at key points. For the applicant, it will include providing complete and accurate information so that the Agency's assessment may be as effective and efficient as possible, and obtaining a decision from the Agency within a reasonable time.

Effectiveness

The process should be designed to support the overarching objective of the licensing framework. In addition, it should be flexible enough to respond to changes in the assisted human reproduction sector, and promote the flow of information to encourage continuous improvement.

Adequate Oversight

The process should allow the Agency to collect information to support the Agency's role to assure that licensees are in compliance with the requirements of the Act, regulations and terms and conditions of a licence. This can be achieved by analysing the information obtained through Agency inspections.

4.0 Process

Graphic representations of the proposed licensing administration process can be found in the Attachments. The licensing process will allow the collection of information at key points to support the overarching objective of the licensing framework. These points include when an applicant submits a licence application, and when a licensee requests a

licence renewal or an amendment.

As noted above, the Agency has the legislative authority under section 40(6) of the AHR Act² to attach terms and conditions in accordance with the regulations at the time a licence is issued or any time after that. This could include when a licensee requests a licence renewal or an amendment, or situations where the Agency decides to attach terms and conditions during the holding of a licence (e.g., to address specific situations such as where a new health and safety risk is identified with respect to a particular controlled activity). While core requirements and other premises-related qualifications will be outlined in the regulations, the attaching of terms and conditions will allow the Agency to tailor licence requirements to individual applicants.

During the licensing process, there will be opportunities for the applicant to communicate with the Agency to ask questions and to seek clarification concerning licensing requirements. In addition, the applicant may wish to communicate with the Agency while the application is being reviewed to ask about the status of the review or to clarify information.

During the licensing process, the Agency will:

- act as the contact point for the applicant;
- review the licence application and seek input, as may be required, in accordance with section 43(1) of the Act³;
- prepare a summary of the application (for a licence, renewal or amendment). The summary will outline factual information pertaining to the application;
- invite the applicant to comment on the summary of the application and to respond to any input received under section 43(1) of the Act;
- report to the Board; and
- record the Board's decisions, and notify the applicant. If the application is approved, the Agency will require the applicant's acceptance, in writing, of any terms and conditions attached. If the application is not approved, the Agency will notify the applicant of the reasons for the Board's decision.

²AHRA, Section 40(6): "The Agency may, in accordance with the regulations, attach terms and conditions to a licence at the time of issuing the licence or at any time after that."

³AHRA, Section 43. (1): "In exercising its powers under sections 40 to 42, the Agency may take into account information and observations offered by any person and may seek the advice of persons having expertise related to the application or of persons representative of any interest affected by the application."

The Board will:

- consider the summary of the application, any input received under section 43(1) of the Act, and the applicant's comments respecting the summary of the application and input received under section 43(1);
- decide whether to approve the application, with or without terms and conditions; and
- make a decision regarding the application and, if the application is approved, determine whether terms and conditions should be attached. If the application is not approved, the Board will provide reasons for its decision.

4.1 Controlled Activity Licensing

Applying for a Controlled Activity Licence

From a list of designated controlled activities, the applicant will select the activities which he or she intends to undertake, identify the qualification requirements specified in the regulations, and submit the completed application form together with information or documentation which substantiate the qualifications and establish compliance with the Act and regulations.

Agency Review and Assessment, Approving or Refusing an Application, Issuing a Controlled Activity Licence for an Approved Application

Upon receipt of the application package, the Agency will send an acknowledgement to the applicant. If the information or documentation submitted is incomplete, the Agency will request further information.

Once a complete application is received, the Agency will begin its review and assessment. The Agency may seek input regarding the application in accordance with section 43(1) of the Act. This may allow the Agency to gather important information for the Board to make its decisions about a licence application. Once the Agency has considered any input received, it will prepare a summary of the licence application. The applicant will be provided with an opportunity to comment on the summary and to respond to any comments received under section 43(1). The Agency will submit the applicant's comments to the Board together with the summary of the licence application, and any input received under section 43(1). In making its decision, the Board will consider whether the applicant meets the requirements for undertaking the controlled activities for which the licence is requested, and whether the person is able to carry out the controlled activities in accordance with the Act and regulations. If the Board approves the

application, it may decide to attach terms and conditions. In this case, the Board will issue a controlled activities licence only after obtaining the applicant's acceptance, in writing, of the terms and conditions attached.

If the Board refuses the application, the Agency will send the applicant a notice outlining the reasons for the refusal. The applicant may submit a new application to address any deficiencies identified in the refusal.

Renewing a Controlled Activity Licence

A controlled activity licence could be renewable after a specified period of time. Some renewal options could include:

- standardizing the renewal period for all controlled activity licences (single or multi-year period):
 - a) licence is renewable on the anniversary of the day on which it was issued; or
 - b) licence is renewable on a fixed date (e.g., December 31st); or
- making case-by-case decisions about the renewal period based on the licensee's qualifications and compliance history, as well as input which could be sought according to section 43(1) of the Act.

Alternatively, a phased approach could be used for licence renewals (e.g., one year for the first renewal, two years for the second renewal, and three years for each subsequent renewal).

To allow sufficient time for the Agency to process the application, it is proposed that the renewal application be received by the Agency 90 days prior to the licence's expiry date. The Agency will acknowledge receipt of the renewal application, and may seek input in accordance with section 43(1) of the Act. It will then prepare a summary of the renewal application, and invite comments from the applicant on the summary and in response to any input received under section 43(1). The Agency will submit the applicant's comments to the Board together with the summary of the renewal application and any input received under section 43(1). In making its decision, the Board will examine whether there is evidence of non-compliance with the Act and regulations or the licence terms and conditions, if applicable, in addition to any other relevant considerations. If the renewal application is approved, and the Board decides to attach new terms and conditions to the licence, the licensee must accept these in writing before the licence is renewed.

If no renewal application is received by the Agency or the application is not received within 90 days of the expiry date, the licence will expire. If the licensee wishes to resume undertaking controlled activities, a new application may be submitted.

Amending a Controlled Activity Licence

A licensee may wish to request an amendment of a controlled activity licence for changes according to the regulations for controlled activities (e.g., to seek changes to the terms and conditions).

The Agency will acknowledge receipt of the amendment application, and may seek input in accordance with section 43(1) of the Act. In reviewing the application, the Agency will consider whether the licensee is qualified for the changes requested and meets any other requirements. The Agency will prepare a summary of the amendment application, and the applicant will be provided with an opportunity to comment on the summary and to respond to any comments received under section 43(1). Following this, the Agency will submit the applicant's comments to the Board with the summary of the amendment application and any input received under section 43(1).

If the Board approves the application, it may decide to attach terms and conditions to the licence, as may be required by the nature of the amendment (where the amendment concerns a request for changes to the existing terms and conditions, new terms and conditions may be attached). In this case, an amended licence will be issued only once the licensee has accepted the terms and conditions, in writing. Once an amended licence is issued, the old licence must be returned to the Agency within 30 days. If the Board refuses the amendment application, the existing licence will continue to be valid.

Relinquishing a Controlled Activity Licence

A licence could be relinquished if the licensee no longer intends to undertake the controlled activities to which the licence pertains, or no longer meets the regulatory requirements for controlled activities or the terms and conditions of the licence, if applicable. In this case, the licensee must notify the Agency and return the controlled activity licence.

4.2 Premises Licensing

The purpose of a premises licence will be to demonstrate that the physical features of the premises are suitable for undertaking controlled activities.⁴

Applying for a Premises Licence

An applicant for a premises licence will need to demonstrate that the premises is physically suitable for undertaking the intended controlled activities. Key areas of information that would be required as part of the application package include the identity of the licensee and premises, and the building design. Specific information or documentation could include:

- location;
- business plan;
- lease contract, if the building or premises is not owned by the applicant, demonstrating that the owner will manage the building or premises in accordance with the Act and regulations, and disclosure of any restrictions that may hinder the maintenance or modification of the buildings for the purpose of compliance with the Act and regulations; and
- building design plan.

Agency Review and Assessment, Approving or Refusing an Application, Issuing a Premises Licence for an Approved Application

Upon receipt of the application package, the Agency will send an acknowledgement to the applicant. If the information or documentation submitted is incomplete, the Agency will request further information. Once a complete application has been received, the Agency will begin the review and assessment.

The Agency may seek input in accordance with section 43(1) of the Act. Once the Agency has considered any input received, it will prepare a summary of the licence application. The applicant will be provided with an opportunity to comment on the summary and to respond to any comments received under 43(1). The Agency will submit the applicant's comments to the Board together with the summary of the licence

⁴For a discussion of the regulatory requirements for premises, please refer to the consultation background paper "Licensing Under the *Assisted Human Reproduction Act*: Premises-Related and Organization-Related Requirements for the Undertaking of Controlled Activities."

application, and any input received under section 43(1). In making its decision, the Board will consider whether the applicant meets the requirements for premises, and the premises is suitable for the controlled activities to be undertaken in the proposed location. If the Board approves the application, it may decide to attach terms and conditions. In this case, the Board will issue a premises licence only after obtaining the applicant's acceptance, in writing, of the terms and conditions attached.

If the Board refuses the application, the Agency will send the applicant a notice outlining the reasons for the refusal. The applicant may submit a new application to address any deficiencies identified in the refusal.

Renewing a Premises Licence

A premises licence could be renewable after a specified period of time. Some options for the renewal period could include:

- standardizing renewal periods for all premises licences (single or multi-year period):
 - a) licence is renewable on the first anniversary of the day on which it is issued; or
 - b) licence is renewable on a fixed date (e.g. December 31st); or
- making case-by-case decisions about the renewal period based on the licensee's compliance history and input which could be sought, according to section 43(1) of the Act.

As noted for controlled activity licences, a phased approach could also be used for the renewal of premises licences.

To allow sufficient time for the Agency to process the application, it is proposed that the renewal application be received by the Agency 90 days prior to the licence's expiry date. The Agency will acknowledge receipt of the renewal application, and may seek input in accordance with section 43(1) of the Act. It will then prepare a summary of the renewal application, and invite comments from the applicant on the summary and on any input received under 43(1). The Agency will submit the applicant's comments to the Board together with the summary of the renewal application and any input received under section 43(1). In making its decision, the Board will examine whether there is evidence of non-compliance with the Act and regulations or the licence terms and conditions, if applicable, in addition to any other relevant considerations. If the renewal application is approved, and the Board decides to attach new terms and conditions to the licence, the

licensee must accept these in writing before the licence is renewed.

If no renewal application is received by the Agency or the application is not received within the prescribed 90 days, the licence will expire. If the licensee wishes to resume undertaking controlled activities in those premises, a new application may be submitted.

Amending a Premises Licence

A licensee may wish to request an amendment for changes according to the regulations for premises (e.g., to seek changes to the terms and conditions, if applicable).

The Agency will acknowledge receipt of the amendment application, and may seek input in accordance with section 43(1) of the Act. In reviewing the application, the Agency will consider whether the premises will still be able to meet regulatory requirements if the changes are made. The Agency will prepare a summary of the amendment application, and the applicant will be provided with an opportunity to comment on the summary and to respond to any comments received under section 43(1). Following this, the Agency will submit the applicant's comments to the Board with the summary of the amendment application and any input received under section 43(1).

If the Board approves the application, it may decide to attach terms and conditions to the licence, as may be required by the nature of the amendment (where the amendment concerns a request for changes to the existing terms and conditions, new terms and conditions may be attached). In this case, an amended licence will be issued only once the licensee has accepted the terms and conditions, in writing. Once an amended licence is issued, the old licence must be returned to the Agency within 30 days. If the Board refuses the amendment application, the existing licence will continue to be valid.

Relinquishing a Premises Licence

A premises licence could be relinquished if a licensee no longer wishes to operate a premises where controlled activities are undertaken, or no longer meets the regulatory requirements for premises or the terms and conditions, if applicable. In this case, the licensee must notify the Agency and return the premises licence.

5.0 Conclusion

This paper has outlined a proposal for the licensing administration process for controlled activities and for premises where controlled activities are undertaken. The process has been designed to reflect basic principles such as fairness, transparency and accessibility. In reflecting these principles, the process aims to support the overarching objective of the licensing framework which is to mitigate health and safety risks.