Health Canada Santé Canada

*Your health and safety… our priority.* *Votre santé et votre sécurité… notre priorité.*

# Risk classification guide for the safety of sperm and ova observations

GUI-0129

**February 4, 2020**

Canada

| | |
|---|---|
| Date issued: | February 4, 2020 |
| Date implemented: | February 4, 2020 |
| Replaces: | New |

**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 provinces to ensure our health care system serves the needs of Canadians.

Également disponible en français sous le titre :
*Guide de classification en fonction du risque des observations liées à la sécurité des spermatozoïdes et des ovules*

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

This publication can be made available in alternative formats upon request.



Publication date: February 2020



Cat.: H139-11/2020E-PDF
ISBN: 978-0-660-33713-5
Pub.: 190549

## 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. |

# About this document

## 1. Purpose

This document is intended for establishments and health professionals who process, import, distribute or make use of donor sperm or ova for the purpose of assisted human reproduction (AHR). It is meant to provide guidance on:

- How Health Canada inspectors classify observations of deviations and deficiencies according to risk.
- How overall compliance ratings are assigned to an inspection, including the situations that may result in a non-compliance rating, and/or compliance and enforcement actions.

It also informs establishments and health professionals of the situations Health Canada considers unacceptable and that may result in a non-compliant (NC) rating for an inspection.

## 2. Scope

This guide applies to sperm and ova regulated under section 10 of the *Assisted Human Reproduction Act* (AHR Act) and the Safety of Sperm and Ova Regulations (Safety Regulations).

The ratings in this guide apply to all establishments, including primary establishments and foreign establishments, and health professionals that are conducting any of the following activities with respect to donor sperm or ova for the purpose 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

This guide is in support of the AHR Act, the Safety Regulations, the *Guidance Document: Safety of Sperm and Ova Regulations*, and the *Inspection Approach for the Safety Regulations* (POL-0125).

# 3. Introduction

Health Canada inspectors may inspect any regulated party that conducts activities under the Safety Regulations. Health Canada inspections support a national compliance and enforcement program. More information on Health Canada's inspection approach is available in the *Inspection Approach for the Safety of Sperm and Ova Regulations* (POL-0125).

During an inspection, an inspector notes deviations or deficiencies from the applicable requirements of the AHR Act and the Safety Regulations. These deviations or deficiencies appear as observations on the inspection Exit Notice provided to the regulated party.

## Three levels of risk for observations

The possible risk ratings for observations are:

- Critical observation (Risk 1) –
    - Describes a situation that directly affects the safety of sperm or ova and is likely to result in a risk to human health and safety.

      Or
    - Describes a situation that involves fraud, misrepresentation or falsification of the sperm or ova processes or data.
- Major observation (Risk 2) – Describes a situation that may affect the safety of sperm or ova, and could result in a risk to human health and safety.
- Minor observation (Risk 3) – Describes a situation that is neither critical nor major, but is a deviation or deficiency from the applicable requirements in the AHR Act or Safety Regulations.

See Appendix A for a list of sample observations Health Canada considers critical (Risk 1), major (Risk 2), and minor (Risk 3). Although the sample observations are assigned a particular rating, the same situation could be assigned a higher or lower rating depending on the nature and extent of the deviation or deficiency. In addition, this list is not exhaustive, and other deviations or deficiencies may be identified during inspections.

All observations recorded on the Exit Notice require corrective action within an appropriate timeframe, regardless of the overall inspection rating assigned to the inspection. The inspector will identify the higher risk observations that require immediate or expedited corrective actions to the regulated party.

## Compliant and non-compliant inspection ratings

When determining the inspection rating, the inspector takes into account the nature and extent of any deviations and deficiencies noted, and provides a rating for the inspection.

The possible overall inspection ratings are:

- 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. A "C" rating does not mean that there were 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 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. A non-compliant rating may have serious consequences. These can include:

- suspension of registration
- cancellation of registration
- recalls
- seizure

When a regulated party is given a non-compliant rating, they must immediately address the high risk deficiencies to mitigate the risk to human health and safety.

If you receive a non-compliant rating and there is immediate risk to human health and safety or the safety of sperm an ova, Health Canada will take action in accordance with the *Compliance and enforcement policy for Assisted Human Reproduction Act (POL-0100)*.

# 4. Guidance

Inspectors use the following criteria to rate observations noted during inspections:

- nature of the deviation or deficiency
- potential or immediate risk to human health and safety or the safety of sperm and ova
- severity of the harm or potential harm
- number of times the deviation or deficiency has occurred
- context of the situation

The inspector will immediately bring any observations rated as Risk 1, along with any other observations requiring immediate corrective actions, to the attention of the regulated party. A deviation or deficiency that happens again in a subsequent inspection (including a re-inspection) is considered a repeat observation. This includes situations in which:

- Deviations or deficiencies reported during a previous inspection were not adequately addressed.
- Suitable corrective actions that would prevent the deviation or deficiency from happening again were not put in place.

The inspector may rate a repeated deviation or deficiency at a higher risk level than it was first rated. The inspector will generally consider the following questions when rating a repeat observation:

- Was there a failure to address the deviation or deficiency?
- Did corrective actions fall short of addressing the deviation or deficiency?
- Did the corrective actions taken produce new risks?
- Was the regulated party willing and able to correct the deviation or deficiency?

## Assigning an inspection rating

An inspector's decision to rate the regulated party as compliant or non-compliant with section 10 of the AHR Act and the associated Safety Regulations takes into account the nature and extent of the observations noted during the inspection.

Generally, a compliant rating will be assigned in the following situations:

- No observations are made.
- Only minor observations are made.
- Some major observations are made; but the regulated party demonstrated that it is in control of its regulated activities.

Situations that may produce a non-compliant rating include:

- A critical observation (Risk 1).
- Any attempt by the regulated party to deceive, misrepresent or falsify documents or records.
- Major observations are made that indicate that the regulated party is not in control of its activities.
- Corrective measures were not implemented for critical or major observations made in previous inspections (e.g. repeat observations).

If the regulated party wants to dispute the results of the inspection or the final rating, methods of dispute will be outlined in the letter accompanying the Exit Notice.

# Appendices

## Appendix A – Sample observations

The following are sample observations inspectors may note during an inspection. It is not intended to be an all-inclusive list, and inspectors may use other observations (e.g. critical, major or minor) where appropriate.

Although the sample observations are assigned a particular rating, the same situation could be assigned a higher or lower rating depending on the nature and extent of the deviation or deficiency. For example:

- An inspector may consider that a combination of several minor observations, none of which on their own may be major, but which may together represent a systemic issue and may result in a major observation on the Exit Notice.
- An inspector may consider an observation that would normally be rated minor or major, be rated a level higher because the same observation was noted during the previous inspection, indicating that corrective actions from the previous inspection were not implemented or not effective.

### Distribution, etc. of gametes

#### Section 10 of AHR Act

##### Critical

- Sperm or ovum was distributed, imported, or used when there was no evidence that tests were performed in accordance with the Safety Regulations, and the sperm or ovum was not obtained, prepared, preserved, quarantined, identified, labelled, stored, and assessed for quality in accordance with the Safety Regulations.

# General Requirements

## Section 2-3 of the Safety Regulations

### Critical

- The primary establishment distributed sperm or ova without ensuring that sperm or ova was processed in accordance with the Safety Regulations.

# Registration and Notification

## Section 4-21 of the Safety Regulations

### Critical

- A primary establishment that was registered for processing sperm did not submit an amendment application to Health Canada prior to processing ova.

### Major

- The primary establishment did not list a testing laboratory that performs donor testing on its behalf on its registration application.

# Donor Suitability

## Sections 22-27, 30-37, and 40 of the Safety Regulations

### Critical

- A sperm or ova donor was not screened for infectious diseases.
- Infectious disease testing was not performed on a donor.
- The questionnaire used to screen a sperm or ova donor did not include all the required screening criteria.
- Donor reassessments were not performed for repeat donors.

### Major

- The test kit used for testing sperm or ova donors for Hepatitis C Virus was a diagnostic test kit and not a donor screening test kit as required.
- There was no documentation of the request from the health professional to the primary establishment to process sperm or ova from a directed donor.

### Minor

- Although the structured questionnaire included all the required screening criteria, it was not prepared by the Medical Director or a physician designated by the Medical Director.

## Quarantine

### Sections 28 – 29, and 38 - 39 of the Safety Regulations

### Critical

- Sperm or ova were released from quarantine using exceptional access; however, a condition for using exceptional access was not met.
- Sperm or ova were released from quarantine by the establishment; however, the medical director did not determine and document that the sperm or ova can be released from quarantine.

## Quality Management

### Section 41 of the Safety Regulations

### Critical

- There were no quality management measures in place to reduce risks to human health and safety.

# Quality Management System

## Sections 42 – 45 of the Safety Regulations

### Major

- There was no standard operating procedure in place for conducting the donor suitability assessment.
- The standard operating procedures in place for processing were incomplete and did not reflect the actual processing conducted.
- An establishment did not carry out an internal audit every two years of the activities that it conducts to ensure that those activities comply with the Safety Regulations and with its standard operating procedures.
- Current versions of standard operating procedures were not easily accessible at all locations where the relevant activity is conducted.
- Standard operating procedures were not reviewed every two years.
- No standard operating procedures in place for reporting errors and accidents to other establishments.
- The internal audit was conducted by a person who had direct responsibility for the activities audited.

# Tracing and Identifying

## Sections 46 - 48 of the Safety Regulations

### Critical

- Donor identification codes were not assigned to each donor or donation codes were not assigned to each donation.
- The establishment's system for tracing sperm or ova did not allow for the tracking of sperm or ova it distributed.

# Labelling and Storage

## Sections 49 - 52 of the Safety Regulations

### Critical

- The immediate container was not labelled with the donor identification code or the donation code.

### Major

- For a directed donation, a statement indicating that the donation is for directed donation only was not on the documentation that accompanied the sperm or ova.
- Although the sperm was shipped in a container with dry ice there were no instructions accompanying the shipment for the handling of the sperm.

### Minor

- The primary establishment's full contact information was not on the documentation that accompanied the sperm or ova.

# Personnel, Facilities, Equipment and Supplies

## Sections 53 - 58 of the Safety Regulations

### Critical

- Access to laboratories and storage area for sperm and ova was not controlled.
- Critical equipment was used in spite of evidence of malfunction.
- Critical equipment was not maintained or calibrated to its specifications.

### Major

- There were no training records or competency evaluations for personnel performing the regulated activities.
- The expiry date of critical supplies was not observed.

# Errors and Accidents

## Sections 59 -68 of the Safety Regulations

### Critical

- Implicated sperm or ova was released from quarantine prior to determining the results of the investigation revealing that the safety of the implicated sperm or ova is not compromised or without meeting the exceptional access conditions for releasing from quarantine.
- An establishment did not initiate an investigation into a suspected error or accident.
- An establishment that had reasonable grounds to believe that an error or accident by another establishment had occurred did not notify every establishment, health professional or recipient to which it distributed the implicated sperm or the establishment from which they received the implicated sperm or ova.

### Major

- Although an error or accident that could lead to an adverse reaction was investigated, no reports were submitted to Health Canada.

# Adverse Reactions

## Sections 69 - 85 of the Safety Regulations

### Critical

- A primary establishment did not initiate an investigation into an adverse reaction.

# Records

## Section 77 - 85 of the Safety Regulations

### Critical

- Distribution records were not kept.
- The donor identification code or donation code was not consistently recorded on records.

## Major

- Records did not accurately reflect the number of immediate containers for donation from a donor.
- Records were stored in a location that was not secured against the entry of unauthorized persons.

## Minor

- Incorrect serial numbers for test equipment used during the maintenance of equipment were referenced on the maintenance records.
- The importer did not keep a copy of the summary document that accompanied the sperm or ova from the primary establishment.

# Appendix B – Glossary

## Acronyms

**AHR Act:** Assisted Human Reproduction Act

## 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.

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

**Human health and safety –** Means the health and safety of a recipient of sperm or ova or a child created from that sperm or those ova to the extent that their health and safety relate to the safety of the sperm or ova.

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.

Observation – A deviation or deficiency to the requirements of the *Assisted Human Reproduction Act* or its regulations that an inspector notes during an inspection, and is confirmed in writing to the regulated party in the inspection Exit Notice. The observations are assigned a risk classification ranging from 1 for “Critical”, to 2 for “Major” and 3 for “Minor”.

# Appendix C – References

## Laws and regulations

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

## Other related documents

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/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/compliance-enforcement-policy-assisted-human-reproduction.html

*Guidance Document: Safety of Sperm and Ova Regulations*
canada.ca/en/health-canada/programs/consultation-safety-sperm-ova-regulations/document.html

*Inspection Approach for the Safety Regulations* (POL-0125)
canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/inspection-approach-sperm-ova-safety.html