Interpretation

1. The definitions in this section apply in these Regulations.

"assisted conception" means a reproductive technique performed on a woman for the purpose of conception, using semen from a donor who is not her spouse or sexual partner. (*reproduction assistée*)

"container" means a straw, vial, ampoule or similar receptacle used to contain semen, that is in direct contact with the semen. (*récipient*)

27-7-00 | "Directive" means the directive entitled *Technical Requirements for Therapeutic Donor Insemination*, published by the Department of Health, Ottawa, July 2000. (*directive*)

1-12-00 | "Director" Repealed by P.C. 2000-1708 of November 30, 2000.

27-7-00 | "Guidelines" Repealed by P.C. 2000-1100 of July 27, 2000.

1-12-00 | "health care facility" means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has common responsibility for the activities carried out in those facilities. (*établissement de santé*)

27-7-00 | "process", in respect of semen, means to collect, test, prepare, preserve, label and store the semen for use in assisted conception, and includes the measures referred to in paragraph 9(1)(a). (*traitement*)

Application

2. These Regulations apply only in respect of semen that is used or intended for use in assisted conception.

Food and Drug Regulations

3. (1) The provisions of Part A of the *Food and Drug Regulations* in respect of the importing, labelling and packaging of drugs do not apply in respect of semen.

(2) Part C of the *Food and Drug Regulations* does not apply in respect of semen.

1-12-00 | **PART 1**
GENERAL

Prohibition

4. (1) No person shall distribute semen unless

(a) the semen has been processed in accordance with sections 9 to 11; and

(b) after the semen has been quarantined for a minimum of six months,

(i) it is determined that the donor is still not within a group set out in the Directive under the heading "Exclusions", and

27-7-00 | (ii) the donor is re-tested as set out in the Directive under the heading "Repeat Screening & Quarantine", using the tests specified therein or other tests that are at least as effective as those tests in detecting the infectious agents specified therein, and the results of the tests are negative.

27-7-00 | (1.1) Any test referred to in subparagraph (1)(b)(ii) must meet the requirements set out in clause 3.5.1.1 of the Directive.

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(2) No person shall distribute semen that is required to be quarantined or destroyed under paragraph 9(1)(b), 15(1)(a), 16(2)(c) or (d) or subsection 17(1) or (3).

(3) Subject to section 5.1, no person shall distribute semen that is required under paragraph 16(3)(c) or (d) or 17(4)(a) to be quarantined, destroyed or reserved for special access distribution.

5. No person shall import semen for distribution unless

(*a*) it meets the requirements set out in subsection 4(1); and

(*b*) the outer shipping container in which the semen is transported displays clearly, on the outside surface of that container,

(i) the name and business address of the processor, and

(ii) a declaration, signed by the processor or an authorized agent of the processor, certifying that the semen has been processed in accordance with these Regulations and quarantined for a minimum of six months.

Exception

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5.1 Despite subsection 4(1) and section 5, a person may distribute or import for distribution semen that has not been processed in accordance with the requirements of paragraphs 4(1)(b) and 9(1)(a) and section 10 or that has been reserved for special access distribution if the person does so in accordance with a special access authorization issued under section 20.

Notice

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6. (1) Every person who processes or imports, or intends to process or import, semen for distribution shall give written notice to the Minister of the processing or importing at least 10 days before the date on which they begin processing or importing semen.

(*a*) on or before August 1, 1996, if they began processing or importing semen before June 1, 1996; or

(*b*) at least 10 days before the date on which they begin processing or importing semen, if that date is on or after June 1, 1996.

(2) The notice shall be signed and dated by the processor or importer, or an authorized agent of the processor or importer, and shall include

(*a*) the name and business address of the processor or importer;

(*b*) if the notice is signed by an authorized agent, the name and title of the agent; and

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(*c*) the date of beginning to process or import semen.

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7. A processor or importer of semen shall provide any additional information that the Minister may in writing request, on or before the date set out in the request, in order to establish that the semen has been processed in accordance with these Regulations.

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8. (1) Every person shall, within 90 days after they have stopped processing or importing semen, give written notice to the Minister indicating that they have stopped processing or importing semen.

(2) The notice shall be signed and dated by the processor or importer, or an authorized agent of the processor or importer, and shall include

(*a*) the name and business address of the processor or importer;

(*b*) if the notice is signed by an authorized agent, the name and title of the agent; and

(*c*) the date on which the processor or importer stopped processing or importing semen.

Screening

9. (1) Every person who processes semen for distribution shall

(*a*) take the following measures:

(i) determine that the donor is not within a group set out in the Directive under the heading "Exclusions",

27-7-00 (ii) perform the tests specified in the Directive under the headings "Work-up", "Repeat Screening & Quarantine" and "Microbiology" or other tests that are at least as effective as those tests in detecting the infectious agents specified therein, and

1-12-00 (iii) take the non-testing measures specified in the Directive under the headings referred to in subparagraph (ii); and

(*b*) where a donor is rejected as a result of measures taken in accordance with paragraph (*a*),

(i) if none of the donor's semen, whenever donated, has been distributed, destroy all of the donor's semen that is in the processor's possession, or

1-12-00 (ii) if some of the donor's semen, whenever donated, has been distributed, take the measures set out in sections 15 to 18.

1-12-00 (*c*) Repealed by P.C. 2000-1708 of November 30, 2000.

27-7-00 (2) Any test referred to in subparagraph (1)(a)(ii) must meet the requirements set out in clause 3.5.1.1 of the Directive.

Laboratory Controls

10. Every person who processes semen for distribution shall ensure that all surfaces, containers and other objects that come in contact with the semen during processing

(*a*) are sterile or are clean and disposable; and

(*b*) are of a material and type that provide adequate protection against contamination of the semen.

Labelling

11. (1) Every person who processes semen for distribution shall

(*a*) mark on each container of the semen, in indelible ink, an identification code that enables the semen to be linked to the donor and to the date of the donation; and

(*b*) distribute with each container of the semen the processor's name and business address.

(2) Every person who distributes semen shall ensure that each container of the semen is marked with, and accompanied by, the information described in subsection (1).

Records

12. (1) Every person who processes semen for distribution shall maintain the following records in respect of each donor:

1-12-00 (*a*) the date of each donation and the tests, screening and monitoring performed in respect of the donor, the dates and results of those measures and, if necessary, an interpretation of the results;

(*b*) in respect of each donation, the identification code marked on each container of the donor's semen, and the number of containers having that identification code;

(*c*) if the processor is a physician who uses the donor's semen in the performance of assisted conception,

1-12-00 (i) the identification code marked on each container of semen and a means to identify the patient on whom the assisted conception was performed, and

(ii) in the case of semen that is distributed in accordance with a special access authorization, the patient's written consent to the use of the semen;

(*d*) if a container of the donor's semen is distributed for further distribution, the name and business address of the person who received the container and the identification code marked on it;

12-1-00 (*d*.1) if a container of the donor's semen is distributed in accordance with a special access authorization, a copy of the authorization; and

(*e*) in respect of each container of the donor's semen that the processor destroys, the identification code marked on it and the reason for its destruction.

(2) Every person who processes semen for distribution shall establish and maintain written standard operating procedures to be followed in

(*a*) processing semen; and

(*b*) tracing semen in accordance with sections 15 to 18.

13. Every person who distributes semen processed by another person shall keep the following records in respect of each container of that semen:

(*a*) the name and business address of the processor and the identification code marked on the container;

(*b*) if the distributor received the container of semen from a person other than the processor, the name and business address of that person;

(*c*) in the case of a container of semen that is in the person's possession, other than one for which a special access authorization has been issued, the following evidence that the semen was processed in accordance with the requirements of these Regulations in force at the time the semen was distributed to the person, namely, the date that the semen was donated, the tests performed in respect of the donor, the dates and results of the tests and, if necessary, an interpretation of the results;

(*c*.1) in the case of a container of semen that the person distributed before December 1, 2000, evidence that the semen was processed in accordance with the requirements of these Regulations in force at the time the person distributed the semen;

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(*c*.2) in the case of a container of semen that the person distributes on or after December 1, 2000, other than one for which a special access authorization has been issued, the following evidence that the semen was processed in accordance with the requirements of these Regulations in force at the time the person distributes the semen, namely, the date that the semen was donated, the tests performed in respect of the donor, the dates and results of the tests and, if necessary, an interpretation of the results;

(*c*.3) in the case of a container of semen for which a special access authorization has been issued,
- (i) a copy of the authorization,
- (ii) a copy of the declaration referred to in paragraph 19(2)(i), and
- (iii) the date that the semen was donated, the tests performed in respect of the donor, the dates and results of the tests and, if necessary, an interpretation of the results;

(*d*) if the distributor is a physician who uses the semen in the performance of assisted conception,
- (i) a means to identify the patient on whom the assisted conception was performed, and
- (ii) in the case of semen that is distributed in accordance with a special access authorization, the patient's written consent to the use of the semen;

(*e*) if the container of semen is distributed for further distribution, the name and business address of the person who received it;

(*f*) in respect of each container of semen that the distributor destroys, the reason for its destruction; and

1-12-00 (*g*) in respect of each container of semen that the processor collects under paragraph 16(2)(c) or (3)(c), the date of its collection.

Tracing of Semen

14. Where a physician who performed assisted conception on a woman has reasonable grounds to believe that an infectious agent was transmitted to the woman through semen used in the performance of the assisted conception, the physician shall, without delay,

(*a*) stop the distribution of all containers of semen in the physician's possession having the same identification codes as that of the semen used for the assisted conception; and

(*b*) provide a written report to each processor of the semen

(i) advising that semen that they processed may be contaminated by an infectious agent, and naming the agent, and
(ii) specifying the identification codes marked on the containers of that semen.

15. (1) Where a processor receives a report under paragraph 14(*b*), or otherwise has reasonable grounds to believe that semen that the processor processed and distributed may be contaminated by an infectious agent, the processor shall, without delay,

(*a*) identify the donors of the semen and quarantine all semen from those donors that is in the processor's possession;

(*b*) use all reasonable means to identify, and locate the business address of, each person who received for further distribution semen obtained from any of those donors;

(*c*) give to each of the following persons a written notice specifying the identification codes marked on the containers of the semen believed to be contaminated, naming the infectious agent and indicating that the semen must be quarantined pending the completion of an investigation or must be destroyed, namely
(i) any person to whom the processor distributed, for further distribution, containers of semen having the identification codes specified in the notice, and
(ii) any other person who the processor believes received, for further distribution, containers of that semen;

(*d*) notify the donors of the semen in writing that an investigation is being conducted to determine whether semen that they donated is contaminated by an infectious agent, and naming the agent; and

(*e*) conduct an investigation to determine whether any of the semen provided by those donors is contaminated by an infectious agent.

(1.1) Despite subsection (1), the processor of semen that has been distributed in accordance with a special access authorization is not required to take the measures specified in that subsection by reason only that

1-12-00 (*a*) a particular infectious agent, other than one referred to in column 1 of the table to subsection 20(1), was not tested for in accordance with the requirements of paragraphs 4(1)(b) and 9(1)(a) during the processing of the semen; or
(*b*) the semen was not processed in accordance with section 10.

(2) Every person who distributed semen that is subject to investigation under paragraph (1)(*e*) shall, at the request of the processor conducting the investigation, provide the name and business address of every person to whom the person distributed the semen for further distribution.

1-12-00 (3) Every processor who conducts an investigation shall provide the Minister with the following information at the following times:

(*a*) within three days after the start of the investigation, the name of the infectious agent with which the semen is believed to be contaminated, the number of donors who donated semen that is believed to be contaminated and the number of containers of semen attributable to each donor; and

(*b*) every 30 days after the start of the investigation, until the final report is provided, an update on the progress made in tracing the semen, including information as to the number of containers used, recovered, quarantined or destroyed, and the number of persons contacted.

16. (1) Where the results of the investigation demonstrate that all or some of the semen is not contaminated by an infectious agent, the processor

(*a*) shall prepare a list specifying the identification codes marked on the containers of the semen that is not contaminated;

(*b*) shall notify each person referred to in paragraph 15(1)(*c*), in writing, that the containers having the identification codes specified in the list may be distributed; and

(*c*) may distribute the containers in the processor's possession that have the identification codes specified in the list.

(2) Where the results of the investigation demonstrate that all or some of the semen is contaminated by an infectious agent, the processor shall

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(*a*) prepare a list specifying the identification codes marked on the containers of the semen that is contaminated;

(*b*) notify each person referred to in paragraph 15(1)(*c*), in writing, that all quarantined containers having the identification codes specified in the list must be collected by the processor;

(*c*) collect and destroy the containers of semen referred to in paragraph (*b*); and

(*d*) destroy the containers of semen in quarantine under paragraph 15(1)(*a*) that have the identification codes specified in the list.

(3) Where the results of the investigation are inconclusive as to whether all or some of the semen is contaminated by an infectious agent, the processor shall

(*a*) prepare a list specifying the identification codes marked on the containers of that semen;

(*b*) notify each person referred to in paragraph 15(1)(c), in writing, either

(i) that all quarantined containers having the identification codes specified in the list must be destroyed or reserved for special access distribution, or

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(ii) that all quarantined containers having the identification codes specified in the list must be destroyed, reserved for special access distribution or kept in quarantine until collected by the processor;

(*c*) if the person to whom the processor gave a notice under subparagraph (b)(ii) informs the processor that the person has chosen to have the processor collect the containers as proposed in the notice, collect those containers and destroy them or reserve them for special access distribution; and

(*d*) destroy the containers of semen in the processor's possession having the identification codes specified in the list or reserve them for special access distribution.

17. (1) Every person who receives a notice of an investigation from a processor shall

(*a*) quarantine all containers of semen having the identification codes referred to in the notice until the person receives a further notice under section 16; or

(*b*) destroy those containers of semen.

(2) Where the person receives a notice referred to in paragraph 16(1)(*b*), the person may distribute the semen specified in the notice.

(3) Where the person receives a notice referred to in paragraph 16(2)(*b*), the person shall

(*a*) keep in quarantine all containers of the semen having the identification codes referred to in the notice until they are collected by the processor, or destroy them; and

(*b*) provide a written report to the processor as soon as possible indicating, for each identification code referred to in the notice, the number of containers received by the person and the number that were distributed or destroyed.

(4) Where the person receives a notice referred to in paragraph 16(3)(b), the person shall

(*a*) take one of the following actions, namely,

(i) destroy all the containers of the semen in the person's possession having the identification codes referred to in the notice,

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(ii) reserve those containers for special access distribution, or

(iii) in the case of a notice that proposes the collection of those containers, if the person chooses this option, inform the processor in writing of this decision and keep those containers in quarantine until they are collected by the processor; and

(*b*) provide a written report to the processor as soon as possible indicating, for each identification code referred to in the notice, the number of containers received by the person and the number of containers that were distributed, destroyed, reserved for special access distribution or kept in quarantine for collection by the processor.

18. Every processor who conducts an investigation under paragraph 15(1)(*e*) shall, on completion of the investigation,

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(*a*) provide the Minister with a detailed report setting out the results of the investigation, including, where the semen is required to be collected, destroyed or reserved for special access distribution, the disposition of all containers of that semen; and

(*b*) notify in writing the donors of the semen of the results of the investigation.

PART 2

SPECIAL ACCESS

Application

19. (1) If a physician wishes to obtain access to semen that has not been processed in accordance with the requirements of paragraphs 4(1)(b) and 9(1)(a) and section 10 or that has been reserved for special access distribution for use in performing assisted conception on a patient whose needs can not be met using semen that has been processed in accordance with those requirements, the physician shall apply in writing to the Minister for a special access authorization that permits the processor, distributor or importer of the semen or several of those persons to distribute or import for distribution the semen for that purpose.

(2) The application shall contain the following:

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(*a*) the name, business address and business telephone number of the physician;

(*b*) the name and business address of the processor of the requested semen;

(*c*) the name and business address of the distributor from whom the physician obtained or will obtain the semen;

(*d*) the name and business address of the person who is in possession of the semen;

(*e*) in the case of semen that is to be imported, the name and business address of the importer of the semen;

(*f*) the name and address of the health care facility to which the semen is to be shipped;

(*g*) the initials and date of birth of the patient;

(*h*) the number of containers of semen requested and the identification code of each requested container;

(*i*) a declaration signed by the processor or an authorized agent of the processor

(i) certifying that the requested semen has been processed in accordance with section 11,

(ii) certifying that the tests referred to in paragraph 20(1)(b) have been performed in respect of the donor of the requested semen and that the results of the tests were negative, and

(iii) indicating which measures required under paragraphs 4(1)(b) and 9(1)(a) have not been taken and the reasons why they have not been taken;

(*j*) the date that the requested semen was donated and the tests, screening and monitoring performed in respect of the donor of the semen and the dates and results of those measures, including, if necessary, an interpretation of the results;

(*k*) a statement by the physician that he or she has obtained information from the processor as to whether the requested semen was processed in accordance with section 10;

(*l*) a statement by the physician indicating that he or she does not have reasonable grounds to believe that an infectious agent may have been transmitted to a woman as a result of assisted conception having been performed on the woman using semen from the same donor as that of the requested semen;

(*m*) a rationale by the physician that outlines

(i) the reasons that justify the use of the requested semen, having regard to the available information on the safety of the semen and the needs of the patient, and

(ii) the reasons why the needs of the patient cannot be met using semen that has been processed in accordance with the requirements of paragraphs 4(1)(b) and 9(1)(a) and section 10;

(*n*) a statement by the physician that, in his or her opinion, the use of the requested semen would not pose

(i) a serious risk to the health of the patient, having regard to the available information on the safety of the semen and the health of the patient, or

(ii) a serious risk of transmitting an infectious agent to a child to be conceived from the semen, having regard to the available information on the safety of the semen; and

(*o*) a statement by the physician that he or she has informed the patient of the risks that the use of the requested semen could pose to the patient and to a child to be conceived from the use of the semen and has obtained the patient's written consent to its use.

(3) The application shall be signed and dated by the physician.

Authorization

20. (1) The Minister shall issue a special access authorization to the processor, distributor or importer referred to in the application made under subsection 19(1), or several of those persons, if

(*a*) the information and documents required under subsection 19(2) have been provided to the Minister;

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(*b*) testing for each infectious agent set out in column 1 of the table to this subsection was done using one of the following tests and the result of each test was negative, namely,

(i) a serological test for the applicable marker set out in column 2 of that table performed on a specimen obtained from the donor of the requested semen at least six months after the date that the requested semen was donated,

(ii) another test that is at least as effective as the test specified in subparagraph (i) in detecting that infectious agent, or

(iii) in the case of testing for the Hepatitis B Virus (HBV) in respect of semen that was processed before March 14, 2000, a serological test for the Hepatitis B surface antigen (HBsAg) performed on two specimens obtained from the donor of the requested semen within six months of each other, one of which was obtained on or before the date that the requested semen was donated and one of which was obtained after that date;

(*c*) the results of any other tests set out in the application pursuant to paragraph 19(2)(j) do not indicate that the semen is contaminated by an infectious agent;

(*d*) in a case in which a test required under subparagraph 4(1)(b)(ii) or 9(1)(a)(ii) has not been performed in respect of the donor in accordance with the requirements of that provision, it is not possible to correct the irregularity; and

(*e*) the authorization is not being sought for the purpose of circumventing the processing requirements of Part 1.

TABLE

	COLUMN I	COLUMN 2
ITEM	INFECTIOUS AGENT	INFECTIOUS AGENT MARKER
1.	HIV-1 and HIV-2	Antibody to HIV-1 and HIV-2
2.	Hepatitis C Virus (HCV)	Antibody to HCV
3.	Hepatitis B Virus (HBV)	Antibody to Hepatitis B core antigen (IgG anti-HBcAg)

(2) The authorization shall clearly indicate

(*a*) the number of containers of semen in respect of which the authorization is issued and the identification code of each container;

(*b*) the name and business address of every person who is authorized to distribute the semen;

(*c*) in the case of semen that is to be imported for distribution, the name and business address of the person who is authorized to import the semen;

(*d*) the name and business address of the physician to whom the semen may be distributed;

(*e*) the name and address of the health care facility to which the semen may be shipped;

(*f*) the initials and date of birth of the patient in respect of whom the semen may be used in the performance of assisted conception; and

(*g*) the fact that the semen may only be distributed in accordance with the authorization.

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Documentation

21. (1) Every person who distributes semen for further distribution in accordance with a special access authorization shall ensure that the container of the semen is accompanied by a copy of the authorization.

(2) Every person who imports semen for distribution in accordance with a special access authorization shall ensure that the outer shipping container in which the semen is transported

(*a*) displays clearly, on the outside surface of that container,
(i) an indication that the semen may only be distributed in accordance with the authorization, and
(ii) the name and business address of the processor; and

(*b*) is accompanied by a copy of the authorization.