Health Canada Santé Canada

Guidance Document:

Interpretation of the Proposed Regulations under the *Assisted Human Reproduction Act*

Canada

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1. Purpose

In October 2016, Health Canada announced that it would take steps to help Canadians who use assisted reproductive procedures build their families safely and with peace of mind. Specifically, the Department announced its intention to proceed with bringing into force the outstanding sections of the *Assisted Human Reproduction Act* (AHR Act) and introducing supporting regulations. The proposed regulations have now been pre-published in *Canada Gazette*, Part I for a 75-day public consultation. The purpose of this guidance is to provide stakeholders with an interpretation of the proposed regulations so that they may more meaningfully provide their feedback. The guidance includes an explanation of key elements of the proposed regulations. Therefore, it should be read in concert with the proposed regulations and the draft Directive: *Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors*, rather than in isolation.

This guidance is presented acknowledging that the proposed regulations are subject to further changes. All comments received during the consultation period will be considered by the Department prior to the regulations being finalized and published in *Canada Gazette*, Part II.

2. Safety of Sperm and Ova Regulations

2.1. Regulated Parties

Primary Establishments

PRIMARY ESTABLISHMENTS AND THEIR RESPONSIBILITIES

A Primary Establishment is the entity responsible for ensuring that, prior to distribution or use in Canada, donor sperm and ova[1] are processed in accordance with the regulations. They are responsible for all processing activities, whether they conduct them themselves or another Establishment does any of the activities on their behalf.

In many cases, the Primary Establishment will be a large commercial sperm or ova bank. However, in certain instances, a fertility clinic or an individual physician may register as a Primary Establishment and take on the responsibility for all processing activities that it conducts itself or that is done on its behalf in order to facilitate a donation.

Example: a fertility clinic that specializes in offering fertility treatments to married couples and sexual partners could decide to expand their business to process sperm and ova from known donors where the recipient is not the spouse, common-law partner or sexual partner of the donor.

[1] "Donor sperm and ova" is understood to be sperm or ova that is obtained from a donor and that is meant for the use of a female person other than a spouse, common-law partner or sexual partner of the donor, or ova that has been obtained from a donor and that is meant for the donor's use as a surrogate mother.

REQUIREMENT TO REGISTER WITH HEALTH CANADA

A Primary Establishment must register with Health Canada by submitting an application for a registration in a form established by the Minister, and must list the name and civic address of all the Establishments that are conducting processing activities on their behalf. An application for registration must also include an attestation from a senior executive officer of the applicant that any other Establishment that conducts any processing activities on its behalf is able to meet the requirements of the regulations.

When a Primary Establishment submits an application for a registration, the application must include an attestation that the Primary Establishment has evidence demonstrating that it, and any other Establishment conducting processing activities on its behalf, meets the requirements of the regulations.

Example: a Primary Establishment that outsources infectious disease testing to a contract laboratory must ensure that the laboratory conducts the testing in accordance with the regulations.

AMENDMENTS, CHANGES, AND CESSATIONS OF REGISTRATIONS BY A PRIMARY ESTABLISHMENT

A registered Primary Establishment that processes sperm or ova can only do so in accordance with its registration. As such, a registered Primary Establishment that processes only sperm or only ova must submit an application to the Minister to amend its registration in advance of beginning to conduct processing activities on the other. For example, if a Primary Establishment only processes sperm, and would like to begin processing ova, they must submit an application to amend their registration prior to conducting any processing activities for ova and that application must not be refused.

For any other changes to the information provided in the application (other than a change that is subject to an application for an amendment to the registration) or a cessation of activities, a Primary Establishment must notify the Minister within 30 days after the change or cessation occurs. For example, if a Primary Establishment already holds a registration and would like to add or change a testing Establishment that is conducting those activities on their behalf, the Primary Establishment must notify Health Canada within 30 days after the day on which the change occurred.

SUSPENSIONS AND CANCELLATIONS OF REGISTRATIONS BY THE MINISTER

In circumstances where the Minister has reasonable grounds to believe that the safety of sperm or ova or human health and safety has been or could be compromised, the Minister has the authority to immediately suspend a registration without prior notice, in whole or in part. When the Minister suspends an Establishment's registration, the Minister must send the Primary Establishment a notice that provides the reasons for the suspension and the effective date of the suspension, as well as an opportunity to be heard. The Minister also has the authority to cancel a registration in certain circumstances, including if the Minister has reasonable grounds to believe that a Primary Establishment does not meet the requirements of the regulations. Before the Minister cancels a registration, the Minister must send a notice that provides the reasons for the proposed cancellation along with its effective date and

provide the Primary Establishment with an opportunity to be heard prior to reaching a final decision on cancellation.

Establishments

ESTABLISHMENTS AND THEIR RESPONSIBILITIES

An Establishment is an entity that imports or distributes donor sperm or ova or conducts any processing activity (see the section "Processing" for a description of processing activities) with regard to such sperm or ova. A Primary Establishment is also considered to be an Establishment.

An Establishment that conducts a processing activity in respect of sperm or ova must do so in accordance with the regulations. If they are conducting that activity on behalf of a Primary Establishment they must be included in the registration of that Primary Establishment.

Example: A testing lab may conduct donor testing on behalf of a Primary Establishment. That testing lab is considered an Establishment, and is subject to the requirements of the Safety of Sperm and Ova Regulations, but is not required to individually register with Health Canada. However, this testing lab is required to be included in the registration for all Primary Establishments for whom it conducts donor testing.

An Establishment that imports donor sperm or ova must notify Health Canada prior to doing so and must ensure that the donor sperm or ova are processed by a Primary Establishment that is registered with Health Canada. Where the Establishment that imports is a Primary Establishment, they must ensure that the donor sperm or ova are processed by a Primary Establishment that is registered with Health or take on the responsibility for ensuring that the sperm or ova they import has been processed in accordance with the regulations.

An Establishment that distributes donor sperm or ova must notify Health Canada prior to doing so.

The notice that is sent to Health Canada by Establishments that import or distribute donor sperm or ova must be in a form established by the Minister. The notice sets out if the Establishment plans to import or distribute sperm, ova, or both, and provides the projected start date. As well, the notice must include information on each Primary Establishment that the Establishment imports or distributes from, including their registration number.

Finally, an Establishment that independently conducts a processing activity (i.e. not on behalf of a Primary Establishment) and is not a Primary Establishment itself, as it does not conduct all processing activities (such as a fertility clinic that stores donor sperm or ova), must do so in accordance with the regulations. However, this type of Establishment is not required to be registered with Health Canada, be included in a Primary Establishment's registration, or notify Heath Canada unless they also distribute or import donor sperm and ova.

ANNUAL ATTESTATION OF COMPLIANCE

Primary Establishments, as well as any Establishment that distribute or import sperm or ova must send an annual attestation, in a form established by the Minister. The attestation must include a statement certifying that the Establishment has evidence to demonstrate that it meets the requirements of the *Safety of Sperm and Ova Regulations*. A Primary

Establishment must also attest that any Establishment that processes sperm or ova on its behalf meets the requirements of the regulations.

When submitting the annual attestation of compliance, specific evidence to demonstrate compliance only needs to be submitted if requested by the Minister.

Health Professionals and Medical Directors

HEALTH PROFESSIONALS AND THEIR RESPONSIBILITIES

A health professional is a person who is authorized by the laws of their province or territory to make use of donor sperm or ova in AHR. A Health Professional is not considered an Establishment when he or she does not conduct activities other than the following:

i) making use of donor sperm or ova, or distributing donor sperm to a recipient for their personal use;
ii) preparing, quarantining, labeling or storing donor sperm or ova only for the purpose of making use of that sperm or ova and who makes use of that sperm or ova; or
iii) preparing, quarantining, labeling or storing donor sperm only for the purpose of distributing sperm to a recipient for their personal use and distributes that sperm to a recipient for their personal use.

As an integral part of the health and safety framework, health professionals are required to meet certain regulatory requirements with regard to records to permit the traceability of the donor sperm or ova, as well as requirements related to errors, accidents, and adverse reactions.

Where a person that is authorized to make use of donor sperm or ova conducts any activity other than those listed in the definition of a health professional, that person would be considered an Establishment and subject to the relevant Establishment requirements that correspond to the activities being carried out.

Example: A Health Professional who prepares, quarantines, labels or stores sperm or ova for the purpose of making use of that sperm or ova or for the purpose of distributing that sperm or ova to a recipient for their personal use is not considered an Establishment. However, where that Health Professional has incorporated their practice, the corporation is considered an Establishment and is subject to quality management requirements, among others. However, they are not required to register with Health Canada, be included in a Primary Establishment's registration, or notify Health Canada about their activities.

If a person was considered a final physician distributor under the current *Processing and Distribution of Semen for Assisted Conception Regulations*, and their activities have not changed, in that they are making use of sperm or ova for the purpose of assisted human reproduction, they are considered a Health Professional under the *Safety of Sperm and Ova Regulations*, unless they have incorporated their practice, in which their corporation would be considered an Establishment.

MEDICAL DIRECTORS AND THEIR RESPONSIBILITIES

The Medical Director is a person in the Primary Establishment who is authorized under the laws of the jurisdiction in which the Primary Establishment is situated to practice the profession of medicine and who is responsible for all medical and technical procedures carried out during the processing of sperm or ova.

The Medical Director plays a number of key roles during processing that are critical to ensuring the safety of the donation. First, based on the review of the information including the results of the donor screening, donor testing and physical examination, the Medical Director determines the suitability of each donor. Second, the Medical Director determines and documents that a donation may be released from quarantine, which allows the donation to be distributed. Finally, after determining that the donor is suitable, the Medical Director must create a summary document that contains donor test results and a confirmation of the donor's suitability.

In the case of Directed Donations (see the section "Donor Suitability Assessment Pathways" for a description of the Directed Donation Process), the Medical Director is responsible for reviewing and documenting the information obtained from the donor suitability assessment and, if applicable, the donor reassessment. In addition, the Medical Director is responsible for documenting any exclusion criteria that were met by the donor or parts of donor suitability assessment that were not conducted, for consideration by the Health Professional.

The Medical Director is also responsible for conducting the physical examination of the donor and for the preparation of the structured questionnaire used to screen the donor. The Medical Director may designate a physician for either of these purposes.

2.2. Processing

General Requirements

PROCESSING

Donor sperm and ova must be processed in accordance with the regulations to reduce the risk of disease transmission to the recipient and the child. Processing includes a number of steps that must be conducted in a manner that maintains the quality of the donor sperm and ova and prevents contamination and cross-contamination.

Specifically, the following processing steps must be done prior to the distribution, importation and use of donor sperm or ova:

- Tests in respect of the sperm or ova have been conducted in accordance with the regulations;
- The sperm or ova has been obtained, prepared, preserved, quarantined, identified, labelled, stored and its quality assessed in accordance with the regulations; and
- The donor of the sperm or ova has been screened and tested, and the donor's suitability has been assessed, in accordance with the regulations.

While the Primary Establishment is responsible for ensuring that donor sperm and ova are processed in accordance with the regulations, an Establishment included in the Primary Establishment's registration may conduct any of the processing activities on the Primary Establishment's behalf. In such an instance, the Primary Establishment is responsible for ensuring that the Establishment conducts its processing activity in accordance with the regulations.

Donor Suitability Assessment

A donor suitability assessment is conducted to identify risk factors that could potentially impact the safety of donor sperm and ova and is based on: donor screening (which includes a review of the donor's medical and social history and clinical status), a physical examination, and donor testing.

Where the results of donor screening, the physical examination or the donor testing do not meet the requirements specified in the regulations, the donor must be considered unsuitable and should, subject to certain exceptions, be excluded from donating.

Example: a potential donor who has been diagnosed with the Zika virus within the past six months would be considered unsuitable to donate.

Donor Screening

DONOR SCREENING REQUIREMENTS

All donors must be screened for the risk factors for, or clinical evidence of, relevant infectious diseases and serious genetic diseases. This information is obtained through a donor interview conducted using a structured questionnaire prepared by the Medical Director or a physician designated by the Medical Director in the case of infectious diseases or, in the case of serious genetic diseases, a structured questionnaire prepared by the Medical Director or a qualified professional designated by the Medical Director.

In addition, the age of a donor can impact the safety of the donation. Beyond a certain age, there is an increased risk that the use of donor sperm and ova could lead to adverse reproductive outcomes (e.g. genetic abnormalities, increased epigenetic risks) and could present a risk for the child born through AHR. Thus, the age of the donor must be listed on the summary document prepared by the Medical Director for consideration by the Health Professional, to enable them to assess the risk of using the donation and inform the recipient of any risk.

An Establishment that conducts the donor screening must develop and maintain standard operating procedures for all steps performed during the donor screening process.

GENETIC DISEASE SCREENING REQUIREMENTS

The Medical Director, or a qualified professional designated by the Medical Director, at the Primary Establishment is responsible for preparing a structured questionnaire that allows for the donor to be screened for the risk of transmitting serious genetic diseases (autosomal dominant, autosomal recessive, and X-linked) based on the medical history of the donor and three generations (including the donor, their parents and grandparents) of family medical history, if available.

In preparing the questionnaire, special consideration should be given to the genetic diseases and disorders that are prevalent in the donor's ethnic background. Donors of sperm or ova are not required to undergo testing for presence of serious genetic diseases; however, if the relevant genetic testing results of the donor are available then those results may be used instead of the genetic disease screening to assess the donor for the risk of serious genetic disease transmission.

Based on the results of genetic disease screening, the Medical Director at the Primary Establishment is responsible for carrying out and documenting an assessment of the risk of genetic disease transmission. This should include an assessment of the risk associated with the donor being a carrier (heterozygous) of a genetic disorder. Before making use of the donation or distributing it to a recipient for their personal use, the Health Professional must create a document stating that he or she has informed the recipient of the risks of genetic disease transmission that the use of the donation could pose to human health and safety.

Examples of serious genetic diseases include, but are not limited to, cystic fibrosis, Tay-Sachs disease and Duchenne muscular dystrophy.

Physical Examination

PHYSICAL EXAMINATION

As part of the donor suitability assessment, the Medical Director or a physician designated by the Medical Director at the Primary Establishment is responsible for performing a physical examination of the sperm and ova donors.

The purpose of a physical examination is to assess any physical evidence that could indicate the presence of an infectious disease and any signs of an infectious or genetic disease. Based on the donor information and medical history, a more tailored examination should be performed to address specific issues or concerns in regards to the donor suitability assessment. A physical examination of the donor by another physician completed within the previous six months, where indications of high-risk for infectious or genetic disease transmission were assessed, may be reviewed and documented in the donor's records in lieu of a new physical examination.

Example: A potential donor whose physical examination reveals evidence of non-medical intravenous drug use would be unsuitable to donate.

Donor Testing

INFECTIOUS DISEASE TESTS

The Primary Establishment is responsible for testing a donor for the presence of the following infectious disease agents, using donor 'screening' test kits, except, in the case of syphilis, chlamydia, and gonorrhoeae in which case either donor 'screening' or 'diagnostic' test kits can be used:

a) Human Immunodeficiency Virus (HIV)-1 and 2;
b) Hepatitis C Virus (HCV);
c) Hepatitis B Virus (HBV);

d) Human T-cell Lymphotropic Virus (HTLV)-I and -II (sperm donor only);
e) *Treponema pallidum* (syphilis)
    i. non-treponemal test; or
    ii. treponemal-specific test.
f) Cytomegalovirus (CMV) (sperm donor only);
g) West Nile Virus (WNV), if the donation is made during the time of year when WNV is potentially transmissible to humans in the donor's country of residence, or if in the preceding 56 days, a donor has lived in or travelled to an area where WNV is endemic;
h) *Chlamydia trachomatis*; and
i) *Neisseria gonorrhoeae*.

A donor must be tested using appropriate and effective test methods and according to the manufacturer's instructions for the type of specimen, the performance of the test (e.g. collection, handling, storage, etc.) and the interpretation of the results. Test kits licensed in Canada must be used for donor testing that is performed in Canada. Where donor testing is performed outside of Canada, test kits licensed in Canada or the United States must be used.

Health Canada considers the following tests to be appropriate and effective for donor testing:

a. *for HIV:*
    I. *anti-HIV-1, anti-HIV-2, and HIV antigen; or*
    II. *anti-HIV-1, anti-HIV-2, and HIV-1 NAT;*
b. *HCV using HCV antibody;*
c. *HBV using surface antigen and total (IgG and IgM) anti-core HBV antibody;*
d. *Treponemal-specific test or non-treponemal test;*
e. *Chlamydia using NAT;*
f. *Gonorrhoeae using NAT;*
g. *HTLV-1 and HTLV-2 using HTLV-1 antibody and HTLV-2 antibody; and*
h. *CMV using IgM and IgG.*

Any Establishment conducting donor testing must have standard operating procedures that describe all infectious disease tests to be performed and the handling of positive and indeterminate test results.

Testing must be performed by a laboratory that meets applicable accreditation requirements of the province in which the laboratory is located. In the case of donor sperm and ova processed in another country, the testing laboratory must be accredited by an organization that is considered an acceptable accreditation organization by the foreign jurisdiction from which the sperm or ova is imported.

Sperm donors must be tested using a specimen collected within 7 days of obtaining the sperm sample. Ova donors must be tested using a specimen collected within 30 days before obtaining the ova or within 7 days of obtaining the ova. Repeat sperm donors must be retested at least every 6 months. Ova donors must be tested at the time of each donation.

Quarantine

QUARANTINE REQUIREMENTS

Donor sperm and ova must be quarantined until the Medical Director of the Primary Establishment that is responsible for the quarantine of the donor sperm or ova has completed the donor suitability assessment and, subject to certain exceptions, the sperm donor is retested and the retesting requirements are met. The quarantined donor sperm and ova must be clearly identifiable as quarantined and kept segregated from the donor sperm or ova that are not required to be quarantined. The segregation can take the form of keeping the donor sperm or ova in a physically separate area designated for such use or through the use of a validated electronic segregation system (e.g. a validated computer system and barcode labeled sperm/ova containers). In addition, an Establishment that quarantines must ensure that the quarantined donor sperm or ova are not distributed.

Donor Suitability Assessment Pathways

THE REGULAR PROCESS

Donors must be screened, tested and physically examined in order for the Medical Director to determine the suitability of the donor. Except under certain exceptional circumstances, the distribution of sperm and ova from donors who are determined to be unsuitable is not permitted.

Donor sperm and ova must be quarantined until the Medical Director has determined that the donor of the sperm or ova is suitable. Furthermore sperm donations must be quarantined for at least 180 days after the date of donation and the donor retested prior to release from quarantine. If a donor is determined to be suitable, the Medical Director must create a summary document confirming the donor's suitability that must accompany the donation throughout the distribution chain.

THE DIRECTED DONATION PROCESS

In the case where the donor and recipient know one another, and at the request of a Health Professional, they may elect to have the donation processed in accordance with the Directed Donation Process, which provides the recipient with more flexibility in selecting their donor, while still prioritizing the safety of the donation.

Under the Directed Donation Process, the donor must still be screened, tested and physically examined, as they would be under the Regular Process. However, a donor is not automatically determined unsuitable even if their screening, testing or physical examination results should have excluded them from donating under the Regular Process. Furthermore, under the Directed Donation process, sperm donors are not required to be retested after a 180 day quarantine period. The use of fresh sperm is permitted.

In the case of Directed Donation, the signed summary document created by the Medical Director must outline any reasons that the donor would have been determined unsuitable under the Regular Process. Based on this information and any risk mitigation measures with respect to the sperm or ova in question, prior to making use of the donor sperm or ova or distributing the donor sperm to a recipient for their personal use, the Health Professional

must create a document stating that in his or her medical opinion the use of the donation would not pose a serious risk to human health and safety of the recipient and the future child.

The Health Professional must create a document stating that he or she has informed the recipient of the risks that the use of the donation could pose to human health and safety.

Additional labeling and storage requirements also apply to donor sperm and ova processed under the Directed Donation Process.

The Directed Donation Process is designed to account for a variety of scenarios where the donor's suitability assessment was not conducted prior to cryopreserving the donation. Such scenarios include where the donor cryopreserved their sperm or ova for their own use and subsequently the donor wishes to donate his or her sperm or ova to a known recipient. In such cases, unless it is not possible to do so, the donor's suitability must be assessed after the fact and the information obtained from the assessment must be included in the summary document created by the Medical Director for consideration by the Health Professional who intends to make use of the donor sperm or ova or distribute the sperm to a recipient for their personal use.

Where the donor suitability assessment is not possible, the Medical Director must review any available medical information about the donor and create a summary document for consideration by the Health Professional who intends to make use of the donor sperm or ova, or distribute the sperm to a recipient for their personal use.

Example #1: A woman cryopreserves her ova for family building purposes with her husband. A complete donor suitability assessment is not conducted at the time of cryopreservation because the regulations do not apply to such a scenario. The woman and her husband fulfill their own reproductive needs and have excess frozen ova. Subsequently, the woman's sister discovers that she requires the use of donor ova to start a family. Despite not having had her suitability assessed at the time of donation, the first sister could donate the cryopreserved ova to the second sister provided the Medical Director at the Primary Establishment reviews any available medical information and available results of any donor screening, physical examination or donor testing that was previously conducted, takes appropriate measures to complete the suitability assessment, and creates summary document for consideration by the Health Professional who intends to make use of the ova.

Example #2: A young man faces a medical procedure that may compromise his fertility. Prior to undergoing this procedure, he decides to cryopreserve his sperm for future family building purposes. A complete donor suitability assessment is not conducted at the time of cryopreservation because the regulations do not apply to such a scenario. Years later, with his fertility unfortunately compromised, the man wants to start a family and does not have a spouse, common-law partner or sexual partner, but has a friend who is willing to be a surrogate. Despite not having had his suitability assessed, the man could donate his sperm for use by the surrogate, provided the Medical Director at the Primary Establishment reviews any available medical information and available results of any donor screening, physical examination or donor testing that was previously conducted, takes appropriate measures to complete the suitability assessment, and creates summary document for consideration by the Health Professional who intends to make use of the ova.

Exceptional Access

EXCEPTIONAL ACCESS

Access to donor sperm and ova that otherwise cannot be released from quarantine (e.g. because it was not processed in accordance with the regulations or is the subject of an error, accident or adverse reaction investigation) may be permitted under exceptional circumstances, including where accessing such a donation is for the purpose of creating a genetic sibling of another donor-conceived child. Similar to donor sperm and ova processed under the Directed Donation Process, a Health Professional must request from the Primary Establishment the donor sperm and ova under Exceptional Access. Additional labelling and storage requirements apply. Likewise, a summary document created by the Medical Director must accompany the donation throughout the distribution chain for consideration by the Health Professional. The summary document must contain the reasons and detailed explanation for each reason why the donor was determined to be unsuitable, or a description of the suspected error, accident or adverse reaction and an explanation of how human health and safety or the safety of the sperm or ova might have been compromised.

2.3. Quality Management

Quality Management – General

REQUIREMENTS FOR ESTABLISHMENTS

Establishments must have an appropriate quality management system to support the objective of consistently conducting activities in such a way as to reduce the risks to the safety of donor sperm and ova and to human health and safety by having appropriate measures for quality management and taking measures to prevent contamination or cross-contamination, to prevent infectious disease transmission and to maintain the quality of donor sperm and ova.

The requirements of a quality management system include process controls, appropriate environmental control and monitoring systems, shipping standards, as well as systems for process validation, process improvement, internal auditing, training of personnel, tracing sperm and ova, and records management. Establishments must also conduct internal audits of the activities it carries out every two years to verify that those activities comply with the regulations and its own standard operating procedures.

REQUIREMENTS FOR HEALTH PROFESSIONALS

While Establishments are required to meet all quality management system requirements, health professionals are only subject to specific quality management provisions regarding error, accident and adverse reaction investigation and reporting, as well as records.

Quality Management System

STANDARD OPERATING PROCEDURES

Standard operating procedures set out the processes for an Establishment to follow in conducting its activities, so that activities are performed and documented consistently and in compliance with regulatory requirements.

An Establishment must develop and maintain written operating procedures describing the significant steps for each regulated activity that it conducts. For example, the Establishment must have operating procedures in place to outline the process to manage critical equipment, supplies and/or services used in any activity they undertake that is regulated under the *Safety of Sperm and Ova Regulations*.

PROCESS CONTROL PROGRAM

Establishments must have a process control program that covers all processing, distributing or importing in respect to sperm or ova.

Establishments should ensure that the processes are carried out under controlled conditions, according to written procedures prepared by qualified personnel. Any changes to the processes, materials, equipment and facilities that may impact the safety of sperm or ova or human health and safety must be reflected in the written procedures and approved before being implemented. Changes to standard operating procedures must be approved by the individual responsible for the quality management system.

PROCESS IMPROVEMENT SYSTEM

Establishments must have a system for process improvement that includes complaint monitoring and the implementation of corrective and preventative actions. Corrective action focuses on eliminating causes of existing nonconformities in order to prevent recurrence whereas preventive action focuses on eliminating the causes of potential nonconformities in order to prevent the occurrence. The Establishment must also have policies, processes and standard operating procedures for the handling of complaints. All complaints must be reviewed, assessed, documented, and investigated in accordance with the Establishment's standard operating procedures, including identifying and implementing corrective and preventive actions, as applicable. All decisions and follow-up actions, taken as a result of a complaint investigation must be recorded.

As part of the Establishment's system for process improvement, if preventive action is required, the preventive actions must be implemented and monitored to reduce the likelihood of a recurrence and to take advantage of the opportunity for improvement. Once corrective and/or preventive actions are implemented, the effectiveness of these actions must be evaluated.

SYSTEM FOR TRAINING AND EVALUATING PERSONNEL

Establishments must have a written training program as well as a formal competency-evaluation program. Personnel must receive initial and on-going training appropriate to their job responsibilities related to activities regulated under the *Safety of Sperm and Ova Regulations*, as defined in their standard operating procedures.

An Establishment must have and maintain a program for the evaluation of the competency of personnel. The elements of a competency program may include, but are not limited to:

(a) direct observation of performance;
(b) monitoring of records;
(c) written tests;
(d) assessment of knowledge of operating procedures and theory; and
(e) for personnel who normally perform routine testing, an assessment of performance through proficiency tests.

ENVIRONMENTAL CONTROL AND MONITORING SYSTEMS

All donor sperm and ova must be stored under defined and controlled environmental conditions, which must be defined in a standard operating procedure developed by the Establishment. Environmental parameters for storage, such as temperature and humidity, must be controlled and must be monitored using calibrated monitoring devices and there should be written procedures describing the actions to be taken in the event of deviations from established storage criteria.

PROCUREMENT AND MAINTENANCE PROGRAM FOR CRITICAL EQUIPMENT, SUPPLIES AND SERVICES

As part of the quality management system, an Establishment must have a system to identify, document and track all critical equipment, supplies, and services used in any activities that are regulated under the *Safety of Sperm and Ova Regulations*. Examples of critical equipment, supplies and services include, but are not limited to, those that are used in the collection of donor sperm and ova, the testing of the donor, and storage. Within this system, written specifications should be available for every component and Establishments should have defined processes for validation and preventative maintenance to ensure that the defined specifications continue to meet the applicable requirements of the *Safety of Sperm and Ova Regulations*.

SYSTEM FOR ERRORS, ACCIDENTS AND ADVERSE REACTIONS INVESTIGATION AND REPORTING

Establishments must have defined processes and standard operating procedures to identify, gather information, and address any errors and accidents and adverse reactions that occur. These standard operating procedures should outline the decision-making processes used in determining whether an investigation is warranted and the implementation of any corrective actions, as appropriate. As well, Establishments must also have a system to conduct recalls of donor sperm and ova. Standard operating procedures must be in place to define steps for a recall and removal of any non-conformant donor sperm and ova from distribution or use and to describe reporting requirements for errors and accidents and adverse reactions to Health Canada as required in the *Safety of Sperm and Ova Regulations*.

DOCUMENT CONTROL AND RECORDS MANAGEMENT SYSTEM

Establishments must define, document and maintain operating procedures to control all quality documents and information relevant to the activities they conduct with respect to the *Safety of Sperm and Ova Regulations*. In particular, the distribution and maintenance of operating procedures and other quality documents, e.g. policies, forms, etc., must be controlled.

Personnel, Facilities, Equipment, and Supplies

FACILITY REQUIREMENTS FOR ESTABLISHMENTS

Facilities must be designed, constructed and adapted to suit the activities to be conducted. Their design and furnishing must minimize the risk of errors and be designed to align with the process flow, so that operations can proceed in an orderly manner. Buildings must be cleaned and maintained and there must be controlled access to areas where activities are conducted.

GENERAL REQUIREMENTS FOR EQUIPMENT

Establishments must ensure that the equipment it uses to conduct its activities are cleaned and maintained. Cleaning must be performed according to established schedules to prevent contamination and maintain the safety of the donor sperm and ova.

Equipment must also be qualified and calibrated according to the manufacturer's instructions, to ensure that it consistently operates within established specifications. Schedules and procedures for the maintenance and calibration of equipment must be maintained and followed according to the specifications in the equipment manual. If equipment has been repaired, moved, or modified, then re-calibration and/or requalification must be conducted in accordance with the Establishment's standard operating procedures and/or the manufacturer's manual before further use. Finally, all qualification, calibration, maintenance and repair activities, including actual results, are to be documented and retained by the Establishment.

Establishments must ensure that the equipment it uses for storage of sperm or ova maintains appropriate environmental conditions.

REQUIREMENTS FOR CRITICAL SUPPLIES

An Establishment must ensure that the critical supplies are validated or qualified, as applicable, prior to their use.

The conditions of use and storage of each supply must meet the conditions specified by the manufacturer. The expiry dates of supplies must be strictly observed.

REQUIREMENTS FOR SHIPPING

During shipping to another Establishment, between different sites of an Establishment, or a Health Professional, the shipping container must maintain the safety of the donor sperm and ova to ensure no tampering occurred that could affect the safety of the donor sperm and ova. A tamper-proof seal is one way of maintaining and verifying the integrity of the container.

The shipping containers must be able to maintain appropriate environmental conditions for the duration of the transport and the packaging materials must also be compatible with the donor sperm and ova in order to prevent any interactions which may cause the package to degrade or chemicals from the packaging to be absorbed by the donor sperm and ova.

Errors and Accidents

ERRORS AND ACCIDENTS

An error means a deviation from the standard operating procedures or applicable laws, including the regulations that could compromise the safety of sperm or ova or human health and safety.

An accident means an unexpected event that is not attributed to a deviation from the standard operating procedures or applicable laws, including the regulations and that could compromise the safety of sperm or ova or human health and safety.

SUSPECTED ERROR OR ACCIDENT – OCCURRED AT ANOTHER ESTABLISHMENT

An Establishment or health professional that has or previously had sperm or ova in their possession and has reasonable grounds to believe that an error or accident by another Establishment has occurred during the processing, distribution or importing of sperm or ova must immediately determine the donor identification code and donation codes of the implicated sperm or ova, quarantine any implicated sperm or ova in their possession or control, and notify the Establishment from which they received the implicated sperm or ova, and, in the case of an Establishment, notify every Establishment, Health Professional or recipient to whom it distributed the implicated sperm or ova.

WHAT TO DO IF YOU RECEIVE A NOTICE OF A SUSPECTED ERROR OR ACCIDENT

An Establishment or Health Professional that receives a notice regarding a suspected error or accident they must quarantine all implicated sperm or ova in their possession or control, and in the case of an Establishment, notify to the same effect every Establishment, Health Professional and recipient to whom it distributed the implicated sperm or ova.

SUSPECTED ERROR OR ACCIDENT – OWN ERROR OR ACCIDENT

An Establishment or Health Professional that has or previously had sperm or ova in their possession and has reasonable grounds to believe that an error or accident has occurred during the processing, distributing or importing of sperm or ova that they conducted must immediately quarantine any implicated sperm or ova in their possession or control, initiate an investigation into the suspected error or accident, and notify every Establishment, health professional or recipient to which it distributed the implicated sperm or ova. Except for exceptional access, the implicated sperm or ova must remain in quarantine until the results of the investigation reveal that its safety is not compromised. The Establishment or Health Professional that conducts an investigation into a suspected error or accident that could lead to an adverse reaction is also responsible for notifying the Minister within 72 hours after the start of the investigation, among other reporting requirements.

Adverse Reactions

ADVERSE REACTION

An adverse reaction is the unexpected presence of an infectious disease agent or the unexpected occurrence of an infectious disease in a recipient of sperm or ova, or a child created from that sperm or those ova.

SUSPECTED ADVERSE REACTION – ROLES AND RESPONSIBILITIES

An Establishment or Health Professional that has reasonable ground to believe that an adverse reaction has occurred must immediately quarantine the implicated sperm or ova and notify the Primary Establishment and, if the sperm or ova was imported, the importing Establishment.

The Primary Establishment is responsible for notifying other Establishments or Health Professionals to whom it distributed the implicated sperm or ova and for conducting an investigation into the suspected adverse reaction. Except for exceptional access, the implicated sperm or ova must remain in quarantine until the results of the investigation reveal that its safety is not compromised. The Primary Establishment is also responsible for issuing reports to the Minister regarding the investigation.

Records

GENERAL RECORD-KEEPING REQUIREMENTS

Records are a critical component of any quality management system as they provide documented evidence of compliance. Records must be accurate, complete, legible, and indelible and kept in a manner that allows them to be audited at any time. Upon coming into force of the *Safety of Sperm and Ova Regulations*, and during the transitional period, records must be created and updated at the same time that each significant step in the processing, distribution, importation, and making use of donor sperm and ova is performed. As well, all records relating to the processing, distribution, importation, and making use of donor sperm and ova must include the donor identification code and the donation code for each unit of sperm or ova. All records should identify the person who conducted the activities and the dates of the various entries.

An Establishment that keeps electronic records must have an electronic system validated for its intended use to ensure the maintenance of the data integrity of those records. Any changes to the electronic system must be evaluated, documented and approved prior to implementation to ensure the integrity of the data and that the records can be retrieved during the required retention period. A history of any changes to electronic records must be available in an audit trail and an Establishment must be able to retrieve and print a hard copy of information that is stored in an electronic record.

STORAGE REQUIREMENTS FOR RECORDS

Record storage areas must maintain the integrity of the records. Environmental parameters for storage, such as temperature, must be appropriate and controlled to the extent necessary in order to safeguard the integrity of the type of records being stored. Access to the storage area must be restricted to authorized persons.

2.4. Transitional Provisions

Primary Establishment

APPLYING AND RECEIVING REGISTRATION NUMBERS DURING THE TRANSITIONAL PERIOD

The *Safety of Sperm and Ova Regulations* come into force six months after they are published in *Canada Gazette,* Part II. Any Primary Establishment that processes sperm or ova before the regulations come into force may continue to do so without a registration provided it submits an application for registration to the Minister within three months after the day on which the regulations come into force. This applies until the registration is issued by the Minister or the application for registration is refused. Similarly, any Establishment that imports or distributes sperm or ova before the regulations come into force may continue to do so without prior notification as long as it sends a notification to the Minister within three months after the day on which the regulations come into force.

Until a Primary Establishment that has applied for registration receives its registration number, any Establishment that distributes or imports sperm or ova processed by that Primary Establishment is responsible for ensuring that the sperm or ova was processed in accordance with the regulations and that the primary Establishment has filed an application for registration within three months of the coming into force of the regulations. This applies until the registration is issued by the Minister or the application for registration is refused.

Sperm Obtained Prior to the Coming into Force Date

SPERM PROCESSED UNDER THE PROCESSING AND DISTRIBUTION OF SEMEN FOR ASSISTED CONCEPTION REGULATIONS

The distribution, use and importation of donor sperm that was processed in accordance with the *Processing and Distribution of Semen for Assisted Conception Regulations* prior to the coming into force of the new regulations is permitted.

THE DONOR SEMEN SPECIAL ACCESS PROGRAMME (DSSAP)

The DSSAP will be closed once the new regulations come into force. The Directed Donation Process and Exceptional Access were designed to account for the vast majority of scenarios that were previously accommodated under the DSSAP. Health Canada will no longer authorize the use of otherwise non-compliant donor sperm and ova. Rather, the new regulations have been designed to provide individuals with flexibility in choosing their donor, while ensuring that important information with respect to the risks that use of a donation may pose is provided to their Health Professional.

3. Reimbursement Related To Assisted Human Reproduction Regulations

3.1. Reimbursement

Purpose of Reimbursement Regulations

The AHR Act prohibits the purchase of sperm and ova from a donor or person acting on behalf of a donor and prohibits the payment to a female person to be a surrogate mother. Despite these prohibitions, Health Canada recognizes that donors and surrogates should not be out-of-pocket for expenditures they incur as a result of their altruistic donation or surrogacy. Similarly, while the purchase and sale of *in vitro* embryos is prohibited by the AHR Act, any person involved in the altruistic donation of *in vitro* embryo should not be out-of-pocket for expenditures related to the maintenance and transport of that embryo for the purpose of the donation.

Although there is no obligation to reimburse, the AHR Act allows the reimbursement of such expenditures, provided the reimbursement is done in accordance with the regulations. The purpose of the regulations is to set broad categories of expenditures eligible for reimbursement and to establish a verifiable process by which expenditures are reimbursed.

Who Can Be Reimbursed

Donors and surrogate mothers who incur expenditures related to their donation or surrogacy that fall within the scope of eligible expenditures set out in the regulations and persons who incur expenditures for the maintenance and transport of an *in vitro* embryo that also fall within the scope of eligible expenditures set out in the regulations may be reimbursed.

Furthermore, the AHR Act allows a surrogate mother to be reimbursed in accordance with the regulation for the loss of work-related income incurred during her pregnancy if a qualified medical practitioner certifies in writing that continuing to work may pose a risk to her health or that of the embryo or foetus.

Limits on Reimbursement

The regulations set out broad categories of expenditures that can be reimbursed, but do not set limits for the amount that may be reimbursed. However, all reimbursements must be for expenditures directly related to the donation or surrogacy or maintenance and transport of an *in vitro* embryo and must, with very few exceptions, be accompanied by a receipt.

The reimbursement of a particular expenditure must not involve financial or other gain. Furthermore, payment of "anticipated expenses" or an "unaccountable allowance" would be considered by Health Canada as a contravention of the prohibition in the AHR Act. Whether or not a specific expense is directly related to the donation or surrogacy depends on the particular circumstance(s) of the donation.

Requirements for Reimbursement

A person who makes a reimbursement under the regulations is required to obtain a signed declaration from the person who is requesting the reimbursement. The declaration must contain information about the expenditure(s) being reimbursed, including the nature of the expenditure(s) and the amount being requested. The person making the reimbursement must maintain records, including the signed declaration forms, receipts and other relevant documents, for a period of six years after the date of reimbursement.

4. Administration and Enforcement of the Assisted Human Reproduction Act

4.1. Inspection Powers

The Scope of Inspection Powers under the Act

Inspectors are designated for the purpose of the administration and enforcement of the Act. Subject to the rules that apply to dwelling houses, under section 47 of the Act, inspectors can enter any place or conveyance to verify compliance or prevent a non-compliance with any of the sections 8 (Consent), 10 (Safety) or 12 (Reimbursement), in which the inspector has reasonable grounds to believe that there is an activity, material or information in respect to any of those sections applies.

4.2. Seizure and Restoration

Seizure of Material or Information

An inspector, designated under the AHR Act, who enters a place or conveyance to verify the compliance or to prevent a non-compliance with sections 8, 10 or 12 of the Act may seize any material or information by means of which, or in relation to which, the inspector believes on reasonable grounds the Act has been contravened.

Process for Having Seized Material or Information Returned

A person from whom material or information is seized, may, within 60 days after the date of the seizure, apply to a provincial court judge within whose jurisdiction the seizure was made for an order of restoration.

Pursuant to the proposed regulations, the person must send a notice to the Minister at least 15 days before the day on which the application for an order of restoration is made.

4.3. Further Measures to be taken with Seized Viable Sperm, Ova or In Vitro Embryos

The Designated Officer under the Act

For the purposes of the AHR Act and the *Regulations on the Administration and Enforcement of the Assisted Human Reproduction Act*, the designated officer is identified as the Director General responsible for overseeing the compliance and enforcement of the AHR Act. Currently that officer is the Director General of the Medical Device and Clinical Compliance Directorate in the Regulatory Operations and Regions Branch in Health Canada.

Further Measures that may be taken with Seized Human Reproductive Material that is not returned

Health Canada must take all reasonable efforts to preserve any viable sperm, ova, or *in vitro* embryos that are seized under the Act or the Criminal Code. If that sperm, ova, or *in vitro* embryo is forfeited to the Crown, then any further measures taken must be consistent with the consent of the donor, which can include the original consent to use from the donor and any consent provided to a clinic by the donor for the destruction of the sperm, ova or *in vitro* embryo, unless it is impossible to obtain consent from the donor.

Further Measures that may be taken when it is Impossible to Obtain Consent of the Donor

If the viable donor sperm, ova or *in vitro* embryos are seized and then forfeited to the Crown, and if it is impossible to obtain the consent of the donor for further measures, the proposed regulations would only permit the designated officer to direct the disposal of the forfeited donor sperm, ova or *in vitro* embryos following 60 days after it had been forfeited.