Artificial Insemination Program

Rewrite of the program

Import/Export Live Animals & Germplasm Section
Animal Import/Export Division
Animal Health Directorate

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This draft document contains a new version of the Artificial Insemination Program based on international standards. This rewrite of the program has been prepared with the intention to replace the current program.
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ARTIFICIAL INSEMINATION PROGRAM

INTRODUCTION

Act:  Health of Animals Act (S.C. 1990, c. 21)
Regulations:  Health of Animals Regulations, (C.R.C., c. 296)

Legislation
The enabling legislation to make regulations prescribing sanitary and health measures for establishments in which animal semen is collected, stored, frozen or processed and generally regulating the manner in which it is collected, stored and distributed, is contained in Section 64(1)(q) of the Health of Animals Act.

The regulations pertaining to animal semen are contained in Sections 2, 69, 115, 116, 117, 118 and 119 of the Health of Animals Regulations.

Section 69(2) of the Health of Animals Regulations requires that semen must remain stored, from time of collection, in an animal semen production centre or another location approved by the Minister to maintain eligibility to export.

Sections 115 to 119 of the Health of Animals Regulations deal with animal semen production centres, including mandatory permit to collect semen from ruminant and porcine, removal from centres animals exposed to communicable diseases, destruction of semen and maintenance of records.

Policy
Since 1961, under established policy, a permit has been issued to operators of officially approved animal semen production centres. A “Permit to Operate a Semen Production Centre” is issued by the Artificial Insemination program National Coordinator for the Minister. This veterinary inspector is responsible for the maintenance of the integrity of the Artificial Insemination program in Canada.

The Canadian regulation uses the term “animal semen production centre” to designate an “artificial insemination centre”. In this program both terms are considered equivalent.

The Artificial Insemination program regulates ruminant and porcine semen produced for distribution in Canada and for export purposes. The program contains different conditions that apply to semen produced for each category.


The Artificial Insemination program also includes sections devoted to export of semen from different species to the European Union. These sections are based on the current European Union legislation. Canada has had an equivalence agreement with the European Union for bovine semen allowing simplified certification of bovine semen to the European Union since 2005.

The Canadian legislation requires that semen collected from a ruminant or a porcine is done under permit. In addition to the requirements of the Artificial Insemination program, a special procedure has been created for owners specifically wanting to have semen from their own animals collected for use in their herd. This special procedure is the “Owner use only” semen procedure and is not part of this Artificial Insemination program. This “Owner use only” semen procedure applies to semen collected from ruminants as this semen may be frozen and kept for long time periods. Collection of porcine fresh semen by the owners themselves and used in females present on the same premises as the collected boar is considered equivalent to moving around a boar to breed owner’s females and does not require a permit issued by the CFIA. This “Owner use only” semen procedure is attached as an Annex to this document for information purposes.

The Artificial Insemination program includes consideration of differences between species. Species specific variations regarding accommodations and procedures are permissible provided that the basic tenants of animal husbandry, biosecurity and semen sanitation are followed.
GLOSSARY

Accredited veterinarian – a private veterinarian who is authorized to perform certain duties or functions under an agreement made under section 34 of the Health of Animals Act. Testing of animals at the farm of origin under the Artificial Insemination program is performed by an accredited veterinarian. The centre veterinarian responsible for an animal semen production centre must be an accredited veterinarian.

Ancillary test – an OIE approved test, other than the prescribed test for a disease included in the Artificial Insemination program, used when an ambiguous result is obtained or prescribed test is not available.

Animal semen production centre – establishment where semen from ruminants or swine is collected or processed. An artificial insemination centre is an animal semen production centre in Canada.

Artificial Insemination Program National Coordinator – a veterinarian employed by the CFIA Animal Import/Export Division, Policy and Programs Branch, responsible for the integrity of the Artificial Insemination program across Canada.

Centre veterinarian – a private veterinarian employed by the management of the centre and accredited by the CFIA. The centre veterinarian provides direct supervision and control over an animal semen production centre.

CFIA – Canadian Food Inspection Agency. This government organisation is responsible for the application of Health of Animals Act and Regulations.

CFIA veterinarian – a veterinarian employed by the CFIA, responsible for the general supervision and control of an animal semen production centre and application of the Artificial Insemination program, including inspections and audits.

Donor animal in production – a male animal, resident at an animal semen production centre, whose semen is under collection.

Donor shelf animal – a male animal, resident at an animal semen production centre, that is temporarily withdrawn from collection for any reason other than failing a sanitary test. Shelf animals may be housed separately from animals in production and may be exempt from certain prescribed tests.

Export testing – supplementary testing beyond the prescribed tests done on a semen donor animal in order to qualify specific semen collections for export to a specific destination country. The test requirements are outlined in the country specific semen export certificate.

Minister – Minister of Agriculture and Agri-Food

Mounting device – an artificial device that donor animals mount for semen collection purposes.

OIE approved test – test approved by the OIE and mentioned in the OIE Manual of diagnostic and vaccines.

Permit to collect ruminant semen – a permit issued by the local CFIA district office to the owner of the premises where semen collection of bison and cervid takes place.

Permit to operate an animal semen production centre – a permit issued by the Artificial Insemination National Coordinator to an individual or organization authorizing them to operate an animal semen production centre in accordance with the provisions of the Artificial Insemination program.

Pre-entry isolation facility – a physically distinct housing unit where qualified animals selected for entry into a semen production centre are maintained in isolation for a minimum period prior to movement to a semen production centre.
Prescribed test – an OIE approved test that is required under the Artificial Insemination program

Semen export testing – analysis of semen from a donor animal to qualify specific semen collections for export to a specific destination country. The test requirements are outlined in the country specific semen export certificate.

Sick pen – a physically separate isolation area within the perimeter of the centre where resident animals are moved when they demonstrate signs of disease or display suspicious or positive reactions to a prescribed test. Animals remain in this area until a final decision is reached concerning their eligibility to remain in the centre and return to collection.

Standard operating procedures (SOP) – document describing in detail the steps of a manipulation or a procedure in an animal semen production centre. An SOP may identify specific critical control points (CCP) and outline procedures that will be followed in the event that deviations to the CCP are identified.

Teaser – a neutered or intact male animal that donor animals may mount for semen collection purposes.
CHAPTER I – REQUIREMENTS FOR ANIMAL SEMEN PRODUCTION CENTRES

Section 1 Procedure to approve an animal semen production centre

This section provides information on the approval process for an animal semen production centre. In addition to the general information mentioned in this section, other sections included in this chapter also provide important information about buildings, biosecurity, operations and procedures to be considered for approval of a semen production centre.

Application procedure
The local CFIA district office provides the applicant with copies of sections 115 to 119 of the Health of Animals Regulations and relevant sections of the Artificial Insemination program. The local CFIA district office also discusses with the applicant the sections pertaining to the applicant’s proposed operations for approval of an animal semen production centre.

The local CFIA district office must advise the applicant that he is responsible for contacting the provincial government to ensure he is respecting any provincial regulations that may apply to artificial insemination. The applicant is also responsible to contact registry organizations of the species and breeds he intends to collect semen to ensure that their requirements are met.

The local CFIA district office may consult the appropriate level in Operations Branch throughout the approval procedure. Operations Branch may in turn contact the National Coordinator of the Artificial Insemination program in Ottawa to obtain technical information regarding the Artificial Insemination program.

One or several inspection visits may be required to ensure that the proposed facilities comply with the program requirements. Initial approval of pre-entry isolation, semen collection centre, laboratory and storage facilities must be done when the centre first applies and must be renewed every five (5) years, except for mobile laboratories that should be re-approved every two (2) years. Facilities must meet all program standards before a centre is approved. Appropriate protocols and procedures should be examined and considered satisfactory. Checklists provided in appendices to this program should be used as guidance.

Once the local CFIA district office has determined that all program standards have been met, they will send an inspection report, along with completed checklists, to the appropriate level of Operations Branch for review. The inspection report must include a recommendation from the local CFIA district office regarding the eligibility of the centre for approval. Once the report has been reviewed by Operations Branch, it is forwarded to the National Coordinator of the Artificial Insemination program in Ottawa for final review and decision regarding the issuance of a permit.

The National Coordinator of the Artificial Insemination program provides the final decision regarding the approval of the centre. If the recommendation by Operations Branch is approved, a “Permit to operate an animal semen production centre” is issued. If the recommendation is refused, a letter will be send back to Operations Branch specifying the reasons for refusal.

Plans
A copy of drawings or plans of the semen production centre facilities is required to be presented to the local CFIA district office when an application is submitted. Professional blueprints are not needed but drawings must be of sufficient detail to accurately represent the facilities and operational flow. The plans must include the dimensions of the rooms within each building, the location and size of all doors and windows, all elements of the ventilation system, location of any stationary equipment and a description of manure handling system. The plans must describe the materials to be used in the construction of the buildings, especially in relationship to the ability to clean and disinfect the buildings. A site plan must also be included showing the location of all buildings, the distance between buildings, distance from adjacent facilities and roads, along with paved areas around buildings and fencing, if any.

Plans of the facility are suggested to be presented to CFIA enough in advance of construction or purchase of land/facilities in order to ensure no fundamental issues with the proposal exist before construction begins.
Standard operating procedures
Written standard operating procedures (SOP) are mandatory for certain critical procedures and must be included in the submission for approval of the centre. Critical procedures should include at the minimum:
1. the movement of animals to the pre-entry isolation facility;
2. the movement of animals to the semen collection facility;
3. the collection of semen and its introduction in the semen laboratory;
4. the processing of semen in the laboratory;
5. and biosecurity protocols for visitors and introduction of equipment and material.

Recommendation
An animal semen production centre can be recommended for approval when the local CFIA district office considers the future centre has the capability to meet the standards mentioned in the Artificial Insemination program document and meet regulations outlined in Sections 115 to 119 inclusive of the Health of Animals Regulations.

Permit
Any person or organization that collects ruminant or porcine semen according to the Artificial Insemination program, either on premises designated for this purpose (centre) or on farm using a mobile laboratory when permitted by the Artificial Insemination program, must be in possession of a “Permit to Operate an Animal Semen Production Centre” issued by the National Coordinator of the Artificial Insemination program in Ottawa.

The permit for a bovine semen production centre, a porcine semen production centre and for an export small ruminant production centre is valid for five (5) years. The permit issued to a mobile laboratory for collection of cervid semen, bison semen and small ruminant semen for distribution in Canada is valid for only two (2) years. A specimen of such permit is included in an annex to this document.

A “Permit to Operate an Animal Semen Production Centre” must be issued by the CFIA before the centre may commence semen collection operations. The permit provides a unique permit number and a unique semen production code to identify all semen collected in the centre. The original of the permit is provided to the applicant and should be recovered by the local CFIA district office when the centre ceases activities.

In the case of the collection of bison and cervid semen, an additional permit must be issued to the owner of the collection premises by the local CFIA district office. This permit is a “Permit to collect ruminant semen” and is valid only for the breeding season.

Establishments or persons only storing semen for distribution in Canada do not need a permit to do so, but are subject to record keeping regulations under Section 119(2) Health of Animals Regulations.

Official approval
An animal semen production centre is officially approved by the CFIA when a permit is issued to the centre.

Official lists of approved animal semen production centres are maintained by the National Coordinator of the Artificial Insemination program.
Section 2  Conditions applicable to artificial insemination centres

The Artificial Insemination program defines the standards and procedures applied to animal semen production centres. These standards and procedures meet international standards recommended by the World Organization for Animal Health (OIE) to support semen production that significantly reduce the likelihood of semen being contaminated by potentially pathogenic micro-organisms.

a) Definition

The artificial Insemination centre is comprised of the following entities:

1. a pre-entry isolation facility
2. a semen collection facilities consisting of:
   a. animal accommodation areas, including a facility for sick animals, and
   b. a semen collection room
3. a semen laboratory area
4. a semen storage area
5. administration offices

Conditions applicable to these entities are described in next sections. There are no requirements in this program regarding administration offices. Administration offices may be located at the artificial insemination centre or at another site. The centre administration will normally include an informatics system.

Donors animals and teasers of the centre should be adequately isolated from farm livestock on adjacent land or building, for instance by natural or artificial means. There is no minimal distance imposed between a centre and neighbouring facilities. Each case must be evaluated individually based on physical facilities and procedures. A proposed location where animal activities not related to the centre are present in close proximity to the centre may be considered, but stricter biosecurity measures will have to be implemented to prevent exposure of resident animals to contagious diseases. The centre must be constructed in a manner that will prevent access by other livestock and wildlife to the animal housing areas.

Animal accommodations must be adapted to the species whose semen is collected in the artificial insemination centre.

Access points to the centre from the road should be dedicated to centre activities. Other activities at the site that are not pertaining to the semen production facility will require a separate access point from the road.

It is highly recommended that visitors to artificial insemination centres are restricted to glass enclosed viewing areas for the semen collection room and semen laboratory.

The centre must be officially approved by the CFIA. The facilities must be approved by the CFIA prior to the commencement of operations. Any significant modification to the facilities after initial approval must be documented and pre-approved by CFIA.

The centre should be under the supervision and control of the CFIA which will be responsible for regular audits, at an interval of no more than 12 months, of protocols, procedures and records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen.

b) Biosecurity

A system should exist to prevent inopporntune entry on the grounds of the centre.

The centre is constructed in such manner that animal housing and the semen collecting, processing and storage facilities can be readily cleaned and disinfected.

The donors and teasers in semen collection facilities should be adequately isolated to prevent the transmission of diseases from farm livestock and other animals. A pest control program should be in place to mitigate the presence of rodents and insects at the centre.

Only animals associated with semen production should be permitted to enter the centre. Mounting devices should be considered for semen collection whenever possible. Male teasers are permitted but must be submitted to the same testing procedures as semen donors. The presence of female animals is discouraged.
but may be tolerated in centres housing seasonal species, such as sheep and goats.

Personnel at the centre should be competent and suitably trained in disinfection procedures and hygienic techniques relevant to the control of the spread of diseases. They should observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Protective clothing and footwear for use only on the centre should be provided.

The entry of visitors in an artificial insemination centre must be strictly controlled. Visitors to the semen collection facility should be discouraged unless approved by centre veterinarian. The centre veterinarian shall create suitable written protocols for the admittance of approved visitors into the artificial insemination centre. Supervision by a staff member and mandatory use of protective footwear and clothing are considered to be minimal precautions where visits to animal holding facilities are necessary. All visitors must register in logs maintained by the centre for this purpose.

c) Operations

The artificial insemination centre should be under the direct supervision and control of a centre veterinarian.

Standard Operating Procedures

Standard Operating Procedures (SOP) must be available for biosecurity critical control points. The centre veterinarian must develop and implement SOPs for these critical control points. These SOPs must be submitted to CFIA for review. Documentation regarding the review by CFIA must be on file.

Records

Complete records must be maintained and readily available for official inspection: At a minimum, records must be available for the following categories:

a) Animals:
   1. donor animals and teasers identification
   2. records of on farm qualification, pre-entry isolation period and results of testing during this period,
   3. date of entry into the centre as qualified resident,
   4. date of departure of the centre and final disposition upon removal from the centre;
   5. test records for resident animals, including disease tested, type of test, test date and laboratory performing the testing;
   6. movements of animals within the centre by date of activity and location of movement.

b) Semen:
   1. semen produced, stored and distributed from the centre, along with semen returned to the centre;
   2. identification of semen produced in the centre, including production code of the centre, donor identification and collection date;
   3. semen exported, including donor identification, collection dates, export date and destination.

All records about animals and semen must be maintained for a minimum of seven years after final disposal of semen. Both electronic and manual records systems are acceptable provided that they contain the required information in a manner that can be readily accessible.

Animal transport

Movement of animals to and from the centre is a biosecurity critical control point requiring a written SOP. All animal movements at a minimum should be done using cleaned and disinfected conveyances and in manner which poses no significant animal health risk.

Transfer between centres

Donor animals and teasers that are resident at an approved semen production centre may be transferred to another approved semen production centre of equivalent status without loss of resident health status. The animal must be accompanied by a certificate of health showing the dates of residency at the centre. The centre veterinarians of the originating and receiving centres are responsible for ensuring that the animal has no contact with animals of lesser status during transport. The animal must be transported in a cleaned and disinfected conveyance and accompanied by appropriate documentation. A template document for transfer between centres is available in an annex to this document.
Section 3  Conditions applicable to pre-entry isolation facilities

Following the completion of prescribed testing done on farm, the pre-entry isolation facility is the second step for animals to enter in a semen production centre. This section described the standards applying to pre-entry isolation facilities.

a) Definition

A pre-entry isolation facility is a housing facility that receives qualified animals following completion of prescribed testing on farm before they are authorized to enter an animal semen production centre. Qualified animals are placed in isolation for a prescribed period of time during which mandatory testing is performed according to the animal species and centre category. An animal is authorized to enter an animal semen production centre only after completion of the prescribed isolation period and mandatory testing.

The pre-entry isolation facility should be adapted to the species for which it will be used. The isolation facility must be able to be cleaned and disinfected.

The pre-entry isolation facility may be located on the grounds of the centre. The facility must have adequate separation from the resident animal’s accommodations. Separation may be achieved through both physical separation (space) and procedures. The pre-entry isolation facility may also be located outside the grounds of the centre.

Pre-entry isolation facilities used for animals destined to a centre approved for export purposes must be approved by the local CFIA district office before the first use. Pre-entry isolation facilities for animals destined to a centre approved only for distribution in Canada are approved by the centre veterinarian.

A document confirming initial approval of the pre-entry isolation facility must be on file. All pre-entry isolation facilities of a semen production centre must be re-approved every five (5) years. A template document for approval of pre-entry isolation facilities is available in an appendix to this document.

b) Biosecurity

Cleaning and disinfection of the pre-entry isolation facility must be done before entry of animals. When they are dedicated to the pre-entry isolation facility, equipment and material used in the facility must be cleaned and disinfected before the facility is used. Equipment and materials not dedicated to the pre-entry isolation facility must be cleaned and disinfected before being introduced in the facility.

Protective clothing and footwear dedicated to the pre-entry isolation facility must be properly cleaned before animals arrive in the facility. In the event that the protective clothing are footwear are not dedicated to the pre-entry isolation, the centre veterinarian must develop protocols to mitigate the sanitary risks associated with the use of the clothing and footwear in other areas of the centre.

Feeds and fodder introduction should be done in a manner not to contaminate animals in isolation.

Manure should be removed in a manner not to contaminate animals in isolation.

The centre veterinarian is responsible for developing suitable procedures for centre staff in contact with animals in isolation. The procedures must include the conditions necessary for staff to return to the resident animals’ accommodations after working in isolation.

No visitors should be allowed in the facility, except with the permission of the centre veterinarian. The centre veterinarian shall create a suitable written protocol for the admittance of approved visitors.

Movement of animals to and from pre-entry isolation facility is a biosecurity critical control point requiring a written standard operating procedure (SOP). At a minimum animal movements should be done using cleaned and disinfected conveyances and in manner which poses no significant animal health risk.
c) Operation

The pre-entry isolation facility is under the direct supervision and control of the centre veterinarian. The centre veterinarian is responsible for the health and welfare of animals in isolation.

Clinical examination and identification confirmation should be done when animals enter the facility. Appropriate documentation must be presented with animals before they are admitted to the isolation facility. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

Sampling of animals in pre-entry isolation should be done under the direct supervision of the centre veterinarian or under a clear delegation provided to another accredited veterinarian. Interpretation of results of tests prescribed in the program should be done by the centre veterinarian. The local CFIA district office may be consulted as required. The diseases to be tested during the isolation period are listed in each appropriate species and centre category section.

Clinical examination to confirm freedom from clinical disease should be done when animals leave the isolation facility. The centre veterinarian is responsible for verifying that all isolation requirements have been completed for each animal placed in isolation. The centre veterinarian shall issue and keep on file a documentation authorizing the movement of the animals to the resident population of the centre. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

Semen collection may be allowed in the pre-entry isolation facility during the prescribed isolation period. Please refer to appropriate species and centre category section for details.
Section 4  Conditions applicable to semen collection facilities

Once animals have gone through the pre-entry isolation procedure, they are admitted to the semen production centres as resident donor animals. This section described the standards applicable to semen collection facilities, including housing of resident animals.

A document confirming initial approval of the semen collection facilities should be on file. Facilities must be re-approved every five (5) years. A template document for approval of the semen collection facilities is available in an appendix to this document.

a) Definition

The semen collection facilities should include separate and distinct areas for accommodating resident animals, for semen collection, for feed storage, for manure storage and for the isolation of animals suspected of being infected. All or part of these areas can be located under the same roof or in separate buildings or location.

Accommodation for resident animals

This is the housing facility for animal resident in an animal semen production centre. The accommodation must be adapted to the species whose semen is collected. Species specific variations regarding accommodations and procedures are permissible provided that the basic tenants of animal husbandry, biosecurity and semen sanitation are followed.

Housing facilities must be in good repair, capable to be readily cleaned and disinfected and kept clean at all times. Watering and manure removal systems should be in place and in good operational status.

A separated isolation area within the animal accommodation facility must be available to allow isolation of sick animals or animals suspected of being infected when they failed a test; this isolation area is often referred to as “sick pen”. At the minimum, this area should be physically separated from other resident animals. Another room or building may be considered depending of the configuration of the premises. A consideration of the characteristics of the suspected disease should be included in the decisions around the suitability of the sick pen for the incident. Additional sanitary procedures may also be required beyond the physical separation. The number of sick pens should be appropriate to the number of animals on site.

Fencing is highly recommended around the semen collection facilities to protect resident donor animals from contact with other livestock or wild animals. Fencing is not required when animals are maintained indoors at all times such as for Canadian porcine semen collection centres. Semen collection facilities approved for export to the EU must be fenced to create a controlled access zone around the barns. Fencing should include appropriate gates to prevent access to the controlled access zone.

A double fence is required when animals have access to the exterior to ensure no access to resident animals by wildlife or other domestic animals may occur.

Semen collection room/area

This is the area where semen is collected from donor animals. This area should be capable of being readily cleaned and disinfected. This area should be adapted to the species and may vary in presentation accordingly. This area must be separate from the resident housing facility. Donors should not be collected in their housing facility due to potential for contamination of the semen.

The floor of the mounting area should be clean and provide safe footing. A dusty floor should be avoided during semen collection. Drainage of the collection area should be considered. The collection room/area should be cleaned daily after collection.

Feed storage

Feed storage equipment may be either on site or outside the facility. Feed storage should be located and built in such a manner as to mitigate sanitary risks. Fodder introduction should be done in a manner which poses no significant animal health risk. Feed distribution equipment should be dedicated to the resident animal facilities. The source of feeds should be documented and procedures put in place by the centre veterinarian to document entry of feeds in the centre.
Manure storage
Manure may be stored either on site or outside the facility. Manure removal should be done in a manner which poses no significant animal health risk. Equipment should be dedicated to the facilities or is cleaned and disinfected before use.

b) Biosecurity
Donors and teasers should be adequately isolated to prevent the transmission of diseases from farm livestock and other animals. Measures should be put in place to prevent the entry of wild animals susceptible to ruminant and swine diseases transmissible by semen.

Only animals associated with semen production should be permitted to enter the semen collection facilities. Other species considered essential to the movement or handling of donors and teasers or for security can be authorized on the premises, but contact with donors and teasers should be minimized.

All animals resident at the semen collection facilities should meet the minimum health requirements for donors as mentioned in Chapter II.

Only animals from the species whose semen is collected may be housed in the same centre. An exception to this prohibition is made for small ruminant semen production centres where sheep and goats may be housed together.

Females are not authorized in semen collection facilities. An exception to this prohibition is made for small ruminant semen production centres where female teasers are permitted due to the particularity of these seasonal species.

Visitors to the semen collection facilities should be kept to a minimum and visits should be subject to formal authorisation and control. The centre veterinarian shall create suitable written protocols for the admittance of approved visitors.

Equipment should be dedicated to the semen collection facilities or cleaned and disinfected prior to entry. All equipment and tools brought on to the premises should be examined to ensure that they cannot introduce disease.

Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.

Movement of animals to and from the centre is a biosecurity critical control point requiring a written standard operating procedure (SOP). All animal movements at a minimum should be done using cleaned and disinfected conveyances and in manner which poses no significant animal health risk.

c) Operations
The centre veterinarian is responsible for the health and welfare of animals resident in the centre. Appropriate records of vaccines used and treatments done on resident animals should be available. This includes samples sent to laboratories for diagnostic purposes other than for diseases included in Chapter II.

Sampling for diseases included in the testing programme of donor animals should be done by the centre veterinarian or under his/her direct supervision or under a clear delegation provided to another accredited veterinarian. Interpretation of results of the tests prescribed in the program should be done by the centre veterinarian, taking into consideration the information provided in Chapter II. Diseases to be tested during residence period are listed in each appropriate species and centre category section.

Additional export testing required by destination countries importing semen is also the responsibility of the centre veterinarian. Samples must be sent to either a CFIA laboratory or a CFIA approved laboratory for export purposes according to the CFIA “Policy on the Use of External Laboratories for Export Testing”. This policy is available at [http://www.inspection.gc.ca/animals/terrestrial-animals/exports/live-animals/external-laboratories/eng/1334692613353/1334692757036](http://www.inspection.gc.ca/animals/terrestrial-animals/exports/live-animals/external-laboratories/eng/1334692613353/1334692757036).

The centre veterinarian is responsible to examine donor animals on a regular basis. The minimum expected frequency when semen is collected for export purposes is at least once a week. Examination of animals may
be delegated by the centre veterinarian to another competent veterinarian when it is impossible for him to perform this duty.

The centre veterinarian is responsible for the management of donor animals to ensure measures are taken to avoid contamination of semen during semen collection, as mentioned in the OIE Terrestrial Code Chapter 4.5 on “General Hygiene in semen collection and processing centres”. These OIE recommendations on management of donor animals should be included in the SOP concerning semen collection.

The centre veterinarian is responsible for the semen collection procedure. The centre veterinarian must develop a written SOP to cover collection procedures and the introduction of collected semen in the laboratory. Procedures must mitigate the risk of sanitary compromise of the semen during the collection process and transfer to the laboratory. OIE recommendations below should be included in the SOP.

The objective is to ensure hygienic collection of semen in order to avoid contamination.

1. A dusty floor should be avoided.
2. The hindquarters of the teaser, whether a mechanical mount or a live teaser animal, should be kept clean.
3. A mechanical mount should be cleaned completely after each period of collection.
4. A teaser animal should have its hindquarters cleaned carefully before each collecting session.
5. The mechanical mount or hindquarters of the teaser animal should be sanitized after the collection of each ejaculate.
6. Disposable plastic covers can be used.

The semen collection procedure may vary between species. The most current collection procedures for ruminants and porcine are described below. Any alternative collection procedure used in the centre must be described, with emphasis on mitigation measures to avoid contamination of semen.

For ruminants, the following guidelines mentioned in the OIE Terrestrial Code Chapter 4.6 on “Collection and processing of bovine, small ruminant and porcine semen” about the use of artificial vaginas should be included in the SOP:

- Preparation of AV’s must be done in a room specially dedicated to this procedure; please refer to section 5 for guidance. A clean and disinfected AV must be used for each animal collected.

- The hand of the person collecting the semen should not come into contact with the animal’s penis. Disposable gloves should be worn by the collector and changed for each collection.

- The lubricant should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.

- The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to reach the contents of the collecting tube.

- When successive ejaculates of the same animal are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the animal has inserted its penis without ejaculating.

- The collection tubes should be sterile, and either disposable or sterilized by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.

- After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

For porcine, semen collection is usually done using a vessel with a liner inserted in which semen is recovered. A filter is also often used to remove extraneous materials picked up during the collection. After preparation a cover should be placed on the vessel to avoid contamination until used.
Section 5  Conditions applicable to semen laboratories

Once collected from donor animals, the semen is brought to the laboratory approved for this purpose to be processed. Manipulation and processing of semen from ruminants and porcine differ slightly, but the same basic principles apply. While almost all semen collected from ruminants is frozen, porcine semen is largely used fresh.

The room where artificial vaginas (AV's) used for ruminants are prepared is associated to the laboratory but not located in the laboratory.

A document confirming initial approval of the semen laboratory facility should be on file. Facilities must be re-approved after five (5) years. A template document for approval of the semen laboratory facilities is available in an appendix to this document.

a) Definition

The semen laboratory is the area where the semen collected from donor animals in the collection area is processed. A semen sexing facility is considered a laboratory processing area and the same program standards apply as for a regular semen laboratory. A semen laboratory or sexing facility must be approved before use.

The laboratory is usually located on the grounds of the semen production centre but may also be located at other premises. Appropriate written procedures must be developed by the centre veterinarian to ensure safe and sanitary transportation of the semen to the laboratory when the laboratory is located on different premises than the semen collection area.

The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing and semen pre-storage. The laboratory should be constructed with materials that permit effective cleaning and disinfection.

Introduction of collected semen in the laboratory should avoid contamination of the laboratory; a double slide pass-through window is often used for this purpose. When another method is used, appropriate documented procedures should be available.

AV room

The AV room must be distinct from the laboratory itself to avoid contamination of the laboratory by soiled AV's. Communication of the AV room with the laboratory is allowed to facilitate procedures but the communication door must be locked during semen collection if there an access to the AV room from the semen collection room.

The centre veterinarian is responsible for the cleaning and disinfection of the collection equipment and material. An appropriate SOP should be written to cover used procedures. The centre veterinarian is responsible for monitoring compliance with the written SOP.

The artificial vagina should be cleaned completely after each collection. It should be dismantled, various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved disinfection techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.

b) Biosecurity

Precautions must be taken when collected semen is moved within the laboratory. The centre veterinarian is responsible for the development of written procedures concerning the entry of freshly collected semen into the laboratory and describing the processes used in the laboratory from reception of semen to packing in final receptacles/straws.

The laboratory and processing areas in which ejaculates are tested, processed and frozen must practice high hygienic standards. Adequate sterilization of equipment and material used is required. The laboratory should
be regularly cleaned. The working surfaces of the laboratory and processing areas must be cleaned and disinfected at the conclusion of each day when semen processing has occurred.

The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.

The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests and documentation should be available.

Entry to the laboratory should be prohibited to unauthorized personnel. Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorization by the centre veterinarian and control. The centre veterinarian shall create suitable written protocols for admittance of approved visitors to the laboratory.

Only semen collected from donors having the same health status may be processed in the laboratory at the same time. All semen from higher status bulls must be completely processed and removed from the evaluation/processing area of the laboratory into separate rooms for equilibration and freezing before lower status semen may enter in the laboratory.

If semen from other species or semen collected outside the centre is processed in the laboratory, a written SOP must be developed by the centre veterinarian describing the sanitary precautions to be followed to prevent contamination of higher status semen. The written procedure must be available for review by the local CFIA district office when requested. Disinfection of working surfaces is required before semen of different species is processed.

The use of commercial sterile extenders is highly encouraged. When diluents are prepared in the laboratory, they should comply with the provisions of appropriate chapter in the OIE Animal Terrestrial Code regarding diluents. Antibiotics must be added to the semen according to OIE Code. Information about diluents and antibiotics must be included in the laboratory SOP. Please refer to OIE Animal Terrestrial Code Chapter 4.6 on “Collection and processing of bovine, small ruminant and porcine semen”, article 4.6.7 for details on these requirements.

Equipment used for sex-sorting sperm should be cleaned and disinfected between batches of sorted semen in accordance with the recommendations of the licensor of the system. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals of same or better health status.

c) Operations

Identification of semen, either fresh or frozen, is of capital importance. semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal recording (ICAR). Semen straws, including sex-sorted semen, should be clearly and permanently identified. Minimum straw/receptacle labelling must include identification of the semen donor animal or semen pool, approved production code of the semen production centre and semen collection date.

When semen is processed elsewhere than in the approved laboratory attached to the semen collection facility, the approval code of the laboratory used must also be included in the identification sequence.

Information regarding all semen processed in the semen laboratory must be recorded. Required information includes the following elements:

1. identification of semen donor, including breed, name and registration number;
2. code of the production centre;
3. collection date;
4. and number of semen doses obtained.

Newly frozen semen should be placed in sterilized/sanitized liquid nitrogen transport container and moved to the approved storage area of the centre.
Section 6  Conditions applicable to storage areas

This section mostly applies to frozen semen, but there is also a transient storage time for fresh semen until distribution. Storage of semen in an approved storage facility is a critical element of the certification process to export semen to international markets. Storage of fresh semen from the completion of processing until distribution must follow the same general principles that apply to frozen semen.

A document confirming initial approval of the semen storage facility should be on file. Facilities must be re-approved every five (5) years. A template document for approval of the semen storage facilities is available in an appendix to this document.

a) Definition

The semen storage area is the area/room/facility where processed semen is stored until distribution or disposal. The storage area is usually located on the grounds of the semen production centre but may also be located at other premises. Appropriate written procedures must be developed by the centre veterinarian to ensure safe and sanitary transportation of the semen from the laboratory to the storage facility when the storage facility is located on different premises than the semen laboratory.

The storage area must be physically separated from animal semen collection area and laboratory area. The storage area should be lockable.

The storage area should be capable of being cleaned and disinfected.

b) Biosecurity

Semen for export should be stored in straws/receptacles separately from other genetic material not meeting the same requirements with fresh liquid nitrogen in previously sterilized/sanitized storage container before being exported.

Individual storage semen containers should be capable of being cleaned and disinfected. The centre veterinarian is responsible for the development of appropriate protocols for disinfection of semen containers. The written procedure must be available for review by the local CFIA district office when requested. Semen containers arriving to the storage area should be either new or submitted to a disinfection procedure. A log must be maintained regarding disinfection of containers.

The liquid nitrogen source must be documented and confirmation obtained that it has not been previously used for animal products.

Only semen originating from an approved production centre or semen legally imported into Canada is permitted in the main storage area of an approved centre. Legally imported semen should be stored in separate tanks from semen produced in the centre in order to avoid compromising the exportability of Canadian export eligible semen.

Equipment used should be dedicated to the storage area. Equipment entering in the storage area is either new or cleaned and disinfected before entry.

c) Operations

Semen must be stored continuously in an approved storage area at either the semen production centre or an approved storage facility in order to maintain export eligibility. Movement of semen between approved semen production centres and/or approved storage facilities is permitted under private seal. Records of semen movements must be kept along with transfer dates and seal numbers.

Any semen moved out of approved premises to an unapproved facility immediately loses export status.
Bovine semen destined to the European Community must be stored separately from all other categories of semen in a room approved by CFIA. Sanitary procedures must be applied to maintain the distinct EU status of this semen.

Semen of different species, embryos and semen returned to the centre other than directly from a centre of equivalent status must be stored in separate containers and in a different room than the semen collected for export at the approved centre.

Prior to export, semen straws should be placed into new liquid nitrogen in a new or sterilized container under the supervision of a CFIA veterinarian. The contents of the container should be verified by the CFIA veterinarian prior to sealing with an official numbered seal before export and accompanied by an appropriate export veterinary certificate listing the contents and the number of the official seal.

A suitable record keeping system should be available to track all semen received for storage and semen distributed. The system should also include any semen brought in the storage area from other centres. Basic required information should include the approved code of the semen production centre, identification of the semen donor, date of collection and number of straws. Records for all semen distributed must include the destination and shipping date.

All records must be maintained for the seven years following disposal of semen.
Section 7  Centre veterinarian roles and responsibilities

This section deals with the roles and responsibilities of the centre veterinarian. Only private veterinarians accredited for this function by the CFIA under the Accredited Veterinarian Program are authorized to be hired by centre management as the centre veterinarian. A centre veterinarian hired by a centre must be immediately confirmed by the local CFIA district office.

The centre veterinarian is the responsible person for all aspects of the Artificial insemination program in a semen production centre.

The centre must be under the direct supervision and control of a centre veterinarian accredited by the CFIA. A semen production centre cannot operate without having a centre veterinarian on duty. A regular physical presence on site is required and this function cannot be done from abroad, except under exceptional circumstances. The centre veterinarian may have competent staff to help him in his duties, but the centre veterinarian alone is fully responsible for all sanitary and biosecurity aspects of the centre.

A centre veterinarian may be responsible for more than one semen production centre. As a regular physical presence is required at the semen production centre, it is not acceptable for the centre veterinarian to be remotely located from a semen production centre. The centre veterinarian may delegate some duties to other accredited veterinarians operating under the authority of the centre veterinarian.

Testing prescribed by the program is the responsibility of the centre veterinarian. This includes verification of testing done on farm of origin, during pre-entry isolation and residence in the centre. The centre veterinarian is responsible for ensuring that animals selected on farm and in pre-entry isolation qualify according to the requirements of the program, including appropriate documentation. The centre veterinarian is directly responsible for testing of animals in isolation, resident animals and teasers in the centre.

Export testing is also the responsibility of the centre veterinarian when additional tests are required by a destination country. Current export testing policies must be respected must be respected.

The centre veterinarian must be in a position to know what is happening daily in the centre, to routinely inspect the animals in the centre and to confirm appropriate SOP’s are respected. The centre veterinarian is responsible to approve SOP’s in place at the centre and to write new ones when requested.

The centre veterinarian’s primary responsibilities are to ensure:

- Confirmation that selected animals on farm comply with the requirements of the program;
- Supervision of the pre-entry isolation facility and determination of eligibility for movement into the centre;
- Supervision of the semen collection facilities;
- Supervision of health and welfare of animals;
- Supervision of mandatory testing according to the program;
- Biosecurity measures of facilities are maintained;
- Availability of appropriate SOP’s mentioned in the program;
- Authorization of visitors to the centre;
- Hygiene standards are satisfactory for semen collection and processing;
- Collection, processing and storage are carried out according to appropriate SOP’s;
- Semen is correctly identified and stored;
- Animal and semen records are up to date and contain appropriate information;
- Verification that semen complies with export conditions;
- Verification that semen certification is correctly completed and signed;
- Report to the CFIA any situation that may compromise the status of the semen production centre.

The centre veterinarian may contact the local CFIA district office at any time for guidance and information.
Section 8 Audits and inspections

This section deals with audits and inspections of semen production centres to be done by the CFIA. In order to have centres audited under the same criteria, audit documents are included in this section and should be used as guidance when audits are performed. The audits should be outcome based as differences in facilities and procedures are expected between approved semen production centres. The basic principles of satisfying regulatory and international trade requirements should form the basis for evaluating the audit findings.

Centre should be under the general supervision and control of the CFIA which are responsible for regular audits at interval of no more than 12 months, of protocols, procedures and records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen. Animal semen production centres approved for export to the European Union should be inspected twice a year.

During inspection visits particular attention must be given to all aspects pertaining to biosecurity, health, sanitary procedures and record keeping. During inspection visits, an examination of the storage tanks inventory should be made. This should include a physical verification of the accuracy of storage records.

The content of inspection and audit report is discussed with the centre veterinarian upon completion of the inspection. The inspection report must be sent to the appropriate level in Operations for review. When approved the report is sent the National Coordinator of the Artificial Insemination program in Ottawa.

A list of appendices is provided below.

Note: Appendices are being developed during final consultation concerning this new program. Subjects of appendices are identified and listed below.

These appendices consist of checklists that may be used by CFIA auditors for the initial approval of facilities and subsequent regular audit and inspections.

Application form for an animal semen production centre
General information summary to accompany all audit reports

For initial approval and every 5 years, to re-issue the permit:
• Approval of a pre-entry isolation facility (physical facilities and procedures))
• Approval of semen collection facilities (procedures, housing buildings, sick pen and collection room)
• Approval of semen laboratory facility (physical facilities and procedures)
• Approval of semen storage facility (physical facilities and procedures)

For initial approval and every 2 years to reissue the permit:
• Approval of a mobile laboratory for semen processing (bison, cervid and small ruminant for distribution in Canada)

For audit:
• Audit of entry procedures in the centre (on farm, pre-entry; animals records, tests)
• Audit of resident health status (tests, records, treatments, movements)
• Audit of semen collection procedures (observation of collection and AV sanitation, if any)
• Audit of semen processing procedures (observation of lab procedures, including sex-sorting if any)
• Audit of semen storage procedures (observation of manipulation; verification of semen identification, records, container disinfection, export certificates)
CHAPTER II - HEALTH REQUIREMENTS FOR DONOR ANIMALS IN SEMEN PRODUCTION CENTRES

This chapter describes the health requirements for animals when they are selected for entry and residence in a semen production centre. This chapter is divided into five sections where conditions for bovine, small ruminants, bison, cervid and porcine animals.

SECTION 1 - BOVINE SEMEN PRODUCTION CENTRES

1. Bovine semen production centres approved for distribution in Canada and export purposes other than European Union

Introduction
The Artificial Insemination Program (AIP) allows for the collection, processing, storage and distribution of bovine semen within Canada and internationally, when export conditions specified by destination countries are met. This program meets the standards of the World Organisation for Animal Health (OIE), an international reference standard. The purpose is to maintain an official sanitary control on collection centres for semen distributed in Canada and allow international distribution of semen with negligible risk for pathogens transmissible by semen.

References
References for testing of bulls and teasers are included in Chapter 4.6 “Collection and processing of bovine, small ruminant and porcine semen” of the OIE Terrestrial Animal Health Code.

References for diagnostic tests of diseases mentioned in this section are included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2016. Diagnostic tests should be performed either in CFIA or CFIA approved laboratories.

“Owner use only” semen procedure
Apart from the Artificial Insemination Program mentioned here, an owner may want to have his bull collected and semen processed allowing him to use frozen semen to conduct breeding operations on his own animals. As ruminant semen collection is regulated in Canada and a permit is mandatory to collect semen from a ruminant, even for personal use by the owner, a bull’s owner may want to use the “Owner use only” semen procedure for this purpose. The “Owner use only” semen procedure is not included in the Artificial Insemination Program and semen collected using this procedure is not authorized for distribution in Canada and not eligible for export. The permission delivered to collect “Owner use only” semen is not related to the permit issued to a semen collection centre approved under the Artificial Insemination program. Please refer to annex “Owner use only” semen procedure attached to this document.

Sampling of animals
Sampling of animals is under the responsibility of private veterinarians accredited by the CFIA, who are authorized to examine and request appropriate testing for animals enrolled in the Artificial Insemination Program. This includes sampling of selected animals before entering the pre-entry isolation facility of a semen collection centre, in the pre-entry isolation facility and during residence of animals in the centre. In exceptional circumstances, a CFIA veterinarian may replace an accredited veterinarian.

Conditions applicable to testing of bulls and teaser animals
Bulls and teaser animals are allowed to enter and reside in a semen collection facility approved for distribution in Canada and export purposes other than the EU when they fulfill all conditions mentioned below. Test results should be negative except otherwise stated.

A. Prior to entering the pre-entry isolation facility
1. Bulls and teaser animals must comply with the following conditions:
   1. Qualification of the herd:
      a. No quarantine measures imposed on the herd
      b. Herd considered free of Brucellosis (B. abortus)
      c. Herd considered free of tuberculosis
   2. Qualification of bulls:
      a. Identified according to the national standards for the species
   3. Clinical examination of selected animals:
a. An accredited veterinarian must examine each animal, find it healthy and free of evidence of infectious diseases.

2. Bulls and teasers must be tested for the following diseases within the 60 days before arrival to the pre-entry isolation facility of an approved semen collection centre:

   1. Brucellosis (\textit{B. abortus}): a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result.

   2. Tuberculosis (\textit{M. bovis}): an intradermal tuberculin test using bovine purified protein derivative (PPD), with negative result at 72 hours.

   3. Bovine viral diarrhoea (BVD):
      a. A virus isolation test (immunoperoxidase (IP) or another OIE recommended or suitable test) or a test for virus antigen approved by the OIE, with negative result;
      b. A serological test (serum neutralisation (SN)) to determine the presence or absence of antibodies; test result may be either negative or positive.

\textbf{Documentation required}

A document signed by an accredited veterinarian must be available for all donor bulls and teasers presented to the pre-entry isolation facility. This document should confirm conditions mentioned above are respected and appropriate testing done; copies of tests results must be requested. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

\textbf{US origin animals}

Animals tested in the US by USDA accredited veterinarians are eligible to enter in the pre-entry isolation facility in Canada when the same documentation as mentioned above is presented with a copy of all tests attached. Testing must have been performed in a USDA or a CFIA approved laboratory.

\textbf{“On farm” testing conducted on the pre-entry isolation facility premises}

Examination and testing of animals selected for entry in a pre-entry isolation facility is usually performed directly on farms of origin. However it is possible to conduct these activities on the site of the pre-entry isolation facility. Biosecurity measures should then be put in place by the centre veterinarian to maintain the integrity of the pre-entry isolation facility when animals are present. When this option is used, pre-entry isolation period cannot begin before all test results are available to the centre veterinarian and compliant with testing results as mentioned above.

\textbf{Control of animals arriving to the pre-entry isolation facility}

The centre veterinarian is responsible to make appropriate verification on all donor bulls and teasers presented for entry in the isolation facility. This includes, but not limited to, identification checks, verification of all identifiers present on animals, verification of documentation presented and clinical examination of animals. The centre veterinarian makes the final decision concerning the approval or refusal of admission for each animal presented for entry in the isolation facility and is responsible for maintenance of appropriate records. The isolation period only begins when animals are on site and admitted into isolation by the centre veterinarian; this date must be recorded and used to start the isolation period.

\textbf{B. Testing in the pre-entry isolation facility prior to entering the semen production centre}

Bulls and teaser animals must be kept for at least 28 days in a pre-entry isolation facility of a semen collection centre and tested as mentioned below. Serological testing may commence after a minimum of 21 days in pre-entry isolation. Tests for \textit{Campylobacter fetus} subsp. \textit{venerealis} and \textit{Tritrichomonas foetus} may commence after a minimum of 7 days in pre-entry isolation. All results must be negative except in the case of BVD antibody serological testing.

   1. Brucellosis (\textit{B. abortus}): a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result

   2. Bovine viral diarrhoea (BVD):
      a. A virus isolation test (immunoperoxidase (IP) or another OIE recommended or suitable test) or a test for virus antigen approved by the OIE, with negative result. Only when all animals in the pre-entry isolation have obtained negative results for this test, may animals in the pre-entry isolation facility
enter in the semen collection centre. Animals younger than 6 months of age at time of the test must be retested later after reaching that age).

b. A serological test (serum neutralisation (SN)) to determine the presence or absence of antibodies; the test result may be either negative or positive.

i. When no seroconversion occurs in animals which tested negative prior to entering pre-entry isolation facility, all animals (seronegative and seropositive) are allowed entry into the semen collection centre.

ii. When seroconversion occurs in animals which tested negative prior to entering pre-entry isolation facility, all animals that remain seronegative are kept in pre-entry isolation facility until there is no more seroconversion in this group when another test is performed after three weeks. Seropositive animals may be allowed to enter the semen collection centre.

3. *Campylobacter fetus* subsp venerealis: *a* monoclonal antibody based capture ELISA test on a preputial washing sample, with negative result. When a positive ELISA result is obtained, the preputial washing sample is subject to a culture test, with negative result.

a. Animals less than 6 months old or kept since that age only in single sex group prior to pre-entry isolation are tested once on a preputial sample, with negative result.

b. Animals aged 6 months or older that could have had contact with females prior to pre-entry isolation are tested three times at weekly intervals on a preputial sample, with negative result in each case.

4. *Tritrichomonas foetus*: *an* agent identification by culture and direct identification, with negative result.

a. Animals less than 6 months old or kept since that age only in single sex group prior to pre-entry isolation are tested once on a preputial specimen, with negative result.

b. Animals aged 6 months or older that could have had contact with females prior to pre-entry isolation are tested three times at weekly intervals on a preputial specimen, with negative result in each case.

Positive results
The standard procedure is to remove immediately from the pre-entry isolation any animal obtaining a positive result to the tests mentioned above, except the BVD serological test. With reference to the epidemiology of the disease, appropriate measures are applied to re-establish eligibility of remaining animals in the group for entry in the collection centre.

Semen collection during pre-entry isolation
Semen collection is authorized during the pre-entry isolation period. Semen collected during pre-entry isolation period is not eligible for export; such semen may be released for distribution in Canada only when results of all applicable tests are available and negative. Records for semen collected during pre-entry isolation and distributed must be on file.

Documentation required
A document signed by the centre veterinarian must be issued for donor animals and teasers presented for entry in the centre. This document should confirm animals were examined and found free of any clinical sign of disease before entry in the centre and were tested for the diseases mentioned above. The date at which the isolation period started and the date when animals left the isolation facility for transfer in the centre must be mentioned in the document. The official date of entry in a semen collection centre is the date an animal is physically moved from the isolation facility to the semen collection centre, accompanied by appropriate documentation. Copies of tests results must be on file. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

C. Semen testing prior to any dispatch of semen from BVD serologically positive bulls
Prior to the initial dispatch of semen collected from BVD serologically positive bulls, one semen sample from each animal must be subjected to a virus isolation or virus antigen test for BVD, with negative result. The semen tested for this purpose can either be collected during pre-entry isolation period or after admission in the collection centre. In the event of a positive result, the bull must be removed from the centre and all its semen destroyed. This procedure is to eliminate the possibility of persistent testicular BVD virus infection for these animals.

D. Testing programme for bulls and teasers resident in a semen production centre
Bulls and teasers resident in a semen collection centre must be tested at least annually for the following diseases:
1. Brucellosis (*B. abortus*): a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result.

2. Tuberculosis (*M. bovis*): an intradermal tuberculin test using bovine purified protein derivative (PPD), with negative result.

3. Bovine viral diarrhoea (BVD): a serological test (serum neutralisation (SN)): this test is conducted only on animals negative to previous serological tests to confirm absence of antibodies. When a previously negative animal obtains a positive result, the following procedure applies:
   a. Semen collection for this animal is immediately stopped.
   b. Every ejaculate already collected from this animal since the last negative serological test should be either destroyed, or tested for the presence of the BVD virus, with negative results.
   c. After examination of semen already collected as above, if this animal is maintained in the centre, the first semen collected when collection resumes must be tested for the presence of the BVD virus, with negative results, before semen distribution from this animal is authorized.
   d. This seropositive animal is not further serologically tested for BVD.

4. *Campylobacter fetus* subsp. *venerealis*: a monoclonal antibody-based capture ELISA test on a preputial washing sample, with negative result. When a positive ELISA result is obtained, the preputial washing sample is subject to a culture test, with negative result. Only bulls on semen collection or bulls having contact with bulls on semen collection need to be tested. Bulls returning to collection after a lay-off of six months and more should be tested within 30 days prior to resuming collection.

5. *Tritrichomonas foetus*: an agent identification by culture and direct identification, with negative result. Only bulls on semen collection or bulls having contact with bulls on semen collection need to be tested. Bulls returning to collection after a lay-off of 6 months or more should be tested within 30 days prior to resuming collection.

**Non-negative results**

When an animal obtain a non-negative result to a test mentioned above, this animal is immediately placed into isolation within the centre and semen collection stopped. All semen from this animal collected from the last negative test result is put on hold for distribution. Additional tests may be performed or, in the case of *Campylobacter fetus* subsp. *venerealis*, a treatment may be initiated, followed by appropriate testing. If the animal is confirmed negative, the donor bull may return to semen production and semen on hold is released for distribution. If the animal is confirmed positive, the donor bull must leave the centre and semen on hold is removed from export storage and disposed of without any compensation.

**Transfer between centres**

Animals may be transferred directly from a semen collection centre to another centre of equivalent health status without isolation or testing, provided that annual testing regime has been carried out on the animal during the 12 months prior to the date of transfer. The transferred animal must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and transport vehicle must have been cleaned and disinfected before use. The animal must be accompanied by a health certificate confirming their health status, including dates of last tests carried out on the animal. A template document for transfer between centres is available in an annex to this document.

**E. Additional tests for donor bulls**

The testing programme mentioned above in section “D. Testing programme for bulls and teasers resident in a semen production centre” may not meet all conditions imposed by destination countries. Centres are responsible to have donor bulls tested to ensuring they meet export conditions when semen is considered for export to a specific destination country. One of the diseases that may be considered by destination countries is bluetongue; please refer to the following paragraph.

1. Bluetongue: refer to the OIE Code chapter on Bluetongue where recommendations for testing are mentioned. Post-collection testing may be required. In some instances, a bluetongue seasonally free period in a bluetongue seasonally free zone may apply.
2. Bovine semen production centres approved for export purposes including European Union

Introduction
The European Union (EU) level of the Artificial Insemination (AI) Program allows for the collection, processing, storage and export of bovine semen to the EU member states. This level meets the standards mentioned in Council Directive 88/407/EEC that must be fulfilled to export bovine semen to the EU. Bovine semen collection centres must be approved by the Canadian Food Inspection Agency (CFIA) as per the Council Directive 88/407/EEC and listed on the EU website to be authorized to export bovine semen to the EU. The purpose of Council Directive 88/407/EEC is to maintain an official sanitary control on collection centres for semen exported to the EU. Supplementary guarantees for some diseases are required in Commission Implementing Decision 2011/630/EU that provides model export certificates to be used for export of bovine semen to the EU; these supplementary guarantees must be taken in consideration by bovine semen collection centres approved for export to the EU in order to have semen collected in the centre be exported to the EU.

In 2005, an equivalence agreement, currently still in place, was signed between Canada and the EU concerning bovine semen. Further to this equivalence agreement, a simplified export certification is used by the CFIA to export bovine semen to the EU, as per Commission Decision 2005/290/EC of 4 April 2005. On Canada’s side, the AI Program version April 2004, was used for the recognition of this equivalence; on the EU side, Council Directive 88/407/EEC of 14 June 1988, last amended by Council Directive 2003/43 of 26 May 2003 was the reference standard.

References
Reference for testing of donor bulls and teasers is included in Council Directive 88/407/EEC, as lastly amended. Reference for supplementary guarantees for bluetongue (BT) and epizootic haemorrhagic disease (EHD) are included in Commission Implementing Decision 2011/630/EU, as lastly amended.

References for diagnostic tests of diseases mentioned in this section are included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2016 or prescribed in EU legislation. Diagnostic tests should be performed either in CFIA or CFIA approved laboratories.

Bovine semen collection centres approved for EU also qualify for distribution in Canada and export destinations other than the EU.

Sampling of animals
Sampling of animals is under the responsibility of private veterinarians accredited by the CFIA and authorized to examine and request appropriate testing for animals enrolled in the AI Program. This includes sampling of selected animals before entering the pre-entry isolation facility of a semen collection centre, in the pre-entry isolation facility and during residence of animals in the centre. In exceptional circumstances, a CFIA veterinarian may replace an accredited veterinarian.

Conditions applicable to testing of bulls and teaser animals
Bulls and teaser animals are allowed to enter and reside in a semen collection approved for EU only when they fulfill all conditions mentioned below. Test results should be negative except otherwise stated.

A. Prior to entering the pre-entry isolation facility
   1. Bulls and teaser animals must comply with the following conditions:
      a. No quarantine measures imposed on the herd
      b. Herd considered free of Brucellosis (*B. abortus*)
      c. Herd considered free of tuberculosis
      d. Enzootic bovine leucosis (EBL): the donor bull should be sourced from a CHAH-EBL free herd OR the uterine dam has been subjected to an EBL ELISA test after weaning of the donor bull, with negative results.
      Note: if this EBL requirement for the uterine dam is not fulfilled, all semen collected from the donor animal is not be eligible for export to the EU until the donor bull reaches 2 years of age and is tested for EBL, with negative results.

2. Qualification of the bulls:
a. Identified according to the national standards for the species

3. Clinical examination of selected bulls:
   a. An accredited veterinarian must examine each animal, find it healthy and free of evidence of diseases.

2. Bulls and teasers must be tested for the following diseases within the 60 days before arrival to the pre-entry isolation facility of an EU approved semen collection centre:

   1. Brucellosis (\textit{B. abortus}): a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result.

   2. Tuberculosis (\textit{M. bovis}): an intradermal tuberculin test using bovine purified protein derivative (PPD), with negative result at 72 hours.

   3. Bovine viral diarrhoea (BVD):
      a. A virus isolation test (immunoperoxidase (IP) or another OIE recommended or suitable test) or a test for virus antigen approved by the OIE, with negative result;
      b. A serological test (serum neutralisation (SN)) to determine the presence or absence of antibodies; test result may be either negative or positive.

   4. Enzootic bovine leucosis (EBL): an ELISA test, with negative result;

   5. Infectious bovine rhinotracheitis (IBR): an ELISA test, with negative result

**Documentation required**

A document signed by an accredited veterinarian must be available for all donor bulls and teasers presented to the pre-entry isolation facility. This document should confirm conditions mentioned above are respected and appropriate testing done; copies of tests results must be requested. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

**US origin animals**

Animals tested in the US by USDA accredited veterinarians are eligible to enter in the pre-entry isolation facility in Canada when the same documentation as mentioned above is presented with a copy of all tests attached. Testing must have been performed in a USDA or a Canadian approved laboratory.

**“On farm” testing conducted on the pre-entry isolation facility premises**

Examination and testing of animals selected for entry in a pre-entry isolation facility is usually performed directly on farms of origin. However it is possible to conduct these activities on the site of the pre-entry isolation facility. Biosecurity measures should then be put in place by the centre veterinarian to maintain the integrity of the pre-entry isolation facility when animals are present. When this option is used, pre-entry isolation period cannot begin before all test results are available to the centre veterinarian and compliant with testing results as mentioned above.

**Control of animals arriving to the pre-entry isolation facility**

The centre veterinarian is responsible to make appropriate verification on all donor bulls and teasers presented for entry in the isolation facility. This includes, but not limited to, identification checks, verification of all identifiers present on animals, verification of documentation presented and clinical examination of animals. The centre veterinarian makes the final decision concerning the approval or refusal of admission for each animal presented for entry in the isolation facility and is responsible for maintenance of appropriate records. The isolation period only begins when all animals are on site and admitted into isolation by the centre veterinarian, this date must be recorded and used to start the isolation period. The pre-entry isolation is a quarantine procedure, using all-in/all-out method.

**B. Testing in the pre-entry isolation facility prior to entering the semen production centre**

Bulls and teaser animals must be kept in quarantine for at least 28 days in a pre-entry isolation facility of a semen collection centre and tested as mentioned below. Serological testing may commence after a minimum of 21 days in pre-entry isolation. Tests for \textit{Campylobacter fetus} subsp. \textit{venerealis} and \textit{Tritrichomonas foetus} may commence after a minimum of 7 days in pre-entry isolation. All results must be negative except in the case of BVD antibody serological testing.
1. Brucellosis (B. abortus): a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result.

2. Bovine viral diarrhoea (BVD):
   a. A virus isolation test (immunoperoxidase (IP) or another OIE recommended or suitable test) or a test for virus antigen approved by the OIE, with negative result. Only when all animals in the pre-entry isolation have obtained negative results for this test, may animals in the pre-entry isolation facility enter in the semen collection centre. Animals younger than 6 months of age at time of the test must be retested later after reaching that age.
   b. A serological test (serum neutralisation (SN)) to determine the presence or absence of antibodies; the test result may be either negative or positive.
      i. When no seroconversion occurs in animals which tested negative prior to entering pre-entry isolation facility, all animals (seronegative and seropositive) are allowed entry into the semen collection centre.
      ii. When seroconversion occurs in animals which tested negative prior to entering pre-entry isolation facility, all animals that remain seronegative are kept in pre-entry isolation facility until there is no more seroconversion in this group when another test is performed after three weeks. Any seropositive animals may be allowed to enter the semen collection centre.

3. Infectious bovine rhinotracheitis (IBR): an ELISA test, with negative results.
   When an animal tested positive to the ELISA test, this animal is removed immediately from the isolation facility and other animals of the same group remain in isolation are retested, with negative results, not less than 21 days after removal of the positive animal.

4. Campylobacter fetus subsp venerealis: a monoclonal antibody-based capture ELISA test on a preputial washing sample, with negative result. When a positive ELISA result is obtained, the preputial washing sample is subject to a culture test, with negative result.
   a. Animals less than 6 months old or kept since that age only in single sex group prior to pre-entry isolation are tested once on a preputial sample, with negative result.
   b. Animals aged 6 months or older that could have had contact with females prior to pre-entry isolation are tested three times at weekly intervals on a preputial sample, with negative result in each case.

5. Tritrichomonas foetus: an agent identification by culture and direct identification, with negative result.
   a. Animals less than 6 months old or kept since that age only in single sex group prior to pre-entry isolation are tested once on a preputial specimen, with negative result.
   b. Animals aged 6 months or older that could have had contact with females prior to pre-entry isolation are tested three times at weekly intervals on a preputial specimen, with negative result in each case.

Positive results
The standard procedure is to remove immediately from the pre-entry isolation any animal obtaining a positive result to the tests mentioned above, except the BVD serological test. With reference to the epidemiology of the disease, appropriate measures are applied to re-establish the eligibility of remaining animals in the group for entry in the collection centre.

Semen collection during pre-entry isolation
Semen collection is authorized during the pre-entry isolation period. Semen collected during pre-entry isolation period is not eligible for export; such semen may be released for distribution in Canada only when results of all applicable tests are available and negative, to the exception of IBR testing. Records for semen collected during pre-entry isolation and distributed must be on file.

Documentation required
A document signed by the centre veterinarian must be issued for donor animals and teasers presented for entry in the centre. This document should confirm animals were examined and found free of any clinical sign of disease before entry in the centre and were tested for the diseases mentioned above. The date at which the isolation period started and the date when animals left the isolation facility for transfer in the centre must be mentioned in the document. The official date of entry in a semen collection centre is the date an animal is physically moved from the isolation facility to the semen collection centre, accompanied by appropriate
documentation. Copies of tests results must be on file. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

C. Semen testing prior to any dispatch of semen from BVD serologically positive bulls
Prior to the initial dispatch of semen collected from BVD serologically positive bulls, one semen sample from each animal must be subjected to a virus isolation or virus antigen test for BVD, with negative result. The semen tested for this purpose can either be collected during pre-entry isolation period or after admission in the collection centre. In the event of a positive result, the bull must be removed from the centre and all its semen destroyed. This procedure is to eliminate the possibility of persistent testicular BVD virus infection for these animals.

D. Testing programme for bulls and teasers resident in a semen production centre
Bulls and teasers resident in a semen collection centre must be tested at least annually for the following diseases:

1. Brucellosis (B. abortus): a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result.

2. Tuberculosis (M. bovis): an intradermal tuberculin test using bovine purified protein derivative (PPD), with negative result after 72 hours.

3. Bovine viral diarrhoea (BVD): a serological test (serum neutralisation (SN)): this test is conducted only on animals negative to previous serological tests to confirm absence of antibodies. When a previously negative animal obtains a positive result, the following procedure applies:
   a. Semen collection for this animal is immediately stopped.
   b. Every ejaculate already collected from this animal since the last negative serological test should be either destroyed, or tested for the presence of the BVD virus, with negative results.
   c. After examination of semen already collected as above, if this animal is maintained in the centre, the first semen collected when collection resumes must be tested for the presence of the BVD virus, with negative results, before semen distribution from this animal is authorized.
   d. This seropositive animal is not further serologically tested for BVD.

4. Campylobacter fetus subsp venerealis: a monoclonal antibody-based capture ELISA test on a preputial washing sample, with negative result. When a positive ELISA result is obtained, the preputial washing sample is subject to a culture test, with negative result. Only bulls on semen collection or bulls having contact with bulls on semen collection need to be tested. Bulls returning to collection after a lay-off of 6 months and more should be tested within 30 days prior to resuming collection.

5. Tritrichomonas foetus: an agent identification by culture and direct identification, with negative result. Only bulls on semen collection or bulls having contact with bulls on semen collection need to be tested. Bulls returning to collection after a lay-off of 6 months or more should be tested within 30 days prior to resuming collection.

6. Enzootic bovine leucosis (EBL): an ELISA test, or another EU approved test, with negative result

7. Infectious bovine rhinotracheitis (IBR): an ELISA test on a blood sample or another EU approved serological test, with negative result. When the ELISA result is non-negative, a serum neutralisation (SN) test according to the OIE methodology is immediately carried out on the same sample by the laboratory, with negative result.

Non-negative results
When an animal obtain a non-negative result to a test mentioned above, to the exception of an animal non-negative to the IBR ELISA test in which case an IBR-SN test is immediately carried out by the laboratory as mentioned above, this animal is immediately placed into isolation within the centre and semen collection stopped. All semen from this animal collected from the last negative test result is put on hold for distribution. Additional tests may be performed or, in the case of Campylobacter fetus subsp venerealis, a treatment may be initiated, followed by appropriate testing. If the animal is confirmed negative, the donor bull may return to semen production and semen on hold is released for distribution. If the animal is confirmed positive, the
donor bull must leave the centre and semen on hold is removed from export storage and disposed of without any compensation.

**Transfer between centres**
Animals may be transferred directly from a semen collection centre to another centre of equivalent health status without isolation or testing, provided that annual testing regime has been carried out on the animal during the 12 months prior to the date of transfer. The transferred animal must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and transport vehicle must have been cleaned and disinfected before use. The animal must be accompanied by a health certificate confirming their health status, including dates of last tests carried out on the animal. A template document for transfer between centres is available in an annex to this document.

**E. Additional tests required for donors bulls whose semen is exported to the EU**

Testing programme mentioned above in section “D. Testing programme for bulls and teasers resident in an EU approved semen production centre” provides the centre with the eligibility to export bovine semen to the EU. But supplementary testing applies to donor bulls whose semen is exported to the EU, as follows:

1. **Bluetongue:** please refer to Commission Implementing Decision 2011/630/EU, [EUR-Lex - 02011D0630-20150409 - EN - EUR-Lex](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011D0630-20150409), as lastly amended, for possible options, either consideration of the seasonally free period in a seasonally free zone or serological or agent identification testing. These options are similar to those mentioned in the OIE Code


Centres are responsible to have donor bulls whose semen is exported to the EU to organise appropriate testing of donor bulls before, during and after collection of semen in order to qualify the semen for export to the EU.
SECTION 2 – SMALL RUMINANT SEMEN PRODUCTION CENTRES

1. Small ruminant semen production centres approved for distribution in Canada

Introduction
The small ruminant Artificial Insemination Program (AIP) allows for the collection, processing and distribution of small ruminant semen within Canada. The purpose is to maintain official sanitary control over collection centres distributing small ruminant semen in Canada.

This section for distribution in Canada allows putting sheep and/or goats in an isolation facility located on farm and have their semen collected on farm eligible for distribution in Canada without any restriction. This approach would allow better dissemination of small ruminant genetic material considering the seasonality of species.

“Owner use only” semen procedure
Apart from the Artificial Insemination Program mentioned here, an owner may want to have his animal collected and semen processed allowing him to use frozen semen to conduct breeding operations on his own animals. As ruminant semen collection is regulated in Canada and a permit is mandatory to collect semen from a ruminant, even for personal use by the owner, a sheep/goat owner may want to use the “Owner use only” semen procedure for this purpose. The “Owner use only” semen procedure is not included in the Artificial Insemination Program and semen collected using this procedure is not authorized for distribution in Canada and not eligible for export. The permission delivered to collect “Owner use only” semen is not related to the permit issued to a semen collection centre approved under the Artificial Insemination program. Please refer to annex “Owner use only” semen procedure attached to this document.

References
Reference for diagnostic tests of diseases mentioned in this section is included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Diagnostic tests should be performed either in a CFIA or CFIA approved laboratory.

Sampling of animals
Sampling of animals is under the responsibility of private veterinarians accredited by the CFIA and authorized to examine and request appropriate testing of sheep and goats enrolled in the small ruminant AIP. This includes sampling of selected animals entering in the isolation facility located on farm to test them for diseases included in this program.

Conditions applicable to testing of rams/bucks and teaser animals
Rams/bucks and teaser animals are allowed to enter in a small ruminant semen collection facility located on farm and approved for distribution in Canada when they fulfill conditions mentioned below. Test results must be negative.

Approval of an isolation facility located on a farm
An isolation facility located on farm is inspected and approved either by a private veterinarian accredited by the CFIA and authorized to examine and request appropriate testing for animals enrolled in the small ruminant AIP or a centre veterinarian of a centre who has been issued a “Permit to operate an animal semen production centre”. The accredited veterinarian dealing with such approval should have been in contact with the centre veterinarian who will later collect semen in this facility. Isolation facility in this case is defined as an area on a farm where animals selected for semen collection and teasers are maintained isolated from other animals present on the farm. This isolation facility may be located in a barn where other animals are housed. Isolated animals must not have direct or fence line contact with other animals of different status. Inspection and approval of the facility must be done before animals are placed in isolation. The accredited veterinarian and/or centre veterinarian must keep a document on file confirming inspection and approval of the isolation facility. Refer to the paragraph “Documentation required” below.

A. Prior to entering the isolation facility located on farm
1. Rams/bucks and teaser animals must comply with the following conditions:
   1. Qualification of the isolation facility:
      a. The isolation facility must meet the requirements mentioned above before use.
   2. Qualification of the flock/herd:
      a. No quarantine measures imposed on the flock/herd.
b. General inspection of the flock/herd confirming absence of diseases that may be transmitted by semen

3. Qualification of animals:
   a. Identification according to the national standards for the species

4. Clinical examination of selected animals:
   a. An accredited veterinarian must examine each animal, find it healthy and free of evidence of infectious or contagious diseases transmissible by semen.

2. When above conditions are met, selected animals are moved to the isolation facility and tested immediately for the diseases mentioned in point 3 below.

3. Rams/bucks and teasers must be tested for the following diseases when they enter in the isolation facility:
   1. Caprine arthritis/encephalitis, for goats only: ELISA test or another OIE recommended or suitable test, with negative result
   2. Ovine epididymitis (*B. ovis*) for sheep only: CF test or another OIE recommended or suitable test, with negative result
   3. Maedi-visna, for sheep only: ELISA test or another OIE recommended or suitable test, with negative result

**Documentation required**

A document signed by an accredited veterinarian must be on file for all donor rams/bucks and teasers placed in the farm isolation facility. This document should confirm conditions mentioned above are respected and appropriate sampling done. A template document confirming approval of on-farm isolation facility and qualification of small ruminant animals moved to isolation facility for semen collection purposes is available in an annex to this document.

**B. Collection in the isolation facility located on farm**

Semen collection can only take place after test results are returned to the accredited veterinarian. Donor animals and teasers must remain isolated during all their collection period. When semen collection from a donor is over, this donor may leave the isolation facility; please refer to the paragraph below titled “Release of animals from isolation”.

**Test results**

After reception of test results, negative rams/bucks and teaser animals are maintained in the isolation facility on the farm. If there is a non-negative test result for an animal in isolation, this animal is removed from the isolation facility. The document required in part A above must be completed with testing results for each animal. Copy of test results must be maintained on file.

**Semen collection**

Semen collection may begin only when test results are known to the centre veterinarian and non-negative animals removed from isolation facility. Semen is collected by the centre veterinarian or under his responsibility. Semen collection may continue until the end of the breeding season.

**Semen processing**

Collected semen is processed according to the program and may be distributed fresh or frozen and stored for future distribution in Canada. An approved mobile laboratory may be used to process the semen or the semen may be transferred to an approved fixed laboratory for processing. The centre veterinarian is responsible for semen processing and identification.

**Documentation required for collected semen**

The centre veterinarian must maintain records for all semen collected, including identity of semen donors, collection date and any other information requested by the program.

**Release of animals from isolation**

When semen collection is over, donor animals and teasers are released from isolation by the centre veterinarian. Release date along with identification of animals must be recorded and placed on file.
2. Small ruminant semen production centres approved for export purposes other than European Union

Introduction
The Artificial Insemination Program (AIP) allows for the collection, processing, storage and distribution internationally to the exception of the European Union (EU), when export conditions specified by destination countries are met. This level of the program meets the standards of the World Organisation for Animal Health (OIE), an international reference standard. The purpose is to maintain an official sanitary control on collection centres to allow international distribution of semen with a negligible risk about pathogens transmissible by semen. The AIP for small ruminants allows to house sheep and goats on the same premises, including pre-entry isolation facility and the center itself; sheep and goats are maintained in separate pens, but they may use common areas.

References
References for testing of rams/bucks and teasers are included in Chapter 4.6 “Collection and processing of bovine, small ruminant and porcine semen” of the OIE Terrestrial Animal Health Code. As mentioned in the OIE Code, testing for diseases that had never been reported in Canada, such as contagious agalactia, peste des petits ruminants and contagious caprine pleuropneumonia, is not required. Testing for brucellosis is included in the program though Canada is free.

References for diagnostic tests of diseases mentioned in this level are included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Diagnostic tests should be performed either in a CFIA or CFIA approved laboratory.

Small ruminant semen collection centres approved for export purposes other than EU also qualify for distribution in Canada.

Sampling of animals
Sampling of animals is under the responsibility of private veterinarians accredited by the CFIA and authorized to examine and request appropriate testing for animals enrolled in the AIP. This includes sampling of selected animals before entering the pre-entry isolation facility of a semen collection centre, in the pre-entry isolation facility and during residence of animals in the centre.

Conditions applicable to testing of rams/bucks and teaser animals
Rams/bucks and teaser animals are allowed to enter and reside in a small ruminant semen collection facility approved for export purposes other than the EU when they fulfill all conditions mentioned below. Test results must be negative except otherwise stated.

A. Prior to entering the pre-entry isolation facility
1. Rams/bucks and teaser animals must comply with the following conditions:
   1. Qualification of the flock/herd:
      a. No quarantine measures imposed on the flock/herd
      b. Herd/flock considered free of tuberculosis
      c. Herd/flock considered free of brucellosis (B. melitensis)
      d. General inspection of the flock/herd confirming absence of diseases that may be transmitted by semen
   2. Qualification of the animal:
      a. Identified according to the national standards for the species
      b. Has been free from clinical signs of paratuberculosis since birth or the last two years
   3. Clinical examination of selected animals:
      a. An accredited veterinarian must examine each animal, find it healthy and free of evidence of infectious or contagious diseases, including clinical signs of bluetongue and scrapie.

2. Rams/bucks and teasers must be tested for the following diseases within the 60 days before arrival to the pre-entry isolation facility of an approved semen collection centre:
   1. Tuberculosis (M. bovis), for goats only: an intradermal tuberculin test using bovine purified protein derivative (PPD), with negative result at 72 hours.
2. Ovine epididymitis (*B. ovis*), for sheep only: CF test or another OIE recommended or suitable test, with negative result

3. Maedi-visna, for sheep only: ELISA test or another OIE recommended or suitable test, with negative result

4. Caprine arthritis/encephalitis, for goats only: ELISA test or another OIE recommended or suitable test, with negative result

Documentation required
A document signed by an accredited veterinarian must be available for all donor rams/bucks and teasers presented to the pre-entry isolation facility. This document should confirm conditions mentioned above are respected and appropriate testing done; copies of tests results must be provided. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

“On farm” testing conducted on the pre-entry isolation facility premises
Examination and testing of animals selected for entry in a pre-entry isolation facility is usually performed directly on farms of origin. However it is possible to conduct these activities on the site of the pre-entry isolation facility. Biosecurity measures should then be put in place by the centre veterinarian to maintain integrity of the pre-entry isolation facility when in use. When this option is selected, pre-entry isolation period for these animals cannot begin before all test results are received and confirmed by the centre veterinarian.

Control of animals arriving to the pre-entry isolation facility
The centre veterinarian is responsible to make appropriate verification on all donor rams/bucks and teasers presented for entry in the isolation facility. This includes, but not limited to, identification checks and verification of all identifiers present on animals, verification of documentation presented and clinical examination of animals. The centre veterinarian makes the final decision concerning the approval or refusal of admission for each animal presented for entry in the isolation facility and is responsible for maintenance of appropriate records. The isolation period only begins when all animals are on site and admitted into isolation by the centre veterinarian. The date at which isolation begins must be recorded and used for reference. Pre-entry isolation is an all-in/all-out procedure.

B. Testing in the pre-entry isolation facility prior to entering the semen production centre
Rams/bucks and teaser animals must be kept for at least 28 days in a pre-entry isolation facility of a semen collection centre and tested as mentioned below. Serological testing may commence after a minimum of 21 days in pre-entry isolation.

1. Brucellosis (*B. melitensis*) for both sheep and goats: a fluorescence polarization assay (FPA) or another OIE approved test, with negative result

2. Ovine epididymitis (*B. ovis*) for sheep only: CF test or another OIE recommended or suitable test, with negative result

3. Maedi-visna, for sheep only: ELISA test or another OIE recommended or suitable test, with negative result

4. Caprine arthritis/encephalitis, for goats only: ELISA test or another OIE recommended or suitable test, with negative result

Non negative results
The standard procedure is to remove immediately from the pre-entry isolation any animal obtaining a positive result to a test mentioned above.

When a non-negative brucellosis test result is obtained, ancillary testing is conducted by a CFIA laboratory on the same sample; when ancillary testing is positive, the situation must be immediately reported to the local CFIA district office.

With reference to the epidemiology of the disease, appropriate measures are applied to re-establish eligibility of remaining animals in the group for entry in the collection centre.
Semen collection during pre-entry isolation
Semen collection is authorized during the pre-entry isolation period. Semen collected during the pre-entry isolation period is not eligible for export; such semen may be released for distribution in Canada. Records for semen collected during pre-entry isolation and distributed must be on file.

Documentation required
A document signed by the centre veterinarian must be issued for donor animals and teasers presented for entry in the centre. This document should confirm animals were examined and found free of any clinical sign of disease before entry in the centre, including bluetongue, and were tested for the diseases mentioned above. The date at which the isolation period started and the date when animals left the isolation facility for transfer in the centre must be mentioned in the document. The official date of entry in a semen collection centre is the date an animal is physically moved from the isolation facility to the semen collection centre, accompanied by appropriate documentation. Copies of tests results must be on file. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

C. Testing programme for rams/bucks and teasers resident in a semen production centre
Rams/bucks and teasers resident in a semen collection centre must be tested at least annually for the following diseases:

1. Brucellosis (B. melitensis) for both sheep and goats: a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result

2. Tuberculosis (M. bovis), for goats only: an intradermal tuberculin test using bovine purified protein derivative (PPD), with negative result at 72 hours.

3. Ovine epididymitis (B. ovis) for sheep only: CF test or another OIE recommended or suitable test, with negative result

4. Maedi-visna, for sheep only: ELISA test or another OIE recommended or suitable test, with negative result

5. Caprine arthritis/encephalitis, for goats only: ELISA test or another OIE recommended or suitable test, with negative result

Non negative results
When an animal obtain a positive result to a test mentioned above, this animal is immediately placed into isolation within the centre and semen collection for this animal is stopped. All semen from this animal collected from the last negative test result is put on hold for distribution. The failed test is repeated for confirmation and/or additional tests may be performed. If the animal is confirmed negative, the animal may return to semen production and semen on hold is released for distribution. If the animal is confirmed positive, the animal must leave the centre and semen on hold is removed from export storage and disposed of without compensation.

Testing records
All testing records must be maintained by the centre veterinarian for any animal admitted in the centre. Any records must be presented to the CFIA on request.

Seasonal small ruminant semen production centres
Testing mentioned below is optional; small ruminant semen collection centres may decide not to test animals leaving the centre before annual testing, but this may compromise export eligibility of semen. The collection centre and semen exporters are responsible to ensure appropriate post collection testing is available for intended destination countries.

When a small ruminant semen collection centre operates seasonally, i.e. only for a few months during the year due to the seasonality of the reproduction period, semen donors having frozen semen stored for export purposes may be tested for diseases mentioned in section C above before they leave the centre, to the exception of brucellosis and tuberculosis. This procedure does not apply to semen donors whose semen is intended for distribution in Canada. Destination countries may require a minimal waiting period for post
collection testing or require post-collection testing for other diseases than those mentioned above, such as bluetongue.

**Transfer between centres**
Animals may be transferred directly from a semen collection centre to another centre of equivalent health status without isolation or testing, provided that annual testing regime has been carried out on the animal during the 12 months prior to the date of transfer. The transferred animal must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and transport vehicle must have been cleaned and disinfected before use. The animal must be accompanied by a health certificate confirming their health status, including dates of last tests carried out on the animal. A template document for transfer between centres is available in an annex to this document.

**D. Additional tests for donor rams/bucks**
The testing programme mentioned above in section C. *Testing programme for rams/bucks and teasers resident in a semen collection centre* may not meet all conditions imposed by destination countries. Centres are responsible to have donor rams/bucks tested to ensure they meet export conditions when semen is considered for export to a specific destination country. One of the diseases that may be considered by destination countries is bluetongue; please refer to the following paragraph.

1. Bluetongue: refer to the OIE Code chapter on Bluetongue where recommendations for testing are mentioned. Post-collection testing may be required. In some instances, a bluetongue seasonally free period in a bluetongue seasonally free zone may apply.
3. Small ruminant semen production centres approved for export purposes including European Union

Introduction
The European Union (EU) level of the Artificial Insemination Program (AIP) allows for the collection, processing, storage and export of small ruminant semen to the EU members states. This level meets the standards mentioned in Council Directive 92/65/EEC that must be fulfilled to export sheep and goat semen to the EU. Small ruminant semen collection centres must be approved by the Canadian Food Inspection Agency (CFIA) as per the Council Directive 92/65/EEC and listed on the EU website to be authorized to export sheep and goat semen to the EU. The purpose of Council Directive 92/65/EEC is to maintain an official sanitary control on collection centres for semen exported to the EU.

Supplementary guarantees for some diseases are required by Commission Decision 2010/472/EU that provides model export certificates to be used for export of ovine/caprine semen to the EU; these supplementary guarantees must be taken into consideration by small ruminant semen collection centres approved for export to the EU in order to have semen collected in the centre eligible for export to the EU.

Rams/bucks whose semen is exported to the EU must meet specific conditions concerning scrapie. Rams/bucks must comply with requirements mentioned in Regulation (EC) No 999/2001, Annex VIII, Chapter A, Section A, points 1.3 (a) to (f). These scrapie requirements are not mandatory for animals entering a small ruminant semen collection centre approved for EU, but are mandatorily required for semen donors whose semen is exported to the EU.

The AIP for small ruminants allows for housing of sheep and goats on the same premises, including pre-entry isolation and center facilities; sheep and goats are maintained in separate pens, but may use common areas.

References

Reference for supplementary guarantees for bluetongue (BT) and epizootic haemorrhagic disease (EHD) are included in Commission Decision 2010/472/EU, as lastly amended.

Reference for diagnostic tests of diseases mentioned in this section are included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals or prescribed in EU legislation. Diagnostic tests should be performed either in a CFIA or CFIA approved laboratory.

Small ruminant semen collection centres approved for EU also qualify for distribution in Canada and export destinations other than EU.

Sampling of animals
Sampling of animals is under the responsibility of private veterinarians accredited by the CFIA and authorized to examine and request appropriate testing for animals enrolled in the AIP. This includes sampling of selected animals before entering the pre-entry isolation facility of a semen collection centre, in the pre-entry isolation facility and during residence of animals in the centre.

Conditions applicable to testing of rams/bucks and teaser animals
Rams/bucks and teaser animals are allowed to enter and reside in a small ruminant semen collection centre approved for EU when they fulfill all conditions mentioned below. Test results should be negative except otherwise stated.

A. Prior to entering the pre-entry isolation facility
1. Rams/bucks and teaser animals must comply with the following conditions:
   a. Qualification of the flock/herd:
      b. Herd/flock considered free of tuberculosis
      c. Herd/flock considered free of brucellosis (B. melitensis)
      d. Paratuberculosis: no case in the last 12 months
      e. Caseous lymphadenitis: no case in the last 12 months
      f. Ovine pulmonary adenomatosis: no case in the last 3 years
3. Rams/bucks and teasers must be tested for the following diseases within the 28 days before arrival to the pre-entry isolation facility of an EU approved semen collection centre:

1. Brucellosis (*B. melitensis*): for both sheep and goats: a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result

2. (1) Tuberculosis (*M. bovis*): for goats only: an intradermal tuberculin using bovine purified protein derivative (PPD), with negative result at 72 hours.

3. Ovine epididymitis (*B. ovis*) for sheep and goats: CF test or another OIE recommended or suitable test, with negative result

4. (1) Maedi-Visna, for sheep only: ELISA test or another OIE recommended or suitable test, with negative result

5. (1) Caprine arthritis/encephalitis (CAE), for goats only: ELISA test or another OIE recommended or suitable test, with negative result

6. Border disease:
   a. A virus isolation test (immunoperoxidase (IP) or another OIE recommended or suitable test) or a test for virus antigen approved by the OIE, with negative result;
   b. A serological test (serum neutralisation (SN)) to determine the presence or absence of antibodies; the test result may be either negative or positive.

**Documentation required**
A document signed by an accredited veterinarian must be available for all donor rams/bucks and teasers presented to the pre-entry isolation facility. This document should confirm conditions mentioned above are respected and appropriate testing done; copies of tests results must be provided. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

**“On farm” testing conducted on the pre-entry isolation facility premises**
Examination and testing of animals selected for entry in a pre-entry isolation facility is usually performed directly on farms of origin. However it is possible to conduct these activities on the site of the pre-entry isolation facility. Biosecurity measures should then be put in place by the centre veterinarian to maintain integrity of the pre-entry isolation facility when in use. When this option is selected, pre-entry isolation period for these animals cannot begin before all test results are received and confirmed by the centre veterinarian.

**Control of animals arriving to the pre-entry isolation facility**
The centre veterinarian is responsible to make appropriate verification on all donor rams/bucks and teasers presented for entry in the isolation facility. This includes, but not limited to, identification checks and verification of all identifiers present on animals, verification of documentation presented and clinical
examination of animals. The centre veterinarian makes the final decision concerning the approval or refusal of admission for each animal presented for entry in the isolation facility and is responsible for maintenance of appropriate records. The isolation period only begins when all animals are on site and admitted into isolation by the centre veterinarian. The date at which isolation begins must be recorded and used for reference. The pre-entry isolation is a quarantine procedure, using all-in/all-out method.

B. Testing in the pre-entry isolation facility prior to entering the semen production centre
Rams/bucks and teaser animals must be kept for at least 28 days in a pre-entry isolation facility of a semen collection centre and tested as mentioned below. Serological testing may only commence after a minimum of 21 days in pre-entry isolation.

1. Brucellosis (*B. melitensis*): for both sheep and goats: a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result

2. Ovine epididymitis (*B. ovis*) for both sheep and goats: CF test or another OIE recommended or suitable test, with negative result

3. (1) *Maedi-visna*, for sheep only: ELISA test or another OIE recommended or suitable test, with negative result

4. (1) Caprine arthritis/encephalitis, for goats only: ELISA test or another OIE recommended or suitable test, with negative result

5. Border disease:
   a. A virus isolation test (immunoperoxidase (IP) or another OIE recommended or suitable test) or a test for virus antigen approved by the OIE, with negative result. Only when all animals in the pre-entry isolation have obtained negative results for this test, may animals in the pre-entry isolation facility enter in the semen collection centre.
   b. A serological test (serum neutralisation (SN)) to determine the presence or absence of antibodies; the test result may be either negative or positive:
      a. When no seroconversion occurs in animals which tested negative prior to entering pre-entry isolation facility, all animals (seronegative and seropositive) are allowed entry into the semen collection centre.
      b. When seroconversion occurs in animals which tested negative prior to entering pre-entry isolation facility, all animals that remain seronegative are kept in pre-entry isolation facility until there is no more seroconversion in this group when another test is performed after three weeks. Any seropositive animals may be allowed to enter the semen collection centre.

6. Epizootic haemorrhagic disease (EHD, serotype EHD-2): c-ELISA or another OIE recommended or suitable test, with negative result. This test only applies to donor rams/bucks.

**Non negative results**
The standard procedure is to remove immediately from the pre-entry isolation any animal obtaining a positive result to a test mentioned above, except for Border disease serological test.

When a non-negative brucellosis test result is obtained, ancillary testing is conducted by a CFIA laboratory on the same sample; when ancillary testing is positive, the situation must be immediately reported to the local CFIA district office.

With reference to the epidemiology of the disease, appropriate measures are applied to re-establish eligibility of remaining animals in the group for entry in the collection centre.

**Semen collection during pre-entry isolation**
Semen collection is authorized during the pre-entry isolation period. Semen collected during the pre-entry isolation period is not eligible for export; such semen may be released for distribution in Canada. Records for semen collected during pre-entry isolation and distributed must be on file.

**Documentation required**
A document signed by the centre veterinarian must be issued for donor animals and teasers presented for entry in the centre. This document should confirm animals were examined and found free of any clinical sign
of disease before entry in the centre, including bluetongue, and were tested for the diseases mentioned above. The document must include a statement confirming the pre-entry isolation facility has been free of important infectious or contagious disease, including foot and mouth disease (FMD), brucellosis (B. melitensis), ovine epididymitis (B. ovis), anthrax and rabies. The date at which the isolation period started and the date when animals left the isolation facility for transfer in the centre must be mentioned in the document. The official date of entry in a semen collection centre is the date an animal is physically moved from the isolation facility to the semen collection centre, accompanied by appropriate documentation. Copies of tests results must be on file. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

C. Testing programme for rams/bucks and teasers resident in a semen production centre

Rams/bucks and teasers resident in a semen collection centre must be tested at least annually for the following diseases:

1. Brucellosis (B. melitensis) for both sheep and goats: a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result

2. (1) Tuberculosis (M. bovis), for goats only: an intradermal tuberculin test using bovine purified protein derivative (PPD), with negative result at 72 hours.

3. Ovine epididymitis (B. ovis) for sheep and goats: CF test or another OIE recommended or suitable test, with negative result

4. (1) Maedi-visna, for sheep only: ELISA test or another OIE recommended or suitable test, with negative result

5. (1) Caprine arthritis/encephalitis, for goats only: ELISA test or another OIE recommended or suitable test, with negative result

6. Border disease: a serological test (serum neutralisation (SN)); this test is conducted only on animals negative to previous serological tests to confirm absence of antibodies. When a previously negative animal obtains a positive result, the following procedure applies:
   a. The animal is immediately tested using a virus isolation test (immunoperoxidase (IP) or another OIE recommended or suitable test) or a test for virus antigen approved by the OIE, with negative result.
   b. When the virus isolation test or the test for virus antigen above is negative, this seropositive animal is allowed to remain in the centre and is not further serologically tested for Border disease.
   c. When the virus isolation test or the test for virus antigen above is positive, this seropositive animal must immediately leave the centre.

7. Epizootic haemorrhagic disease (EHD, serotype EHD-2): c-ELISA or another OIE recommended or suitable test, with negative result. This test only applies to donor rams/bucks.

Non negative results

When an animal obtain a positive result to a serological test mentioned above, including border disease, this animal is immediately placed into isolation within the centre and semen collection is stopped. All semen from this animal collected from the last negative test result is put on hold for distribution. The failed test is repeated for confirmation and/or additional tests may be performed. Concerning Border disease, refer to the testing procedure mentioned above. If the animal is confirmed negative, including Border disease, the animal may return to semen production and semen on hold is released for distribution. If the animal is confirmed positive, including Border disease, the animal must leave the centre and semen on hold is removed from export storage and disposed of without any compensation.

Transfer between centres

Animals may be transferred directly from a semen collection centre to another centre of equivalent health status without isolation or testing, provided that annual testing regime has been carried out on the animal during the 12 months prior to the date of transfer. The transferred animal must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and transport vehicle must have been cleaned and disinfected before use. The animal must be accompanied by a health certificate confirming their health status, including dates of last tests carried out on the animal. A template document for transfer between centres is available in an annex to this document.
Testing records
All testing records must be maintained by the centre veterinarian for any animal admitted in the centre. Any records must be presented to the CFIA on request.

Seasonal small ruminant semen collection centres
The EU requires a minimal waiting period for post collection testing (reference EHD) or requires post-collection testing for other diseases than those mentioned above, such as bluetongue; refer to section D below.

D. Additional tests or conditions required for donor rams/bucks whose semen is exported to the EU
Testing programme mentioned above in “C. Testing programme for rams/bucks and teasers resident in an EU approved semen production centre” provides donor animals with eligibility to export semen to the EU. But supplementary testing applies to donor rams/bucks whose semen is exported to the EU, as follows:

1. Bluetongue: please refer to Commission Decision 2010/472/EU, as lastly amended, EUR-Lex - 02010D0472-20150101 - EN - EUR-Lex for possible options, either consideration of the seasonally free period in a seasonally free zone or serological or agent identification testing in order to qualify the semen for export to the EU. These options are similar to those mentioned in the OIE Code chapter on Bluetongue.

2. Epizootic haemorrhagic disease (EHD): please refer to Commission Decision 2010/472/EU, as lastly amended, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02010D0472-20150101 for other possible options to qualify semen for export to the EU. EHD serological testing conducted during pre-entry isolation and annually during residence in centre qualifies semen to be exported to the EU, as far as a post-collection test is conducted at least 21 days after the collection of semen exported to the EU.

3. Scrapie: Rams/bucks whose semen is exported to the EU must meet specific conditions concerning scrapie. Rams/bucks must have been kept continuously for the last 3 years before the collection of semen to be exported in a holding or holdings which have been complying for at least 3 years with requirements mentioned in Regulation (EC) No 999/2001, Annex VIII, Chapter A, Section A, points 1.3 (a) to (f). Refer to annex Scrapie to qualify herd/flock for centres to export to the EU attached to this document. An alternative is offered for sheep only, where animals are genotype tested and confirmed to be animals of ARR/ARR prion protein genotype.

Centres are responsible to have donor rams/bucks whose semen is exported to the EU to organise appropriate testing of donor animals before, during and after collection of semen in order to qualify the semen for export to the EU.

(1) Tuberculosis, Maedi-Visna and CAE tests are not required by the EU. These diseases are included here to allow small ruminant semen collection centres approved for EU to also qualify for export to other destinations than EU, as per section 2. “Small ruminant semen collection centres approved for export purposes other than European Union.”
SECTION 3 - BISON SEMEN PRODUCTION CENTRES

1 Bison semen production centres approved for distribution in Canada and export purposes other than European Union

Introduction
The Artificial Insemination Program (AIP) allows for the collection, processing, storage and distribution of bison semen within Canada and internationally, when export conditions specified by destination countries are met. The purpose is to maintain an official sanitary control on collection centres for semen distributed in Canada and allow international distribution of semen with negligible risk for pathogens transmissible by semen.

References
References for diagnostic tests of diseases mentioned in this section are included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2016. Diagnostic tests should be performed either in CFIA or CFIA approved laboratories.

“Owner use only” semen procedure
Apart from the Artificial Insemination Program mentioned here, an owner may want to have his bull collected and semen processed allowing him to use frozen semen to conduct breeding operations on his own animals. As ruminant semen collection is regulated in Canada and a permit is mandatory to collect semen from a ruminant, even for personal use by the owner, a bison owner may want to use the “Owner use only” semen procedure for this purpose. The “Owner use only” semen procedure is not included in the Artificial Insemination Program and semen collected using this procedure is not authorized for distribution in Canada and not eligible for export. The permission delivered to collect “Owner use only” semen is not related to the permit issued to a semen collection centre approved under the Artificial Insemination program. Please refer to annex “Owner use only” semen procedure attached to this document.

Sampling of animals
Sampling of animals is under the responsibility of private veterinarians accredited by the CFIA, who are authorized to examine and request appropriate testing for animals enrolled in the Artificial Insemination Program. This includes sampling of selected animals during the isolation facility located on farm.

Conditions applicable to bulls
Bulls are allowed to enter and reside in a semen collection facility approved for distribution in Canada and export purposes other than the European Union when they fulfill all conditions mentioned below. Test results should be negative.

Approval by the CFIA of an isolation facility located on a farm
An isolation facility located on farm must be inspected and approved by a CFIA veterinarian. Isolation facility in this case is defined as an area on a farm where animals selected for semen collection are maintained isolated from other animals present on the farm. This isolation facility may be located in a barn where other animals are housed. Isolated animals must not have direct or fence line contact with other animals of different status. Inspection and approval of the facility must be done before animals are placed in isolation. Following inspection, the local CFIA district office confirms approval of the isolation facility by issuing a “Permit to collect ruminant semen” to the owner of the facility. A copy of the permit is kept on file at the district office. A specimen of such permit is included in an annex to this document.

A. Prior to entering the isolation facility
1. Bulls must comply with the following conditions:
   1. Qualification of the isolation facility:
     a. The isolation facility must meet the requirements mentioned above before use.
   2. Qualification of the herd:
     a. No quarantine measures imposed on the herd
     b. Herd tested free of Brucellosis (B. abortus) as per current Canadian standard
     c. Herd tested free of tuberculosis as per current Canadian standard
     d. General inspection of the herd confirming absence of diseases that may be transmitted by semen
   3. Qualification of bulls:
     a. Identified according to the national standards for the species
4. Clinical examination for selected bulls:
   a. An accredited veterinarian must examine each animal, find it healthy and free of evidence of infectious or contagious diseases.

2. No test is required from bulls before placing them in the isolation facility of an approved semen collection centre.

**Documentation required**
A document signed by an accredited veterinarian must be available for all bulls presented to the isolation facility. This document should confirm conditions mentioned above are respected, including approval of the isolation facility by the CFIA. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

**Control of animals arriving to the isolation facility**
The centre veterinarian should be provided with the document signed by the accredited veterinarian for all animals presented to the isolation facility located on farm. This document must be kept on file with the permit issued by the local CFIA district office. The centre veterinarian is responsible to make appropriate verification on all bulls presented for entry in the isolation facility. This includes, but not limited to, identification checks, verification of all identifiers present on animals, verification of documentation presented and clinical examination of animals. The centre veterinarian makes the final decision concerning the approval or refusal of admission for each animal presented for entry in the isolation facility and is responsible for maintenance of appropriate records. The isolation period only begins when animals are on site and admitted into isolation by the centre veterinarian, this date must be recorded and used to start the isolation period.

**B. Testing in the isolation facility**
Bulls must be kept for at least 28 days in on-farm isolation facility and tested as mentioned below. Serological testing may commence after a minimum of 21 days in pre-entry isolation. Tests for *Campylobacter fetus* subsp. *venerealis* and *Tritrichomonas foetus* may commence after a minimum of 7 days in pre-entry isolation. All results must be negative.

1. Brucellosis (*B. abortus*): a fluorescence polarization assay (FPA) or another OIE approved test, with negative result

2. Tuberculosis (*M. bovis*): an intradermal tuberculin test using bovine purified protein derivative (PPD), with negative result.

3. *Campylobacter fetus* subsp *venerealis*: a monoclonal antibody-based capture ELISA test on a preputial washing sample, with negative result. When a positive ELISA result is obtained, the preputial washing sample is subject to a culture test, with negative result.
   a. Animals less than 6 months old or kept since that age only in single sex group prior to pre-entry isolation are tested once on a preputial sample, with negative result.
   b. Animals aged 6 months or older that could have had contact with females prior to pre-entry isolation are tested three times at weekly intervals on a preputial sample, with negative result in each case.

4. *Tritrichomonas foetus*: an agent identification by culture and direct identification, with negative result.
   a. Animals less than 6 months old or kept since that age only in single sex group prior to pre-entry isolation are tested once on a preputial specimen, with negative result.
   b. Animals aged 6 months or older that could have had contact with females prior to pre-entry isolation are tested three times at weekly intervals on a preputial specimen, with negative result in each case.

**Test results**
After reception of test results, negative animals are maintained in the isolation facility on the farm which becomes a bison semen production centre. If there is a non-negative test result for an animal in isolation, this animal is removed from the isolation facility. With reference to the epidemiology of the disease, appropriate measures are applied to confirm eligibility of remaining animals in the group. Copy of test results must be maintained on file.
Documentation required
A document signed by the centre veterinarian must be issued for donor animals presented for entry in the centre. This document should confirm animals were examined and found free of any clinical sign of disease before entry in the centre and were tested for the diseases mentioned above. The date at which the isolation period started and the date when animals left the isolation facility for transfer in the centre must be mentioned in the document. The official date of entry in a semen collection centre is the date an animal is physically moved from the isolation facility to the semen collection centre, accompanied by appropriate documentation. Copies of tests results must be on file. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

Semen collection during the isolation period
Semen is collected by the centre veterinarian or under his responsibility. Semen collection is authorized during the isolation period. Semen collected during the minimal 28 days isolation period and until test results are returned negative is restricted from distribution. When results are negative all semen collected is eligible for distribution in Canada and export purposes. Records for semen collected and distributed must be on file.

Semen processing
Collected semen is processed according to the program and stored. An approved mobile laboratory which has been granted a “Permit to operate an animal semen production centre” may be used to process the semen or the semen may be transferred to an approved fixed laboratory for processing. The centre veterinarian is responsible for semen processing and identification.

Documentation required for collected semen
The centre veterinarian must maintain records for all semen collected, including identity of semen donors, collection date and any other information requested by the program.

Release of animals from isolation/centre
When semen collection is over, donor animals are released from isolation by the centre veterinarian. Release date along with identification of animals must be recorded and placed on file. The centre veterinarian is responsible to maintain all records concerning donor animals and semen and insure frozen semen is stored in an approved storage area according to the program.

C. Additional tests for donor bulls
The testing programme mentioned above may not meet all conditions imposed by destination countries. Centres are responsible to have donor bulls tested to ensuring they meet export conditions when semen is considered for export to a specific destination country. One of the diseases that may be considered by destination countries is bluetongue; please refer to the following paragraph.

1. Bluetongue: refer to the OIE Code chapter on Bluetongue where recommendations for testing are mentioned. Post-collection testing may be required. In some instances, a bluetongue seasonally free period in a bluetongue seasonally free zone may apply.

2. If donor bulls are maintained in the isolation facility for a period of more than 12 months, they should be retested for tuberculosis and brucellosis every 12 months.
SECTION 4 - CERVID SEMEN PRODUCTION CENTRES

Note: The same procedures described below for cervid may also apply to other wild ruminant animals raised in captivity.

1 Cervid semen production centres approved for distribution in Canada and export purposes other than European Union

Introduction
The Artificial Insemination Program (AIP) allows for the collection, processing, storage and distribution of cervid semen within Canada and internationally, when export conditions specified by destination countries are met. The purpose is to maintain an official sanitary control on collection centres for semen distributed in Canada and allow international distribution of semen with negligible risk for pathogens transmissible by semen.

References
References for diagnostic tests of diseases mentioned in this section are included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2016. Diagnostic tests should be performed either in CFIA or CFIA approved laboratories.

“Owner use only” semen procedure
Apart from the Artificial Insemination Program mentioned here, an owner may want to have his male animal collected and semen processed allowing him to use frozen semen to conduct breeding operations on his own animals. As ruminant semen collection is regulated in Canada and a permit is mandatory to collect semen from a ruminant, even for personal use by the owner, a cervid owner may want to use the “Owner use only” semen procedure for this purpose. The “Owner use only” semen procedure is not included in the Artificial Insemination Program and semen collected using this procedure is not authorized for distribution in Canada and not eligible for export. The permission delivered to collect “Owner use only” semen is not related to the permit issued to a semen collection centre approved under the Artificial Insemination program. Please refer to annex “Owner use only” semen procedure attached to this document.

Sampling of animals
Sampling of animals is under the responsibility of private veterinarians accredited by the CFIA, who are authorized to examine and request appropriate testing for animals enrolled in the Artificial Insemination Program. This includes sampling of selected animals during the isolation facility located on farm.

Conditions applicable to male animals
Male animals are allowed to enter and reside in a semen collection facility approved for distribution in Canada and export purposes other than the European Union when they fulfill all conditions mentioned below. Test results should be negative.

Approval by the CFIA of an isolation facility located on a farm
An isolation facility located on farm must be inspected and approved by a CFIA veterinarian. Isolation facility in this case is defined as an area on a farm where animals selected for semen collection are maintained isolated from other animals present on the farm. This isolation facility may be located in a barn where other animals are housed. Isolated animals must not have direct or fence line contact with other animals of different status. Inspection and approval of the facility must be done before animals are placed in isolation. Following inspection, the local CFIA district office confirms approval of the isolation facility by issuing a “Permit to collect ruminant semen” to the owner of the facility. A copy of the permit is kept on file at the district office. A specimen of such permit is included in an annex to this document.

A. Prior to entering the isolation facility
1. Male animals must comply with the following conditions:
   1. Qualification of the isolation facility:
      a. The isolation facility must meet the requirements mentioned above before use.
   2. Qualification of the herd:
      a. No quarantine measures imposed on the herd
      b. Herd tested free of Brucellosis (B. abortus) as per current Canadian standard
      c. Herd tested free of tuberculosis as per current Canadian standard
      d. General inspection of the herd confirming absence of diseases that may be transmitted by semen
3. Qualification of male animals:
   a. Identified according to the national standards for the species
4. Clinical examination for selected male animals:
   a. An accredited veterinarian must examine each animal, find it healthy and free of evidence of infectious or contagious diseases.

2. No test is required from male animals before placing them in the isolation facility of an approved semen collection centre.

**Documentation required**
A document signed by an accredited veterinarian must be available for all male animals presented to the isolation facility. This document should confirm conditions mentioned above are respected, including approval of the isolation facility by the CFIA. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

**Control of animals arriving to the isolation facility**
The centre veterinarian should be provided with the document signed by the accredited veterinarian for all animals presented to the isolation facility located on farm. This document must be kept on file with the permit issued by the local CFIA district office. The centre veterinarian is responsible to make appropriate verification on all male animals presented for entry in the isolation facility. This includes, but not limited to, identification checks, verification of all identifiers present on animals, verification of documentation presented and clinical examination of animals. The centre veterinarian makes the final decision concerning the approval or refusal of admission for each animal presented for entry in the isolation facility and is responsible for maintenance of appropriate records. The isolation period only begins when animals are on site and admitted into isolation by the centre veterinarian, this date must be recorded and used to start the isolation period.

**B. Testing in the isolation facility**
Male animals must be kept for at least 28 days in the on-farm isolation facility and tested as mentioned below. Serological testing may commence after a minimum of 21 days in isolation. All results must be negative.

1. Brucellosis (*B. abortus*): a fluorescence polarization assay (FPA) or another OIE approved test, with negative result
2. Tuberculosis (*M. bovis*): an intradermal tuberculin test using bovine purified protein derivative (PPD), with negative result.

**Test results**
After reception of test results, negative animals are maintained in the isolation facility on the farm which becomes a cervid semen production centre. If there is a non-negative test result for an animal in isolation, this animal is removed from the isolation facility. With reference to the epidemiology of the disease, appropriate measures are applied to confirm eligibility of remaining animals in the group. Copy of test results must be maintained on file.

**Documentation required**
A document signed by the centre veterinarian must be issued for donor animals presented for entry in the centre. This document should confirm animals were examined and found free of any clinical sign of disease before entry in the centre and were tested for the diseases mentioned above. The date at which the isolation period started and the date when animals left the isolation facility for transfer in the centre must be mentioned in the document. The official date of entry in a semen collection centre is the date an animal is physically moved from the isolation facility to the semen collection centre, accompanied by appropriate documentation. Copies of tests results must be on file. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

**Semen collection during the isolation period**
Semen is collected by the centre veterinarian or under his responsibility. Semen collection is authorized during the isolation period. Semen collected during the isolation period and until test results are returned negative is restricted from distribution. When results are negative, all semen collected during isolation becomes eligible for distribution in Canada and export purposes. Records for semen collected and distributed must be on file.
Semen processing
Collected semen is processed according to the program and stored. An approved mobile laboratory which has been granted a “Permit to operate an animal semen production centre” may be used to process the semen or the semen may be transferred to an approved fixed laboratory for processing. The centre veterinarian is responsible for semen processing and identification.

Documentation required for collected semen
The centre veterinarian must maintain records for all semen collected, including identity of semen donors, collection date and any other information requested by the program.

Release of animals from isolation/centre
When semen collection is over, donor animals are released from isolation by the centre veterinarian. Release date along with identification of animals must be recorded and placed on file. The centre veterinarian is responsible to maintain all records concerning donor animals and semen and insure frozen semen is stored in an approved storage area according to the program.

C. Additional tests for donor male animals
The testing programme mentioned above may not meet all conditions imposed by destination countries. Centres are responsible to have donor animals tested to ensuring they meet export conditions when semen is considered for export to a specific destination country. One of the diseases that may be considered by destination countries is bluetongue; please refer to the following paragraph.

1. Bluetongue: refer to the OIE Code chapter on Bluetongue where recommendations for testing are mentioned. Post-collection testing may be required. In some instances, a bluetongue seasonally free period in a bluetongue seasonally free zone may apply.

2. If donor bulls are maintained in the isolation facility for a period of more than 12 months, they should be retested for tuberculosis and brucellosis every 12 months.
SECTION 5 - PORCINE SEMEN PRODUCTION CENTRES

1. Porcine semen production centres approved for distribution in Canada

Introduction
The porcine Artificial Insemination Program (AIP) allows for the collection, processing, storage and distribution of porcine semen within Canada.

Conditions applicable to boars
Boars are allowed to enter and reside in a porcine semen collection centre approved for distribution in Canada when they fulfill conditions mentioned below.

A. Prior to entering the pre-entry isolation facility
   1. Boars must comply with the following conditions:
      a. Qualification of the herd:
         i. no quarantine measures imposed on the herd.
         ii. herd considered free of brucellosis (\textit{B. suis})
         iii. herd considered free of Aujeszky's disease
      2. Qualification of boars:
         a. identified according to the national standards for the species
      3. Clinical examination of selected boars:
         a. within 30 days prior to arrival to the pre-entry isolation facility, an accredited veterinarian must examine each animal, find it healthy and free of evidence of infectious or contagious diseases transmissible by semen.

   2. No test is required from boars before placing them in the isolation facility of an approved semen collection centre.

Documentation required
A document signed by an accredited veterinarian must be available for all boars presented to the pre-entry isolation facility. This document should confirm conditions mentioned above are respected. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

Boars imported in Canada and destined to a semen collection centre
When a boar is imported to Canada and released from post-import quarantine, the animal may proceed directly to the pre-entry isolation facility. The required documentation mentioned above should be based on available import certificate documents and information on the herd of origin gathered by an accredited veterinarian.

Control of animals arriving to the pre-entry isolation facility
The centre veterinarian is responsible to make appropriate verification for all boars presented to the pre-entry isolation facility. This includes, but not limited to, identification checks and verification of all identifiers placed on boars, verification of documentation presented and clinical examination of animals at time of admission in isolation. The centre veterinarian makes the final decision concerning the approval or refusal of admission for each animal presented for entry in the isolation facility and is responsible for maintenance of appropriate records. Centres may impose higher sanitary conditions. Isolation period only begins when all animals are on site and admitted into isolation by the centre veterinarian. The date at which isolation begins must be recorded and used for reference. Pre-entry isolation is an all in-all out procedure.

B. Testing in the pre-entry isolation facility prior to entering the semen production centre
Boars must be kept for at least 14 days in a pre-entry isolation facility of porcine semen collection centre.

Documentation required
A document signed by the centre veterinarian must be issued for boars presented for entry in the centre. This document should confirm animals were examined and found free of any clinical sign of disease immediately before entry in the centre. The date the isolation period started and the date animals leave the isolation facility for transfer in the centre must appear on the document. The official date of entry in a semen collection centre is the date an animal is physically moved from the isolation facility to the semen collection centre,
accompanied by appropriate documentation. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

C. Testing programme for boars resident in a semen production centre

Boars resident in a semen collection centre for distribution in Canada are not subjected to further testing during their stay in the semen collection centre.

Transfer between centres

A boar may be transferred from a semen collection centre to another centre of equivalent health status following conditions decided between both centre veterinarians. At the minimum the transferred boar must not come into direct or indirect contact with cloven-hoofed animals of lower health status and transport vehicle must have been cleaned and disinfected before use. The boar must be accompanied by a health certificate confirming their health status. This document is developed by the centre veterinarian.
2. Porcine semen production centres approved for export purposes other than European Union

Introduction
The porcine Artificial Insemination Program (AIP) allows for the collection, processing, storage and distribution of porcine semen internationally, when export conditions specified by destination countries are met. This section meets the standards of the World Organisation for Animal Health (OIE), an international reference standard. The purpose is to maintain official sanitary control over collection centres and allow international distribution of semen with negligible risk of pathogen transmission.

References
Reference for testing of boars is included in Chapter 4.6 “Collection and processing of bovine, small ruminant and porcine semen” of the OIE Terrestrial Animal Health Code. As mentioned in the OIE Code, testing for diseases Canada is free, such as foot-and-mouth disease, African swine fever and classical swine fever, is not required. Testing for Aujeszky’s disease and brucellosis is included in the program though they are not present in Canada.

References for diagnostic tests of diseases mentioned in this section are included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Diagnostic tests should be performed either in a CFIA or CFIA approved laboratory.

Porcine semen collection centres approved for export purposes other than European Union (EU) also qualify for distribution of porcine semen in Canada.

Sampling of animals
Sampling of animals is under the responsibility of private veterinarians accredited by the CFIA and authorized to examine and request appropriate testing of boars enrolled in the porcine AIP. This includes taking samples from selected animals before entering the pre-entry isolation facility of a semen collection centre, in the pre-entry isolation facility and during residence of animals in the centre.

Conditions applicable to testing of boars
Boars are allowed to enter and reside in a porcine semen collection facility approved for export purposes other than the EU when they fulfill all conditions mentioned below. Test results must be negative.

A. Prior to entering the pre-entry isolation facility
1. Boars must comply with the following conditions:
   1. Qualification of the herd:
      a. no quarantine measures imposed on the herd.
      b. herd considered free of brucellosis (B. suis)
      c. herd considered free of Aujeszky's disease
      d. no case of TGE reported in the herd for the last 12 months.
   2. Qualification of the animal:
      a. identified according to the national standards for the species
   3. Clinical examination of selected boars:
      a. within 30 days prior to arrival to the pre-entry isolation facility, an accredited veterinarian must examine each animal, find it healthy and free of evidence of infectious or contagious diseases transmissible by semen.

2. Boars must be tested for the following diseases within 30 days prior to arrival to the pre-entry isolation facility of an approved semen collection centre:
   1. Brucellosis (B. suis): a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result
   2. Transmissible gastroenteritis (TGE): ELISA test, or another OIE recommended or suitable test, with negative result
   3. Aujeszky's disease: ELISA test or another OIE recommended or suitable test, with negative result
4. Porcine reproductive and respiratory syndrome (PRRS): ELISA test, or another OIE recommended or suitable test, with negative result

**Documentation required**
A document signed by an accredited veterinarian must be available for all boars presented to the pre-entry isolation facility. This document should confirm conditions mentioned above are respected and appropriate testing done; copies of tests results must be provided. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

**Boars imported in Canada and destined to a semen collection centre**
When a boar is imported to Canada and submitted to a post-import quarantine, the procedure described above, including testing, may only begin when the boar is released from quarantine. Disease testing done for import purposes may be used to qualify a boar to enter in the pre-entry isolation facility as far as the 30 days testing period is respected. The required documentation mentioned above should be based on available import certificate document and information on the herd of origin gathered by an accredited veterinarian.

**“On farm” testing conducted on the pre-entry isolation facility premises**
Examination and testing of animals selected for entry in a pre-entry isolation facility is usually performed on farms of origin. However it is possible to conduct these activities on the site of the pre-entry isolation facility. Biosecurity measures should then be put in place by the centre veterinarian to maintain integrity of the pre-entry isolation facility when in use. When this option is selected, pre-entry isolation period for these animals cannot begin before all test results are received and confirmed by the centre veterinarian.

**Control of animals arriving to the pre-entry isolation facility**
The centre veterinarian is responsible to make appropriate verification for all boars presented to the pre-entry isolation facility. This includes, but not limited to, identification checks and verification of all identifiers placed on boars, verification of documentation presented and clinical examination of animals at time of admission in isolation. The centre veterinarian makes the final decision concerning the approval or refusal of admission for each animal presented for entry in the isolation facility and is responsible for maintenance of appropriate records. Isolation period only begins when all animals are on site and admitted into isolation by the centre veterinarian. The date at which isolation begins must be recorded and used for reference. Pre-entry isolation is an all in-all out procedure.

**B. Testing in the pre-entry isolation facility prior to entering the semen production centre**
Boars must be kept for at least 30 days in a pre-entry isolation facility of a semen collection centre and tested as mentioned below. Serological testing may begin after a minimal period of 21 days in pre-entry isolation. All boars present in the pre-entry isolation facility must be tested negative for admission in the semen collection centre.

1. Brucellosis (*B. suis*): a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result
2. Transmissible gastroenteritis (TGE): ELISA test, or another OIE recommended or suitable test, with negative result
3. Aujeszky’s disease: ELISA test or another OIE recommended or suitable test, with negative result
4. Porcine reproductive and respiratory syndrome (PRRS): ELISA test, or another OIE recommended or suitable test, with negative result

**Non negative results**
The standard procedure is to remove immediately from the pre-entry isolation any animal obtaining a positive result to a test mentioned above.

When non-negative brucellosis test result is obtained, ancillary testing is conducted by a CFIA laboratory on the same sample; when ancillary testing is positive, the situation must be immediately reported to the local CFIA district office.
Non-negative Aujeszky’s disease test result must be reported immediately to the local CFIA district office. No movement of animals is allowed without CFIA authorization.

When positive PRRS test result is obtained, the boar is removed from the pre-entry isolation and other boars in isolation are retested negative for PRRS at least 14 days after the positive animal had left the facility.

When non-negative TGE test result is obtained, other OIE recommended or suitable test may be conducted. Further to subsequent testing, non-negative boars are removed from pre-entry isolation and other boars in isolation are retested negative for TGE at least 14 days after the non–negative animal had left the facility.

**Documentation required**
A document signed by the centre veterinarian must be issued for boars presented for entry in the centre. This document should confirm animals were examined and found free of any clinical sign of disease immediately before entry in the centre and were tested negative as mentioned above. The date the isolation period started and the date animals leave the isolation facility for transfer in the centre must appear on the document. The official date of entry in a semen collection centre is the date an animal is physically moved from the isolation facility to the semen collection centre, accompanied by appropriate documentation. Copies of tests results must be on file. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

**C. Testing programme for boars resident in a semen production centre**
Boars resident in a semen collection centre must be tested at least annually for the following diseases:

1. Brucellosis (*B. suis*): a fluorescence polarization assay (FPA) or another OIE recommended or suitable test, with negative result

2. Transmissible gastroenteritis (TGE): ELISA test, or another OIE recommended or suitable test, with negative result

3. Aujeszky’s disease: ELISA test or another OIE recommended or suitable test, with negative result

4. Porcine reproductive and respiratory syndrome (PRRS): ELISA test, or another OIE recommended or suitable test, with negative result

**Non negative results**
When a boar obtains a positive or suspicious result to a serological test mentioned above, this animal is immediately placed into isolation within the centre and semen collection stopped for this animal. All semen from this animal collected from the last negative test result is put on hold for distribution.

For brucellosis and Aujeszky’s disease reactors, the local CFIA district office must be contacted; refer to section 2.B above, under “Non-negative results”.

For TGE and PRRS, the failed test is repeated for confirmation of the test result and additional tests may be performed. If the boar is confirmed negative, the animal may return to semen production and semen on hold is released for distribution. If the animal is confirmed positive, the animal must leave the centre and semen on hold is removed from export storage and disposed of without compensation.

**Testing records**
All testing records must be maintained by the centre veterinarian for any animal admitted in the centre. Any records must be presented to the CFIA on request.

**Transfer between centres**
Animals may be transferred directly from a semen collection centre to another centre of equivalent health status without isolation or testing, provided that annual testing regime has been carried out on the boar during the 12 months prior to the date of transfer. The transferred boar must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and transport vehicle must have been cleaned and disinfected before use. The boar must be accompanied by a health certificate confirming their health status, including dates of last tests carried out on the animal. A template document for transfer between centres is available in an annex to this document.
3. Porcine semen production centres approved for export purposes including European Union

Introduction
The European Union (EU) level of the Artificial Insemination Program (AIP) allows for the collection, processing, storage and export of porcine semen to EU members states. This level meets the standards mentioned in Council Directive 90/429/EEC that must be fulfilled to export porcine semen to the EU. Porcine semen collection centres must be approved by the Canadian Food Inspection Agency (CFIA) as per the Council Directive 90/429/EEC and listed on the EU website to be authorized to export porcine semen to the EU. The purpose of Council Directive 90/429/EEC is to maintain an official sanitary control on collection centres for semen exported to the EU.

References
Reference for testing of boars is included in Council Directive 90/429/EEC, as lastly amended. The EU imposes a specific procedure for official approval; a questionnaire and a certificate must be completed by the CFIA and sent to the EU for official approval.

References for diagnostic tests of diseases mentioned in this section are included in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals or prescribed in EU legislation. Diagnostic tests should be performed either in a CFIA or CFIA approved laboratory.

Porcine semen collection centres approved for EU also qualify for distribution in Canada and export destinations other than EU.

Sampling of animals
Sampling of animals is under the responsibility of private veterinarians accredited by the CFIA and authorized to examine and request appropriate testing for animals enrolled in the AIP. This includes taking samples from selected animals before entering the pre-entry isolation facility of a semen collection centre, in the pre-entry isolation facility and during residence of animals in the centre.

Conditions applicable to testing of boars
Boars are allowed to enter and reside in a porcine semen collection centre approved for export to the EU when they fulfill all conditions mentioned below. Test results should be negative.

A. Prior to entering the pre-entry isolation facility
1. Boars must comply with the following conditions:
   1. Qualification of the herd:
      a. no quarantine measures imposed on the herd
      b. herd considered free of brucellosis (B. suis)
      c. Aujeszky’s disease: no clinical, serological, virological or pathological evidence has been detected in the preceding 12 months
      d. no case of TGE reported in the herd for the last 12 months.
   2. Qualification of the animal:
      a. identified according to the national standards for the species
      b. has not been kept previously in a herd that does not qualify as above
   3. Clinical examination of selected boars:
      a. within 30 days prior to arrival to the pre-entry isolation facility, an accredited veterinarian must examine each animal, find it healthy and free of evidence of infectious or contagious diseases transmissible by semen.

2. Boars must be tested for the following diseases within the 30 days before arrival to the pre-entry isolation facility of an EU approved semen collection centre:
   1. Brucellosis (B. suis): an ELISA test, with negative result
      When an animal is positive to the ELISA test, boars with negative results from the same herd must not be admitted in the pre-entry isolation facility until the brucellosis-free status of the herd of origin is confirmed by the CFIA.
2. \(^{(1)}\) Transmissible gastroenteritis (TGE): ELISA test, or another OIE recommended or suitable test with negative result

3. Aujeszky’s disease: ELISA test or another OIE recommended or suitable test, with negative result

4. \(^{(1)}\) Porcine reproductive and respiratory syndrome (PRRS): ELISA test, or another OIE recommended or suitable test, with negative result

Documentation required
A document signed by an accredited veterinarian must be available for all boars presented to the pre-entry isolation facility. This document should confirm conditions mentioned above are respected and appropriate testing done; copies of tests results must be provided. A template document to accompany animals selected on farms to the pre-entry isolation facility is available in an annex to this document.

Boars imported in Canada and destined to an AI centre
When a boar is imported to Canada and submitted to a post-import quarantine, the procedure described above, including testing, may be applied when the boar is released from quarantine. Disease testing done for import purposes may be used to qualify a boar to enter in the pre-entry isolation facility as far as the 30 days testing period is respected. The required documentation mentioned above should be based on available import certificate document and information on the herd of origin gathered by an accredited veterinarian.

“On farm” testing conducted on the pre-entry isolation facility premises
Examination and testing of animals selected for entry in a pre-entry isolation facility is usually performed on farms of origin. However it is possible to conduct these activities on the site of the pre-entry isolation facility. Biosecurity measures should then be put in place by the centre veterinarian to maintain integrity of the pre-entry isolation facility when in use. When this option is selected, pre-entry isolation period for these animals cannot begin before all test results are received and confirmed by the centre veterinarian.

Control of animals arriving to the pre-entry isolation facility
The centre veterinarian is responsible to make appropriate verification for all boars presented for entry in the isolation facility. This includes, but not limited to, identification checks and verification of all identifiers placed on boars, verification of documentation presented and clinical examination of animals at time of admission in isolation. The centre veterinarian makes the final decision concerning the approval or refusal of admission for each animal presented for entry in the isolation facility and is responsible for maintenance of appropriate records. Isolation period only begins when all animals are on site and admitted into isolation by the centre veterinarian. The date at which isolation begins must be recorded and used for reference. The pre-entry isolation is a quarantine procedure, using all-in/all-out method.

B. Testing in the pre-entry isolation facility prior to entering the semen production centre
Boars must be kept for at least 30 days in a pre-entry isolation facility of a semen collection centre and tested as mentioned below. Serological testing may commence after a minimum of 21 days in pre-entry isolation. All boars present in the pre-entry isolation facility must be tested negative for admission in the semen collection centre.

1. Brucellosis (\(B. \textit{suis}\)): an ELISA test, with negative result

2. \(^{(1)}\) Transmissible gastroenteritis (TGE): ELISA test, or another OIE recommended or suitable test with negative result

3. Aujeszky’s disease: ELISA test or another OIE recommended or suitable test, with negative result

4. \(^{(1)}\) Porcine reproductive and respiratory syndrome (PRRS): ELISA test, or another OIE recommended or suitable test, with negative result

Non negative results
The standard procedure is to remove immediately from the pre-entry isolation any animal obtaining a positive result to a test mentioned above.
When a non-negative brucellosis test result is obtained, the situation must be immediately reported to the local CFIA district office. A specific procedure applies as mentioned in Directive 90/429/EEC and an alternative test should be done on the animal.

Non-negative Aujeszky’s disease test result must be reported immediately to the local CFIA district office. No movement of animals is allowed without CFIA authorization.

When positive PRRS test result is obtained, the boar is removed from the pre-entry isolation and other boars in isolation are retested negative for PRRS at least 14 days after the positive animal had left the facility.

When non-negative TGE test result is obtained, other OIE recommended or suitable test may be conducted. Further to subsequent testing, non-negative boars are removed from pre-entry isolation and other boars in isolation are retested negative for TGE at least 14 days after the non–negative animal had left the facility.

**Documentation required**

A document signed by the centre veterinarian must be issued for boars presented for entry in the centre. This document should confirm animals were examined and found free of any clinical sign of disease immediately before entry in the centre and were tested negative as mentioned above. The date the isolation period started and the date animals leave the isolation facility for transfer in the centre must appear on the document. The official date of entry in a semen collection centre is the date an animal is physically moved from the isolation facility to the semen collection centre, accompanied by appropriate documentation. Copies of tests results must be on file. A template document to accompany animals from the pre-entry isolation facility to the semen production centre is available in an annex to this document.

**C. Testing programme for boars resident in a semen production centre**

Boars resident in a semen collection centre must be tested at least annually for the following diseases. All boars leaving the centre before being included in a first annual testing must be tested for brucellosis and Aujeszky’s disease before they leave the centre.

1. Brucellosis (*B. suis*): an ELISA test, with negative result
2.  
   (1) Transmissible gastroenteritis (TGE): ELISA test, or another OIE recommended or suitable test with negative result
3. Aujeszky’s disease: ELISA test or another OIE recommended or suitable test, with negative result
4.  
   (1) Porcine reproductive and respiratory syndrome (PRRS): ELISA test, or another OIE recommended or suitable test, with negative result

**Non negative results**

When a boar obtains a positive or suspicious result to a serological test mentioned above, this animal is immediately placed into isolation within the centre and semen collection stopped for this animal. All semen from this animal collected from the last negative test result is put on hold for distribution.

For brucellosis and Aujeszky’s disease reactors, the local CFIA district office must be contacted; refer to section 3.8 above, under “Non-negative results”. In the case of brucellosis and Aujeszky’s disease, semen collected from other boars in the semen collection centre since the date of the last negative test of the positive animal is put on hold for export to the EU until the health status of the centre has been reconfirmed.

For TGE and PRRS, the failed test is repeated for confirmation of the test result and additional tests may be performed. If the animal is confirmed negative, the animal may return to semen production and semen on hold is released for distribution. If the animal is confirmed positive, the animal must leave the centre and semen on hold is removed from export storage and disposed of without compensation.

**Testing records**

All testing records must be maintained by the centre veterinarian for animals admitted in the centre. Any records must be presented to the CFIA on request.
**Transfer between centres**

Animals may be transferred directly from a semen collection centre to another centre of equivalent health status without isolation or testing, provided that an annual testing regime has been carried out on the boar during the 12 months prior to the date of transfer. The transferred boar must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and transport vehicle must have been cleaned and disinfected before use. The boar must be accompanied by a health certificate confirming their health status, including dates of last tests carried out on the animal. A template document for transfer between centres is available in an annex to this document.

(1) TGE and PRRS tests are not required by the EU. These diseases are included here to allow porcine semen collection centres approved for EU to also qualify for export to other destinations than EU, as per section 2. “Porcine semen collection centres approved for export purposes other than European Union”.
List of Annexes

These annexes are documents attached to the Artificial Insemination program to provide guidance to centre veterinarians and help them fulfil the requirements of the program. The centre veterinarian may use other documents than those proposed but essential information must be available. References to these annexes are mentioned in the Artificial Insemination document in sections where these annexes apply.

These documents are listed below:

Annex “Owner use only” semen procedure

Annex “Permit to operate an animal semen production centre” (new permit)

Annex “Permit to collect ruminant semen” (rdims 9196132)

Annex Documents to accompany animals selected on farms to the pre-entry isolation facility
  (ACIA/CFIA 1634 PDF fillable rdims 5538164 + Supplementary declaration PDF fillable rdims 5537793, both to be modified)

Annex Document to accompany animals from the pre-entry isolation facility to the semen production centre
  (Isolation worksheet & Authorization release PDF fillable, rdims 5538418, to be modified)

Annex Document confirming approval of on-farm isolation facility and qualification of small ruminant animals moved to isolation facility for semen collection purposes
  (ACIA/CFIA 1634 PDF fillable rdims 5538164 + Supplementary declaration PDF fillable rdims 5537793, both to be modified)

Annex Scrapie to qualify herd/flock concerning scrapie for centres to export to the EU (rdims 9226368)

Annex Document to transfer a resident animal to another centre
  (ACIA/CFIA 1634 PDF fillable rdims 5538164)
Annex “Owner use only” semen procedure

“Owner use only” Semen Procedure
This “Owner use only” procedure is not part of the Artificial Insemination program; this is a procedure created to accommodate a breeder who wants to have some semen collected from his own animal. This procedure applies mainly to cattle but may also be used for sheep, goats, cervid and bison.

General information
“Owner use only” semen must only be collected and processed by a person or an organisation to whom is issued a Permit to collect and process animal semen for Owner use only. This module applies to semen collected from a donor for the use by the owner of the animal in his herd. The semen straws must be labelled with the appellation “Owner use only” along with the name of the owner of the animal at the time of the semen collection. When there is multi-ownership of the animal, the name of only one owner must be placed on each straw. A semen collection may be split between different owners of the same donor animal, but only the owner whose name has been placed on the straw can use it. This module does not apply to semen being collected for the purpose of evaluating the fertility of a donor and that is not intended to be used in a female.

Restrictions of “Owner use only” semen
“Owner use only” semen must be used by the owner identified on the straws. As this procedure is an exception to the Artificial Insemination program, this semen is restricted for use and cannot be traded, given away, sold or disposed of by the owner, except by destruction. When a herd is sold or dispersed, owner use semen may be kept on the premises for future use by the owner or destroyed. When a herd changes ownership and remains on the same premises, the semen can be used by the new owner of the herd on these premises only. The semen must never leave the premises.

Permit
A Permit to collect and process animal semen for Owner use only must be issued by the National Coordinator of the Artificial Insemination program. This permit is issued under section 115 of Health of Animals Regulations and is only valid for the specific purpose of collecting semen to be used by the owner. The permit identifies the permit holder, bears a unique registered permit number of the format “X-OWS-XX” and shows an expiry date. Semen can be collected only during the validity period of the permit.

Permit issuance
The role of the district office is to provide appropriate information about the permit and conditions and monitor applications. A copy of this annex should be provided to the applicant. A permit application form must be completed by the applicant and sent to the local CFIA district office for review. The laboratory where owner use semen is intended to be processed must be identified and approved by the district office as an issuance condition (see below). After review and recommendation the district office forwards the application to the appropriate Operations level for approval or refusal. If approved, the application is then sent to the National Coordinator of the Artificial Insemination program who will issue the permit. The original of the permit is returned by mail to the district office for delivery to the permit holder. The district office should also provide the following documents to the permit holder: document Model Template Information Record for Owner use only semen collection and distribution and document Conditions of use of semen labelled “Owner use only”. If application is not approved, the CFIA should outline the reasons for approval being denied.

Laboratory approval
The laboratory where owner use semen is intended to be processed can be either fixed or mobile. It must be identified on the application form and inspected by the district office to further process the application. When the laboratory is already approved to process semen according to a Permit to operate an animal semen production centre delivered under the Artificial Insemination program, the district office must approve the procedures which are to be used for owner use semen in order to prevent any semen contamination. In all other cases the applicant should be knowledgeable about industry standards concerning semen processing and the laboratory confirmed to have appropriate equipment and material to process, freeze and store semen. Information about semen extender and antibiotics to be used should be obtained and procedures to properly identify semen straws as per this procedure reviewed with the applicant.

Collection premises
There is no collection premises approval required to collect “Owner use only” semen. Owner use semen can be collected at any location deemed satisfactory to the permit holder. Owner use semen may be collected from
animals during isolation procedures done at an animal semen production centre under the conditions specified by the Artificial Insemination program.

Except for the situation mentioned above, collection premises for owner use semen must not be located on the grounds of an animal semen production centre approved for export purposes. The collection premises may be located on the grounds of an animal semen production centre approved for distribution in Canada, but in a location separate from regular collection operations and housing. A clear separation must be present with no potential contact with resident animals in the animal semen production centre.

Donor testing
There is no test required on donor animals collected for “Owner use only” semen.

Gathering of information by the permit holder before collection
The permit holder is responsible for the verification of the identification of the donor animal and identification of owner(s). They must identify the owner(s), obtain a written confirmation concerning the ownership of the donor animal and confirm which owner name will appear on straws. They must also identify the donor animal and, in advance of the collection, provide appropriate information to the owner about restrictions on the use of semen. This information must be kept on file and made available to CFIA upon request. A model template form is provided by CFIA.

Semen collection
The permit holder must take appropriate measures during collection procedures to avoid contamination of the semen. Appropriate equipment and material should be used. Semen should be collected in cleaned and disinfected containers and the integrity of the ejaculate should be preserved until processing of the semen.

Semen processing
The semen must be processed in a laboratory approved by the district office for this purpose. Appropriate equipment and material to process and freeze semen should be used. Semen should be diluted in sterile containers and appropriate antibiotic mixture must be added to the semen or the extender to meet industry standards. Before freezing, straws must be properly labelled as mentioned below.

Semen identification
Every straw of semen must be clearly identified with the words “Owner use only”. The name of the owner (or one of the owners) of the donor at the time of collection (see above in “General information” paragraph concerning multi-ownership) must also be mentioned on each straw; no code is permitted. The identification of the donor bull (full name and registration number (if available), the breed of the donor bull, the permit number of the person or organisation who collects and processes the semen and the date of semen collection must also clearly appear on each semen straw. It is strongly suggested that these mandatory information be placed on straws in the order mentioned above; alternate order is acceptable as long as all required information is present on straws.

Semen distribution
Semen labelled “Owner use only” must be released only to the owner whose name is mentioned on semen straws. When semen is released, an information document provided by CFIA describing restrictions concerning usage of owner use semen must be completed by the permit holder with the details required. The owner should sign the document, keep the original and a copy must be put on file by the permit holder. The number of straws released to the owner must be recorded.

Semen storage
Semen labelled “Owner use only” must be stored solely either at the farm of the owner of the bull whose name is labelled on the straws or at a CFIA approved storage centre. In a CFIA approved storage centre, owner use semen must not be stored in the same container as semen intended for distribution in Canada or in rooms dedicated to the storage of semen for export. A permit holder is allowed to store owner use semen collected on the behalf of owners as far the permit has not expired; when such storage occurs, an inventory of stored semen must be maintained by the permit holder. If the permit expires and is not renewed, the semen must be distributed to the owner identified on straws.

Semen collection records
Section 119.(2) of Health of Animals Regulations requires that every person or organization who collects, stores or distributes animal semen must keep and make available to a CFIA inspector records of dates of collection, number of semen straws produced and distribution of semen. Records must also contain identification of donor.
animals (full name and registration number) and identification of the owner of the donor animal mentioned on straws. A model template form is provided by CFIA. As per section 119 (3) of Health of Animals Regulations, these records must be kept for a minimum period of seven years following distribution of semen.

**Inspection**

An inspection must be conducted by the district office and is conditional to the renewal of the Permit to collect and process animal semen for Owner use only. This inspection should be conducted near the end of the validity of the permit at the discretion of the district office. The district office must inspect the laboratory where the semen is processed, audit the procedures followed by the permit holder concerning the processing of semen, verify straw identification, inspect semen storage if any, and verify semen collection records. A copy of the document Model Template Information Record for Owner use only semen collection and distribution, or same information provided in another format should be obtained for all collections performed during the validity period of the permit for traceability purposes.

**Renewal of permit**

Renewal of the permit is conditional to the inspection by the district office as mentioned above. When the district office is satisfied with inspection results, the same procedure as mentioned in the paragraph “Permit issuance” above is followed: a new application is completed and sent to the district office for review, the district office forwards the recommended application to the appropriate Operations level to approve permit renewal. The application is then sent to the National Coordinator of the Artificial Insemination program to renew the permit for another period. The new permit is returned to the district office for distribution to the permit holder. When the district office is not satisfied with inspection results, the request to renew the permit can be denied. An appropriate report should then be sent to appropriate Operations level to review and confirm or refute the district office decision. If the renewal is not approved, the CFIA should outline the reasons for approval being denied.

Documents for application of the “Owner use only” semen procedure:
1. Application form to obtain a permit to collect and process animal semen for Owner use only (rdims 2535002)
2. Model Template Information Record for Owner use only semen collection and distribution rdims 9226370
3. Conditions of use of semen labelled “Owner use only” (information document) rdims 9226371
Annex “Permit to operate an animal semen production centre” (new permit)
### Annex “Permit to collect ruminant semen”  
(RDIMS 9196132)

<table>
<thead>
<tr>
<th>PERMIT TO COLLECT RUMINANT SEMEN</th>
<th>PERMIS POUR PRÉLEVER DU SPERME DE RUMINANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health of Animals Act</td>
<td>Loi sur la santé des animaux</td>
</tr>
<tr>
<td>Permit no. / N° de permis</td>
<td>Issue date / Date d’émission</td>
</tr>
<tr>
<td></td>
<td>(yyyy-mm-dd / aaaa-mm-jj)</td>
</tr>
</tbody>
</table>

This permit is issued pursuant to Section 115 of the Health of Animals Regulations for the operation of premises on which semen will be collected. The permit holder must comply with the conditions of the species selected below as mentioned in the Artificial Insemination program.

Ce permis est émis en vertu du paragraphe 115 du Règlement sur la santé des animaux autorisant la collecte de sperme dans un lieu. Le titulaire de ce permis doit satisfaire aux conditions du Programme d’Insémination Artificielle concernant l’espèce sélectionnée plus bas.

Issued to the owner of premises approved for semen collection / Émis au propriétaire du lieu agréé de collecte de sperme

<table>
<thead>
<tr>
<th>Address of premises for semen collection / Adresse du lieu de collecte du sperme</th>
<th>Legal location of premises for semen collection / Cadastre du lieu de collecte de sperme</th>
</tr>
</thead>
</table>

**Expiry date of this permit / Date d’expiration de ce permis :**  
(yyyy-mm-dd / aaaa-mm-jj)

Semen may be collected from the following species / Le sperme peut être recueilli de l’espèce suivante

(Circle selected species / Encercler l’espèce choisie)

- Bison/Bison
- Cervid/Cervidé
- *Other/*Autre

*Specify/*Spéciﬁer :

This permit may be used only by the owner of the premises named above, is valid only for the collection of semen from the species speciﬁed above, is not transferable to any other location and is valid only for the period from the date of issuance to the expiry date. Any violation of the conditions stated in the Health of Animals Act and Regulations, or in the Artificial Insemination program, or the occurrence of a disease outbreak on the premises may result in suspension or cancellation.

Ce permis ne peut être utilisé que par le propriétaire du lieu mentionné ci-dessus, n’est valide seulement que pour la collecte de sperme de l’espèce indiquée, n’est pas transférable à un autre lieu et n’est valide que pour la période allant de la date d’émission à la date d’expiration. Toute violation des exigences mentionnées dans la Loi et le Règlement de la santé des animaux ou dans le programme d’Insémination artificielle, ou encore toute éclosion de maladie sur les lieux peuvent amener la suspension ou la révocation de ce permis.

Inspector, Health of Animals Act  
Inspecteur, Loi sur la santé des animaux  

Signature / Signature  

RDIMS # 9196132
Annex Document to accompany animals selected on farms to the pre-entry isolation facility

(ACIA/CFIA 1634 PDF fillable rdims 5538164 + Supplementary declaration PDF fillable rdims 5537793, both to be modified)
Annex Document to accompany animals from the pre-entry isolation facility
to the semen production centre

(Isolation worksheet & Authorization release PDF fillable, rdims 5538418, to be modified)
Annex Document confirming approval of an on-farm isolation facility and qualification of small ruminant animals moved to isolation facility for semen collection purposes

(ACIA/CFIA 1634 PDF fillable rdims 5538164 + Supplementary declaration PDF fillable rdims 5537793, both to be modified.)
Annex Scrapie to qualify herd/flock concerning scrapie for centres to export to the EU
(RDIMS 9226368)

This Annex includes the conditions mentioned in Regulation (EC) No 999/2001, Annex VIII, Chapter A, Section A, points 1.3 a) to f) concerning the conditions a herd/flock should meet to be considered a holding with a controlled risk of classical scrapie.

The herd/flock should meet the following conditions and any small ruminant selected for entry in a semen production centre for export to the EU must at least be 3 years of age and have spent the last 3 years before semen collection in a qualified herd/flock/centre (holding).

1. Holdings with a negligible risk of classical scrapie and a controlled risk of classical scrapie:
   1.1 ...
   1.2 ...
1.3. A holding of ovine animals, caprine animals or ovine and caprine animals may be recognised as having a controlled risk of classical scrapie provided that it has complied with the following conditions for a period of at least the preceding three years:
   (a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;
   (b) records of movements of ovine and caprine animals in and out of the holding are maintained;
   (c) only the following ovine and caprine animals are introduced into the holding:
      (i) ovine and caprine animals from holdings with a negligible or a controlled risk of classical scrapie;
      (ii) ovine and caprine animals from holdings which have met the conditions set out in points (a) to (f) for a minimum period of the preceding three years or for at least the same period of time as the period of time during which the holding, where they are to be introduced, has met the conditions set out in those points;
      (iii) ovine animals of the ARR/ARR prion protein genotype;
      (iv) ovine or caprine animals that comply with the conditions set out in point (i) or (ii) except during the period when they were kept at a semen collection centre, provided that the semen collection centre complies with the following conditions:
         - the semen collection centre is approved in accordance with Chapter I(1) of Annex D to Directive 92/65/EEC and supervised in accordance with Chapter II(1) of that Annex,
         - for a period of the preceding three years, only those ovine or caprine animals from holdings which have fulfilled during that period the conditions set out in points (a), (b) and (e), and which were subject to regular checks by an official veterinarian or a veterinarian authorised by the competent authority, were introduced into the semen collection centre,
         - no case of classical scrapie has been confirmed at the semen collection centre during the period of the preceding three years,
         - biosecurity measures are in place at the semen collection centre to ensure that ovine and caprine animals kept at that centre and coming from holdings with a negligible or a controlled risk status for classical scrapie have no direct or indirect contact with ovine and caprine animals coming from holdings of a lower classical scrapie status;
   (d) the holding is subject to regular checks to verify compliance with the conditions set out in points (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis from 1 January 2014;
   (e) no case of classical scrapie has been confirmed;
   (f) Until 31 December 2013, all ovine and caprine animals referred to in Annex III, Chapter A, Part II, point 3 over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie.
From 1 January 2014, all ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie.

By way of derogation from the conditions set out in the first and second paragraphs of point (f), Member States may decide that all the ovine and caprine animals over 18 months of age with no commercial value culled at the end of their productive life instead of being slaughtered for human consumption, are inspected by an official veterinarian, and all those exhibiting wasting signs or neurological signs are tested in a laboratory for classical scrapie.

Note: The EU conditions mentioned above are considered similar to the conditions of the Voluntary Scrapie Flock Certification Program as mentioned in the Accredited Veterinarian’s Manual, Module 7. Voluntary Scrapie Flock Certification Program.
Annex Document to transfer a resident animal to another centre

(ACIA/CFIA 1634 PDF fillable rdims 5538164)
List of Appendices

Note: Appendices are being developed during final consultation concerning this new program. Subjects of appendices are identified and listed below.

These appendices consist of checklists that may be used by CFIA auditors for the initial approval of facilities and subsequent regular audit and inspections.

Application form for an animal semen production centre
General information summary to accompany all audit reports

For initial approval and every 5 years, to re-issue the permit:
- Approval of a pre-entry isolation facility (physical facilities and procedures)
- Approval of semen collection facilities (procedures, housing buildings, sick pen and collection room)
- Approval of semen laboratory facility (physical facilities and procedures)
- Approval of semen storage facility (physical facilities and procedures)

For initial approval and every 2 years to reissue the permit:
- Approval of a mobile laboratory for semen processing (bison, cervid and small ruminant for distribution in Canada)

For audit:
- Audit of entry procedures in the centre (on farm, pre-entry; animals records, tests)
- Audit of resident health status (tests, records, treatments, movements)
- Audit of semen collection procedures (observation of collection and AV sanitation, if any)
- Audit of semen processing procedures (observation of lab procedures, including sex-sorting if any)
- Audit of semen storage procedures (observation of manipulation; verification of semen identification, records, container disinfection, export certificates)