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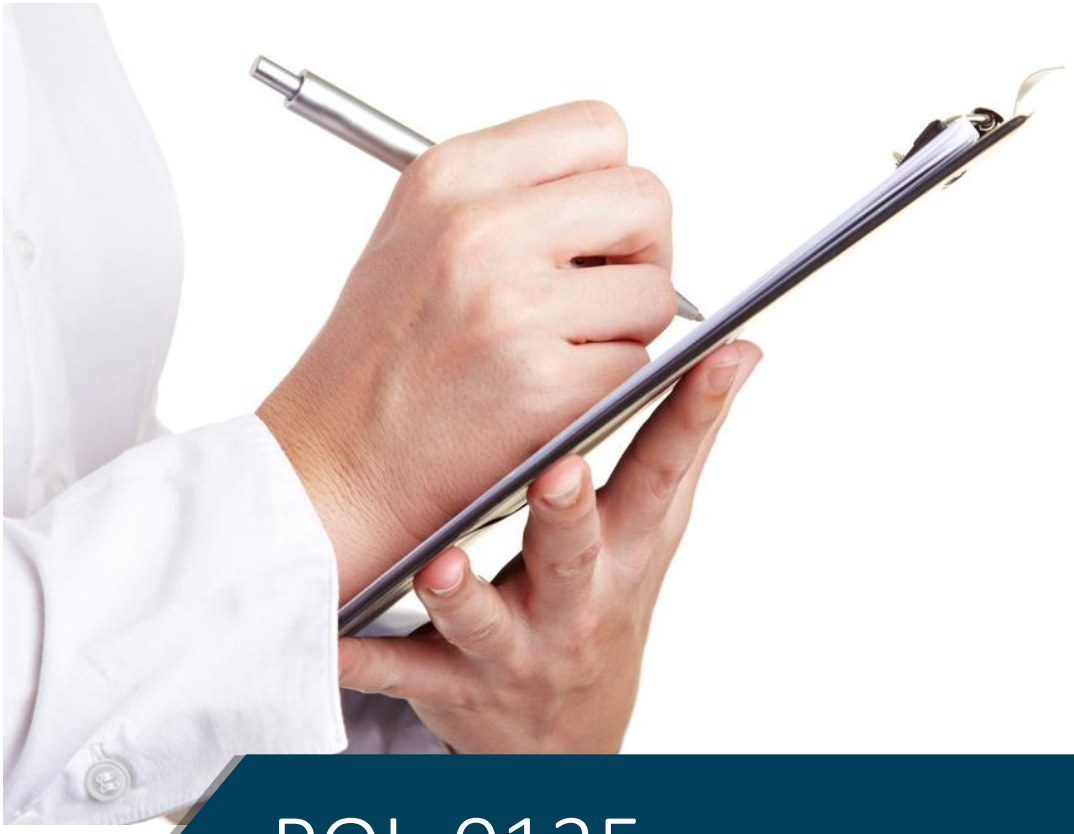
Inspection approach for the *Safety of Sperm and Ova Regulations*



POL-0125

February 4, 2020

Canada

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Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinc to ensure our health care system serves the needs of Canadians.

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For more information, please contact:

Health Canada
Address Locator 0900C2, Ottawa, ON K1A 0K9
Tel.: 613-957-299
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
Email: publications@hc-sc.gc.ca

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Disclaimer

This document does not constitute part of the *Assisted Human Reproduction Act* (AHR Act) or its regulations and in the event of any inconsistency or conflict between the AHR Act or regulations and this document, the AHR Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the AHR Act, the regulations and the applicable administrative policies.

Table of contents

The following table shows the two types of icons used in this document, and the way they are intended to be used.

	**Important:** Key or cautionary information for people to know.
	**Information:** Supplementary information like quotes and legal references.

1. Introduction

The Safety of Sperm and Ova Regulations (Safety Regulations) came into force on February 4, 2020 and apply to establishments and health professionals who process, import, distribute or make use of donor sperm or ova for the purpose of assisted human reproduction. In addition, the Safety Regulations apply to donor sperm that is distributed by an establishment or health professional to a recipient for their personal use; however, they do not apply to that person's own use of donor sperm to self-inseminate.

The majority of the provisions outlined in the Safety Regulations, under the *Assisted Human Reproduction Act* (AHR Act), came into force on February 4, 2020, with some exceptions related to registration numbers as outlined in section 87 of the Safety Regulations.

The Safety Regulations are intended to reduce the risks to human health and safety arising from the use of donor sperm or ova in Canada for the purpose of AHR. This includes the risk of infectious disease transmission from the donor to the recipient, and to the child born of AHR, as well as the risk of genetic disease transmission from the donor to the child.

The Safety Regulations apply to donor sperm and ova intended for use in AHR by a recipient who is not the spouse, common-law partner or sexual partner of the donor, including donor sperm and ova that is intended to be used in AHR techniques (e.g. in vitro fertilization). The Safety Regulations also apply to ova that have been obtained from a donor and that are meant for the donor's use as a surrogate mother.

The Safety Regulations do not apply to sperm and ova from a spouse, common-law partner or sexual partner of the recipient.

Health Canada's *Guidance Document: Safety of Sperm and Ova Regulations* provides information to all establishments and health professionals on how to comply with the requirements of the Safety Regulations.

Health Canada is the federal authority responsible for regulating the safety of donor sperm and ova in Canada for the purposes of AHR. The AHR Act provides the authority for the Minister to designate inspectors for the purposes of the administration and enforcement of the AHR Act. The authority of an inspector designated under the AHR Act to inspect against section 10 and its associated regulations comes from section 47.

Health Canada's Regulatory Operations and Enforcement Branch (ROEB) is responsible for compliance and enforcement activities in relation to the AHR Act. The *Compliance and Enforcement Policy for the Assisted Human Reproduction Act* (POL-0100) describes the national

compliance and enforcement approach for materials and activities subject to the AHR Act and its regulations.

2. Purpose

The purpose of this document is to describe Health Canada's approach for inspecting establishments in order to assess their compliance with:

- section 10 of the AHR Act
- the Safety Regulations

The main objectives of Health Canada's inspection approach for the Safety Regulations are to:

- Minimize the risks to human health and safety associated with the use of donor sperm or ova for the purpose of AHR
- Assess the compliance of regulated parties with the regulatory requirements that apply to the processing, importing and distributing and use of donor sperm or ova
- Take compliance and enforcement action when needed
- Maintain a consistent approach to inspections

3. Background

Prior to the Safety Regulations coming into force, there were no safety requirements related to donor ova, and donor sperm for assisted conception was regulated under the Processing and Distribution of Semen for Assisted Conception Regulations (Semen Regulations) under the Food and Drugs Act. Semen establishments were inspected as per the *Inspection Strategy for Semen Establishments* (POL-0023) which has since been archived as the Semen Regulations were repealed when the Safety Regulations came into force.

4. Scope

This inspection approach applies to all establishments, including primary establishments and foreign establishments, and health professionals that are conducting any of the following regulated activities with respect to donor sperm or ova for the purposes of AHR:

- processing, which means
    - performing donor suitability assessments
    - obtaining the sperm or ova from a donor
    - preparing

    - identifying
    - testing
    - preserving
    - assessing quality
    - labelling
    - quarantining
    - storing
- distributing
- importing
- making use

Foreign establishments that process sperm or ova, may register with Health Canada as a primary establishment to allow the distribution of sperm and ova that they process in Canada, or be listed on the registration of a primary establishment as an establishment that is conducting processing activities on behalf of the primary establishment.

5. Inspection Process and Duration

An inspection is an assessment of compliance against the applicable requirements of the AHR Act and its associated regulations by a designated inspector.

Before an inspection

Health Canada may contact a regulated party to schedule the inspection and may also request certain information and documents in advance of the inspection.

Health Canada is not required to provide advance notice of inspections and may conduct unannounced inspections if, for example:

- There is an immediate risk to human health and safety, or
- This approach will better assess compliance with the AHR Act and its regulations.

During an inspection

During an inspection, inspectors observe and discuss the establishment's or health professional's processes, which can involve the review of records, documents and procedures.

Inspectors look carefully at the establishment's or health professional's compliance with the applicable requirements set out in the Safety Regulations, which may include:

- quality management system
- adequacy of facilities
- record keeping
- validation processes
- equipment qualification and maintenance
- training of staff
- written procedures
- donor testing and donor suitability assessments
- exceptional access records
- error and accident investigations and reporting
- adverse reaction investigations and reporting
- labelling
- storage

Observations

During the inspection, the inspector will make observations if there are areas where the establishment or health professional is not adequately meeting its regulatory requirements. Each observation is classified by level of risk; critical, major, or minor.

For more information on the rating of observations and the overall inspection rating, please refer to the *Risk Classification Guide for Sperm and Ova Observations* (GUI-0129).

During the inspection, the establishment or health professional may require immediate corrective actions to address observations, depending on the severity and risk of the observation. The inspector will identify the observations for immediate action to the regulated party. If not, the establishment or health professional must take corrective actions after the inspection to address the observations.

Inspection Duration

In general, inspectors determine the length of each inspection on a case-by-case basis. The average time for an inspection will vary depending on the:

- complexity and number of activities conducted
- number of inspectors conducting the inspection
- size of the regulated party

After an inspection

Exit Meeting

At the end of an inspection, the inspector will discuss the draft observations with the establishment or health professional during the exit meeting.

Exit Notice

After completing an inspection, the inspector creates an Exit Notice which outlines the final observations (deficiencies), if any, noted by the inspector. The Exit Notice gives the establishment or health professional an overall inspection rating. This rating is based on the number and risk level of observations at the time of the inspection. When an NC rating is under consideration, or the final rating needs further review, Health Canada will review the final rating before the inspector issues the Exit Notice.

Following the issuance of the Exit Notice, the establishment or health professional will be given 20 business days to provide a written response to the observations. This response must address all of the deficiencies noted and include a detailed corrective and preventive action plan to prevent their reoccurrence, with target dates for completion.

Compliance Rating

A “compliant” or “non-compliant” rating is included in the Exit Notice that is provided to the establishment or health professional once the inspection is completed.

Compliant (C) – At the time of the inspection, the regulated party has demonstrated that the activities it conducts comply with the *Assisted Human Reproduction Act* and its associated Regulations.

Disclaimer - A “C” rating does not mean that there are no observations or corrective actions required.

Non-compliant (NC) – At the time of the inspection, the regulated party has not demonstrated that the activities it conducts comply with the *Assisted Human Reproduction Act* and its associated Regulations.

When an establishment or health professional is given a non-compliant rating, the establishment must immediately address high risk deficiencies to mitigate the risk to human health and safety. Where necessary, Health Canada will consider specific enforcement actions (e.g. suspension or cancellation of a registration) in accordance with the Compliance and Enforcement Policy for *Assisted Human Reproduction Act* POL-0100.

Drug and health product inspections database

Shortly after the inspection exit meeting and before the Exit Notice is issued to the establishment, Health Canada will post online an Initial Inspection Deficiencies (IID) report, which provides a preliminary overview of any initial deficiencies found during the inspection. After the Exit Notice is issued to the establishment, Heath Canada will post the Inspection Report Card (IRC) to summarize the inspection observations and rating. These reports can be found on the Drug and Health Product Inspections Database.

6. Inspection Frequency

Health Canada applies a risk-based approach to the frequency of inspections, taking into consideration a number of factors. Establishments or health professionals that are subject to regular inspections may be considered higher, medium or lower risk.

Inspection frequency is determined based on risk, therefore not all establishments or health professionals who conduct activities regulated under the Safety Regulations (e.g. health professionals that only make use of sperm or ova) are subject to regular inspections due to the limited number of regulatory requirements that are applicable to them. However, if information suggests that a regulated party may be a higher risk, they will be placed on a routine inspection frequency.

The frequencies set out in this policy are for regular inspections of domestic and foreign primary establishments, establishments that are conducting activities on behalf of a primary, and domestic establishments that import or distribute sperm or ova for the purpose of AHR. Table 1 Inspection Frequency provides the length of time between inspections. Re-assessments and re-inspections may be conducted sooner, as required.

Table 1. Inspection Frequency

Type	Inspection Frequency
Higher risk	12-18 months
Medium risk	2 years
Lower risk	3 years

Despite the above inspection frequencies, any establishment or health professional regulated under the Safety Regulations may be subject to inspection.

Factors

Health Canada's risk-based approach for monitoring compliance with the Safety Regulations uses a number of different risk factors to determine the frequency at which inspections should be conducted. These factors may include, but are not limited to:

- Type of activities (e.g. processing is considered the highest risk activity and making use is considered the lowest risk activity).
- Regulated party (e.g. primary establishments have more regulatory requirements compared to establishments that import or distribute sperm or ova.
- Type of donation process
- Compliance history

Health Canada will use information gathered through inspections and will review the information to determine if the inspection approach needs to be updated.

Appendices

Appendix A – Glossary

Acronyms

AHR Act: *Assisted Human Reproduction Act*

IID: Initial Inspection Deficiencies

IRC: Inspection Report Card

ROEB: Regulatory Operations and Enforcement Branch

Terms

These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Assisted Human Reproduction Act* or associated regulations, the definition in the AHR Act or regulations prevails.

Compliance – The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement.

Compliance monitoring – Actions planned to maintain regular surveillance in order to evaluate compliance with applicable requirements of the *Assisted Human Reproduction Act* and its associated Regulations. This includes a wide variety of fact gathering and assessment activities such as inspections, market surveys and product sampling program.

Compliance promotion – Actions taken to educate about roles and responsibilities prescribed by the *Assisted Human Reproduction Act* and Regulations.

Directed Donation Process: Sets out the minimum requirements for assessing donor suitability that may be used in cases where the sperm or ova donor and the recipient know each other. Other processing requirements, such as identifying and labeling, quarantining, and storage must also be met prior to the distribution or use of donor sperm and ova subject to the Directed Donation Process.

Donor sperm and ova – 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.

Enforcement – Actions that may be taken to compel or induce compliance in order to mitigate the risk identified by non-compliance with the *Assisted Human Reproduction Act* and its associated regulations.

Establishment – A person, partnership, unincorporated entity or a part of any of them that conducts an activity (processing, importing or distributing) but only includes a health professional if the health professional conducts an activity that is not referred to in the definition for health professional.

Health professional – A person who is authorised under the laws of a province to make use of sperm or ova in that province and who:

- Makes use of the sperm or ova, or distributes sperm to a recipient for their personal use;
- Prepares, quarantines, labels or stores sperm or ova for the purpose of their use by that person; or
- Prepares, quarantines, labels or stores sperm for the purpose of its distribution by that person to a recipient for their personal use.

Inspection – With respect to verifying compliance or preventing non-compliance with sections 8,10 or 12, monitoring and assessment against the applicable requirements of the Assisted Human Reproduction Act and its associated regulations. Inspections may also be routinely conducted based on risk to assess compliance.

Inspector – Any person designated as an inspector under section 46 of the *Assisted Human Reproduction Act*.

Primary Establishment – an establishment that conducts all processing activities in respect of sperm or ova, whether it conducts them itself or another establishment conducts any of the activities on its behalf.

Regular Inspection – An inspection during which all of the applicable requirements of the *Assisted Human Reproduction Act* and its associated regulations are assessed.

Regular Process – Sets out the minimum requirements for assessing and determining donor suitability in order to minimize the risk to human health and safety arising from the use of donor sperm and ova for AHR. Other processing requirements, such as identifying and labeling,

quarantining, and storage must also be met prior to the distribution or use of all donor sperm and ova subject to the Regular Process for donation.

Re-Assessment – A follow-up inspection carried out in situations where, although the establishment was assigned a Compliant (C) rating on the previous inspection, the number or type of observations contained in the previous inspection Exit Notice require corrective action in a timely manner. The inspection is focused on, but not restricted to, those sections of the Act and its associated regulations where observations were made.

Re-Inspection – A follow-up inspection carried out in response to the assignment of a non-compliant (NC) inspection rating. The inspection is focused on, but not restricted to, those requirements of the Assisted Human Reproduction Act and its associated regulations where violations were observed.

Appendix B – References

Laws and regulations

Assisted Human Reproduction Act
laws-lois.justice.gc.ca/eng/acts/a-13.4/

Other related information

Assisted human reproduction on Health Canada's website
canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/legislation-guidelines/assisted-human-reproduction.html

Compliance and enforcement policy for the Assisted Human Reproduction Act (POL-0100)
canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/compliance-enforcement/information-health-product/compliance-enforcement-policy-assisted-human-reproduction/pol0100-eng.pdf

Compliance and enforcement on Health Canada's website
canada.ca/en/ health-canada/services/drugs-health-products/compliance-enforcement/assisted-human-reproduction.html

Drug and health product inspections database
canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/drug-health-product-inspections.html