Australian Government
Department of Agriculture, Water and the Environment

Program for the approval of embryo transfer veterinarians, and the approval and accreditation of export embryo facilities

Collection and processing of embryo/s for export

Cataloguing data

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Introduction

The current approach to the regulation of international trade in embryo/s recognises the importance of sanitary handling and processing procedures, animal disease testing, and quarantine procedures to eliminate certain organisms and thereby reduce the potential for disease transmission via embryo/s. These handling, processing, and testing procedures are progressively becoming standardised internationally. Consequently, Australian regulatory authorities seek to ensure that embryo/s for export are collected, processed, stored, and transported in accordance with internationally agreed procedures. The integrity of the veterinary health certificate that accompanies export embryo/s and confirms that these procedures have been carried out correctly, is essential to maintain international market access.

In order to provide credible health certification with respect to international trade in embryo/s, the Australian Department of Agriculture, Water and the Environment requires all collections, processing, and storage of export embryo/s to follow export requirements. These requirements include the need for export embryo/s to be collected and processed at a facility approved or accredited by the Department of Agriculture, Water and the Environment and by an embryo collection team under the supervision of an Embryo Transfer Veterinarian (ETV) approved by Department of Agriculture, Water and the Environment.

The Department of Agriculture, Water and the Environment approved ETV may work alone, or as a veterinarian supervising all operations of a team with one or more technicians who are competent in embryo collection, handling, and processing procedures. Should a veterinarian lose approval status for any reason, or transfer from the team, the embryo collection team for which that veterinarian was responsible would not be able to process embryo/s for exportation until supervision by an approved ETV is restored.

ETV approval for embryo export requires the following:

1) Demonstrated commercial experience and knowledge in the field of embryo transfer in the species for which they are applying for ETV Approval
2) Demonstrated theoretical and technical competence in embryo collection through successful completion of an examination and pre-approval audit prepared by the Embryo Transfer Veterinarian Technical Management Committee (ETVTMC)
3) The implementation of an approved program compliance arrangement with the Department of Agriculture, Water and the Environment.
4) The implementation of an on-going approval compliance program with the ETVTMC.

This program is not intended to train applicants in the field of embryo transfer.

In light of the rapid advancements in embryo technology and the critical nature of sanitary handling, washing and treatment regimens in assuring embryo/s being certified are of the required health status, the validity of ETV approval is for a maximum of three (3) years and species specific. For continuous approval in the following years approved ETVs must adhere to the on-going approval process.

Department of Agriculture, Water and the Environment ETV approval is subject to triennial review. All approved ETVs must be reviewed at least once every 3 years.

Embryo export facilities, which ETVs supervise, are audited by the Department of Agriculture, Water and the Environment at least once a year, and twice per year if they produce embryo/s for export to the European Union (EU).

1 Objectives

The Department of Agriculture, Water and the Environment ETV approval program is for veterinarians seeking eligibility to collect embryo/s for export, or to supervise a team that collects embryo/s for export. The program addresses the following elements:

1.1 ETVTMC management or oversight

- Competence in embryo transfer theory and technology requiring completion of the ETVTMC ETV Competency Program, ETV Approval Examination and ETV Pre-Approval Audit
- Competence in embryo classification and record keeping procedures requiring completion of the ETVTMC ETV Competency Program, ETV Approval Examination and ETV Pre-Approval Audit
- Submission to triennial review of on-going approval requirements

1.2 Department of Agriculture, Water and the Environment management or oversight

- Accredited or approved isolation facility, permanent or mobile processing laboratory and storage facility standards
- Compliance with importing country requirements
- The approved use of representative samples of flush fluids, washing fluids, degenerated embryo/s and non fertilised ova for official examination
- The facilities development of a program compliance arrangement (Operational Manual) providing assurance that correct procedures will be followed in every case
- Submission to annual audit and supervisory visits from Department of Agriculture, Water and the Environment of embryo collection facilities and embryo collection team under the supervision of the ETV, or more frequently if required

2 ARV and Department of Agriculture, Water and the Environment approval

This program was developed by the joint forces of the Australian Reproductive Veterinarians (ARV) and Department of Agriculture, Water and the Environment. The ARV is a special interest group (SIG) within the Australian Veterinary Association (AVA). The aims of the ARV related to Department of Agriculture, Water and the Environment export embryo approval are:

1) to improve the standards of embryo transfer (ET)
2) to further the research and knowledge of ET
3) to promote co-operation between veterinarians involved in ET
4) to examine competence in ET technology
5) in conjunction with Department of Agriculture, Water and the Environment, to monitor the implementation of IETS Standards (current edition), for the production of embryo/s for export
6) to participate in the revision of the Department of Agriculture, Water and the Environment approval program as required.

The ETV Technical Management Committee for the Approval of ETVs was established as a collaboration between the Department of Agriculture, Water and the Environment, ARV and industry. The members of the committee consist of the ARV president; Department of Agriculture, Water and the Environment – Animal Biosecurity Branch; Department of Agriculture, Water and the Environment's Veterinary Export and Meat Group – Reproduction Hub (ReproHUB) and a currently approved ETV for each species (cattle and small ruminants).

3 Steps to obtain Department of Agriculture, Water and the Environment embryo transfer veterinarian approval

The Department of Agriculture, Water and the Environment ETV approval program encompasses the following aspects:

3.1 Payment of ETV approval processing fee

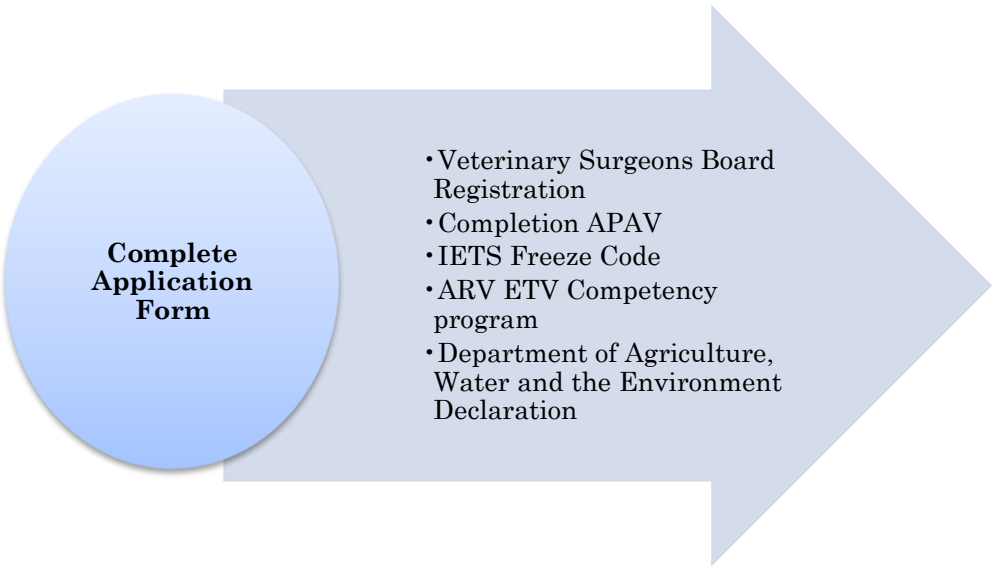
A single fee is paid for the processing of the application and the examination on the AVA on-line learning management system. Once the fee is paid the applicant has 3 months to submit their application and is granted 3 months access to the examination.

3.2 Submit an application

Applications are submitted to the ARV for review by the ETVTMC. The application must include:

- Registration details of the veterinarian with the Veterinary Surgeons Board of the state/s within which they practice.
- Proof of completion of the Accreditation Program for Australian Veterinarians (APAV) maintained by Animal Health Australia (AHA).
- The applicants IETS freeze code.
- Complete ARV ETV Competency Program (Refer to Section 4. *Competence in Embryo Transfer Technology*).
- Complete the Department of Agriculture, Water and the Environment Declaration.

Figure 1 Application to submit to the ARV



3.3 Approval process – examination

Successfully complete the ARV ETV Examination to demonstrate theoretical and technical competence in embryo collection and processing procedures. The examination is also demonstrating a working knowledge of OIE and IETS procedures. The examination is an open book multi-choice examination that the applicant has 3 months to complete.

3.4 Approval process – audit

Successfully pass a pre-approval audit of procedures by the ARV ETVTMC. The pre-approval audit is performed by a Department of Agriculture, Water and the Environment Approved ETV, who has successfully completed at least one tri-annual review to obtain on-going approval; or an auditor approved by the ETVTMC. A list of potential auditors can be obtained from the ETVTMC. The pre-approval procedures audit of applicants can occur at an approved or accredited facility; or a location approved by the ETVTMC.

It is the responsibility of the applicant to approach a potential auditor and negotiate the fee for the audit at an agreed location. For further information on fee guidelines please refer to the *ARV ETVTMC – Program for the Department of Agriculture, Water and the Environment Approval of ETVs (Approved ETV)* 5.10.3. This document is available from the AVA – ARV office.

The outcome of the audit will be reported to the Department of Agriculture, Water and the Environment by the ETVTMC.

3.5 ETV approval in additional species

If an already approved Export ETV wishes to apply for approval for an additional species the following requirements need to be met:

- Submit an application to the ARV for review by the ETVTMC for the approval of ETVs in an additional species. The application must include:

- A completed ARV ETV Competency Program for the applicable species (refer to Section 4. Competence in Embryo Transfer Technology).
- Payment of the application fee for the additional species ETV Approval.

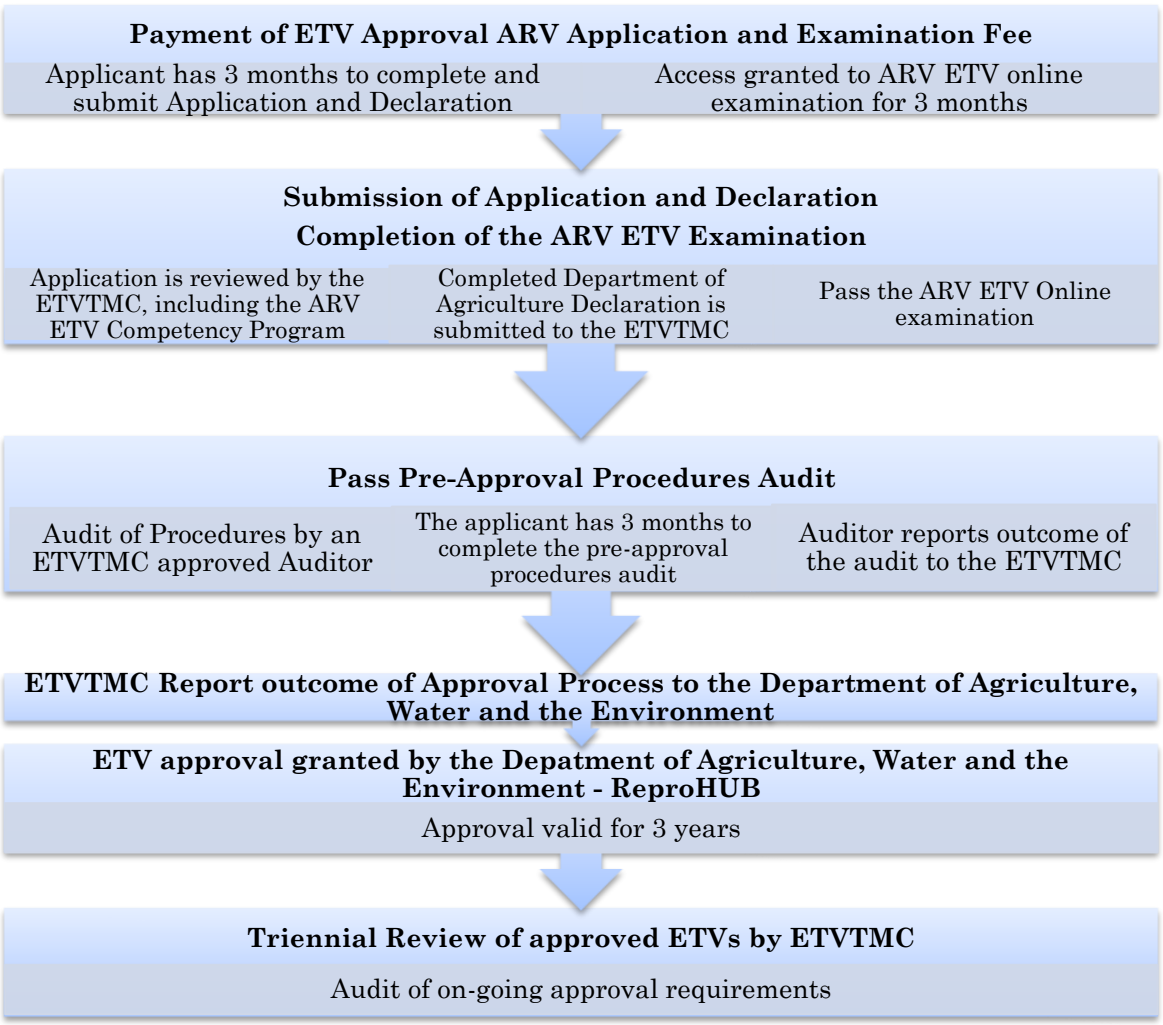
After review the ARV ETVTMC will inform the applicant and the Department of Agriculture, Water and the Environment of the outcome of the assessment for additional species approval.

3.6 ETV on-going approval

The Department of Agriculture, Water and the Environment approval of ETVs is valid for 3 years. (Refer to section 16.1 *ETVTMC review of ETV On-going approval requirements*). The triennial approval of ETVs also depends on the compliance to on-site annual audits performed by the Department of Agriculture, Water and the Environment of the embryo collection team, under the supervision of the approved ETV and the accredited or approved facility under the supervision of the approved ETV.

For further information on the Approval Process refer to the *ARV ETVMC – Program for the Department of Agriculture, Water and the Environment Approval of ETVs (Approved ETV)*. This document is available from the AVA – ARV office.

Figure 2 ETV process for approval



4 Competence in embryo transfer technology – ARV ETV competency program, ARV ETV examination and ETV pre-approval audit

Veterinarians who wish to be approved by the Department of Agriculture, Water and the Environment for the certification of embryo/s for export must initially be found to be technically competent prior to proceeding with any of the remaining elements of the approval program.

The present method of determining competency is the successful completion of the ARV ETV Competency Program and successful completion of the ETV Approval Examination and ETV Pre-approval Audit. The ARV ETV Competency Program, ETV Approval Examination and ETV Pre-approval Audit ensures that a competent ETV possesses both the theoretical principles and the necessary technical expertise to satisfactorily perform or supervise embryo transfer work for production of embryo/s for exportation.

4.1 ARV ETV Competency Program

The ARV ETV Competency Program has the following requirements:

Provide to the ETVTMC, proven experience and performance in the collection and processing of embryo/s. To satisfy this requirement, the applicant must provide the following proof:

- Practical ET experience

No less than 1 years' practical ET experience. In the context of the application, experience is defined as direct involvement in the superovulation, collection and processing of embryo/s, which must include the evaluation and appropriate handling of embryo/s for immediate transfer, or the evaluation and steps involved in the cryo-preservation of embryo/s, in the species for which application is being made.

- Training in Embryo Transfer

At least 40 hours species specific training with an Approved ETV or a form of training approved by the ETVTMC, in the species in which the applicant is applying for ETV approval, within the past 2 years. Evidence of training needs to be submitted to the ETVTMC on application. The ETVTMC may require the applicant to perform additional training after review.

OR

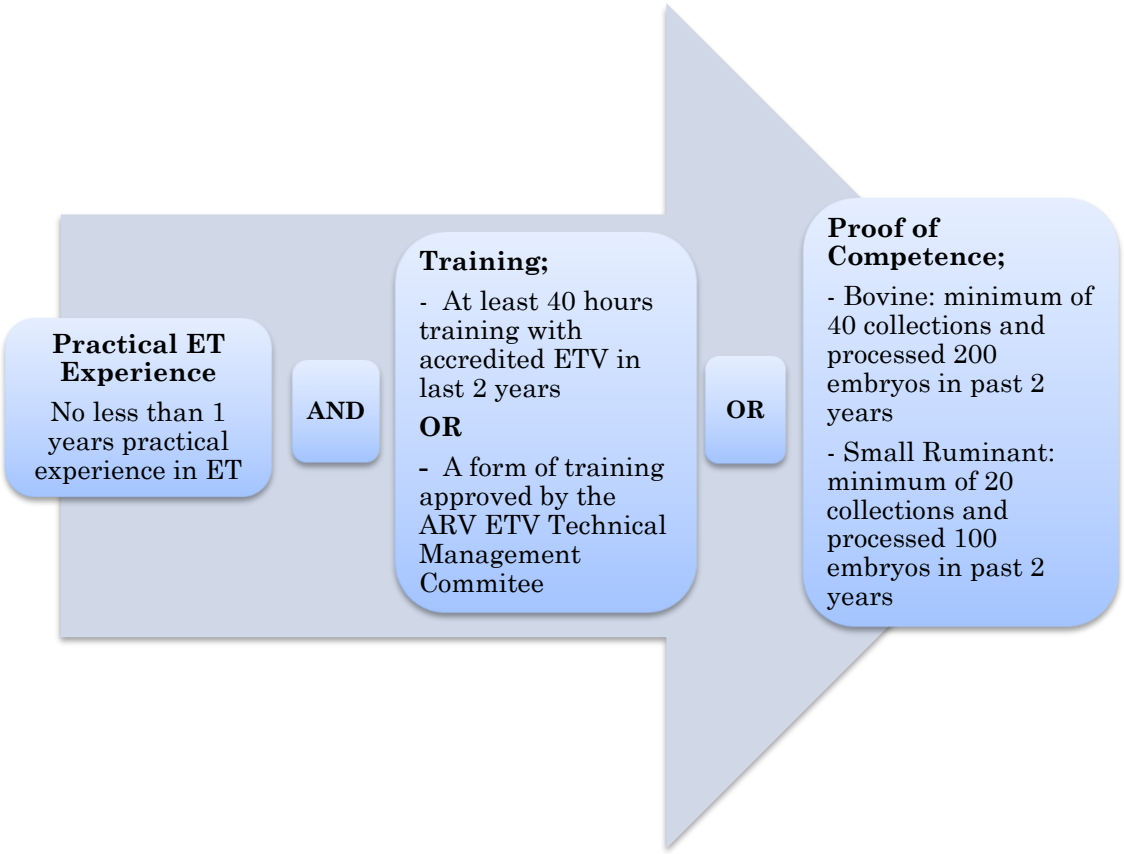
- Proof of Competence

Bovine: For bovine embryo approval, the applicant must provide proof in the form of worksheets of having conducted, a minimum of 40 collections from bovine donors and processed 200 embryo/s within the past 2 years. The collection and processing of embryo/s for domestic use can contribute to the verification of competency. The thawing and direct transfer

of frozen embryo/s previously evaluated does not contribute to the number which must be processed for the purposes of the application.

Small Ruminants: For small ruminant embryo approval, the applicant must provide proof in the form of worksheets of having conducted, a minimum of 20 collections from small ruminant donors and processed 100 embryo/s within the past 2 years. The collection and processing of embryo/s for domestic use can contribute to the verification of competency. The thawing and direct transfer of frozen embryo/s previously evaluated does not contribute to the number which must be processed for the purposes of the application.

Figure 3 ARV ETV Competency Program



4.2 ETV Approval Examination

The ARV ETV Approval Examination has the following requirements:

Successful completion of the ARV ETV Approval open book examination to demonstrate theoretical and technical competence, plus an understanding of the OIE and IETS requirements and procedures.

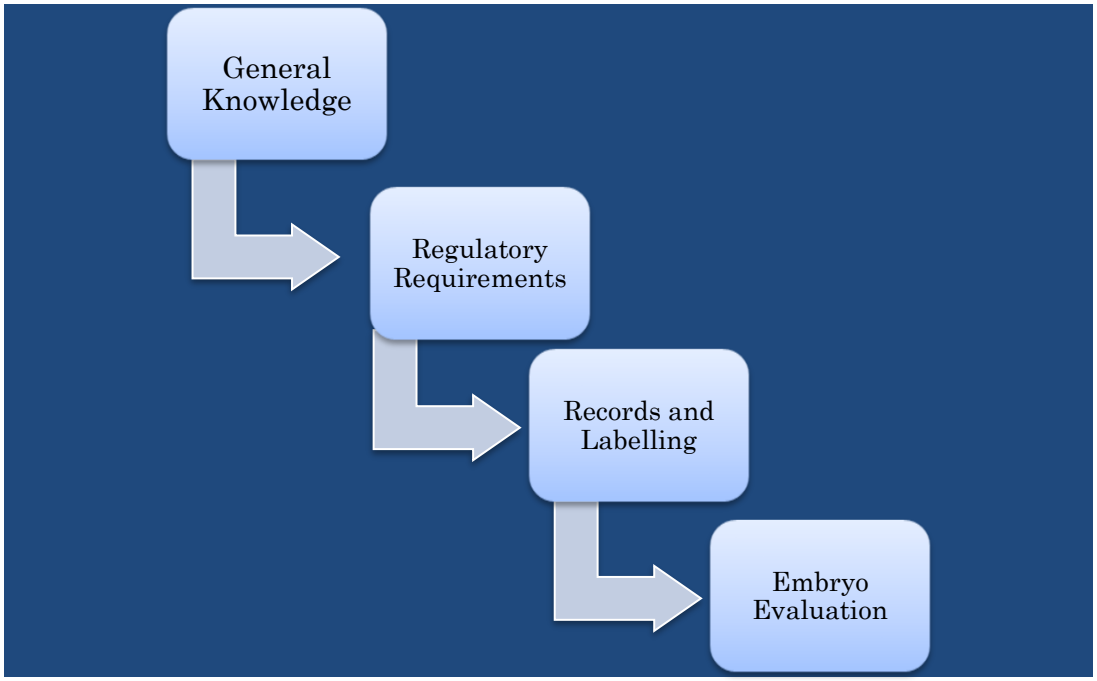
As a guide, the ARV ETV Approval Examination consists of **FOUR MAIN SECTIONS**, each comprising 25% of the multichoice examination:

- **Section A: General knowledge** – Demonstrate a working knowledge of reproductive physiology and endocrinology, folliculogenesis, superovulation, donor and recipient management, oestrus synchronisation and factors affecting results and embryo freezing.

- **Section B: Regulatory requirements** – Demonstrate knowledge of general sanitary procedures and health regulations for domestic and export embryo collection and processing.
- **Section C: Records and labelling** – Be able to describe the protocols for labelling straws, goblets and canes as described in the IETS manual.
- **Section D: Embryo evaluation** – Demonstrate knowledge of embryo evaluation, including embryo development, morphology, and classification.

The examination only allows candidates to progress to the next section after successfully completing the preceding section, by achieving a pass mark of 80% or more. The sequence of the examination is listed above. If a candidate fails a section, they can repeat that section immediately.

Figure 4 ARV ETV Approval Examination



4.3 ETV pre-approval audit

The final stage in the approval process is the applicant successfully passing a pre-approval audit of procedures. This audit is based on the applicant demonstrating technical skills and competencies in the collection and processing of embryo/s for export, as described in the IETS Manual. An applicant has 3 months to complete the pre-approval audit from the time they have submitted their application and completed the examination.

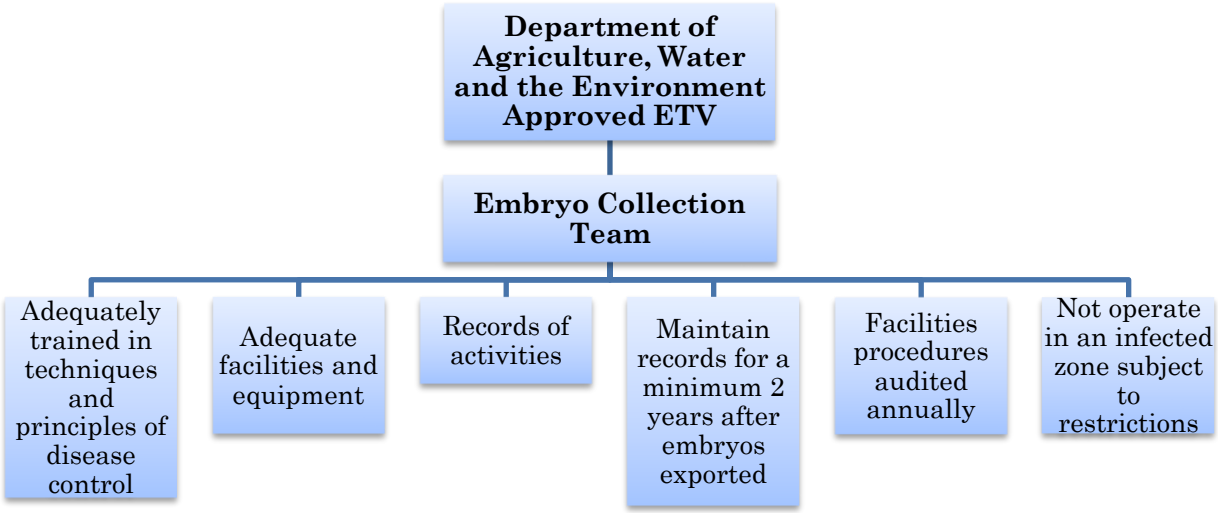
For further information on the ARV ETV Competency Program, ARV ETV Approval Examination and ETV Pre-Approval Audit refer to the *ARV ETVTMC – Program for the Department of Agriculture, Water and the Environment Approval of ETVs (Approved ETV)*. This document is available from the AVA – ARV office.

5 Embryo Collection Team

In many instances, embryo/s for export are collected by a team that is supervised by an approved ETV. The OIE Terrestrial Animal Health Code specifies the requirements for approving embryo collection teams and the Department of Agriculture, Water and the Environment must ensure that the following general conditions relating to animal health and embryo quality are adhered to for the international movement of embryo/s:

1) The export embryo collection team must be directly supervised by a Department of Agriculture, Water and the Environment approved Embryo Transfer Veterinarian (Approved ETV).
2) The team veterinarian is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors, disinfection, and all hygienic procedures.
3) Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practiced precluding the introduction of infection.
4) The collection team must have access to adequate facilities and equipment for:
    a) collecting embryo/s;
    b) the processing and treatment of embryo/s at a permanent site or purpose-built, mobile laboratory;
    c) storing embryo/s.
5) As these facilities are not necessarily at the same location, the collection team must keep a record of its activities.
6) The embryo collection team must keep records of its activities, which are maintained for inspection by the Department of Agriculture, Water and the Environment auditor/s for a period of at least two years after the embryo/s have been exported.
7) The facility under the supervision of an ETV will be subjected to regular audits at least once a year, unless otherwise stipulated by the importing country, to ensure compliance with procedures for the sanitary collection, processing, and storage of embryo/s. The annual audit of the facility is performed by the Department of Agriculture, Water and the Environment.
8) The collection team must not operate in an infected zone subject to any restriction by the State Veterinary authority in relation to animal health.

Figure 5 Embryo Collection Team



6 Isolation facility for embryo collection

The collection of embryo/s for export can be carried out in any facility approved or accredited by the Department of Agriculture, Water and the Environment.

For the export collection of embryo/s, the following facilities must be present:

- An isolation facility for donors – the facility for the pre- and post-collection isolation of donors must follow the Department of Agriculture, Water and the Environment standards for a pre-export isolation facility and are to be located as close to the embryo collection facility as possible.
- An embryo collection facility and embryo processing laboratory.

All donors of embryo/s must be held in isolation for the period specified by the relevant importing country, or from commencement of any procedure e.g. testing for which certification will be required. The importing country's requirements supersede any additional requirements stipulated in these conditions.

There are two classes of pre-export isolation facilities: Department of Agriculture, Water and the Environment accredited and Department of Agriculture, Water and the Environment approved isolation facilities.

6.1 Department of Agriculture, Water and the Environment accredited isolation facility

A Department of Agriculture, Water and the Environment accredited isolation facility is a premise which is capable of being maintained for continuous use e.g. continuous collection of embryo/s for export from the same farm.

1) The accredited facilities and procedures must be included/added to the operational manual.
2) The accredited isolation facility must undergo an initial inspection by a Department of Agriculture, Water and the Environment Officer before the commencement of donor preparation for export embryo collection.
3) This facility is subject to an annual audit for the renewal of its accreditation.
4) The standard Department of Agriculture, Water and the Environment fee for service will apply for the initial and annual inspections.

6.2 Department of Agriculture, Water and the Environment approved isolation facility

Department of Agriculture, Water and the Environment approved isolation facility, is a premise which is only intended for individual export collection of embryo/s.

1) A Department of Agriculture, Water and the Environment approved ETV must carry out an inspection of the isolation facility, prior to the beginning of the isolation period and report

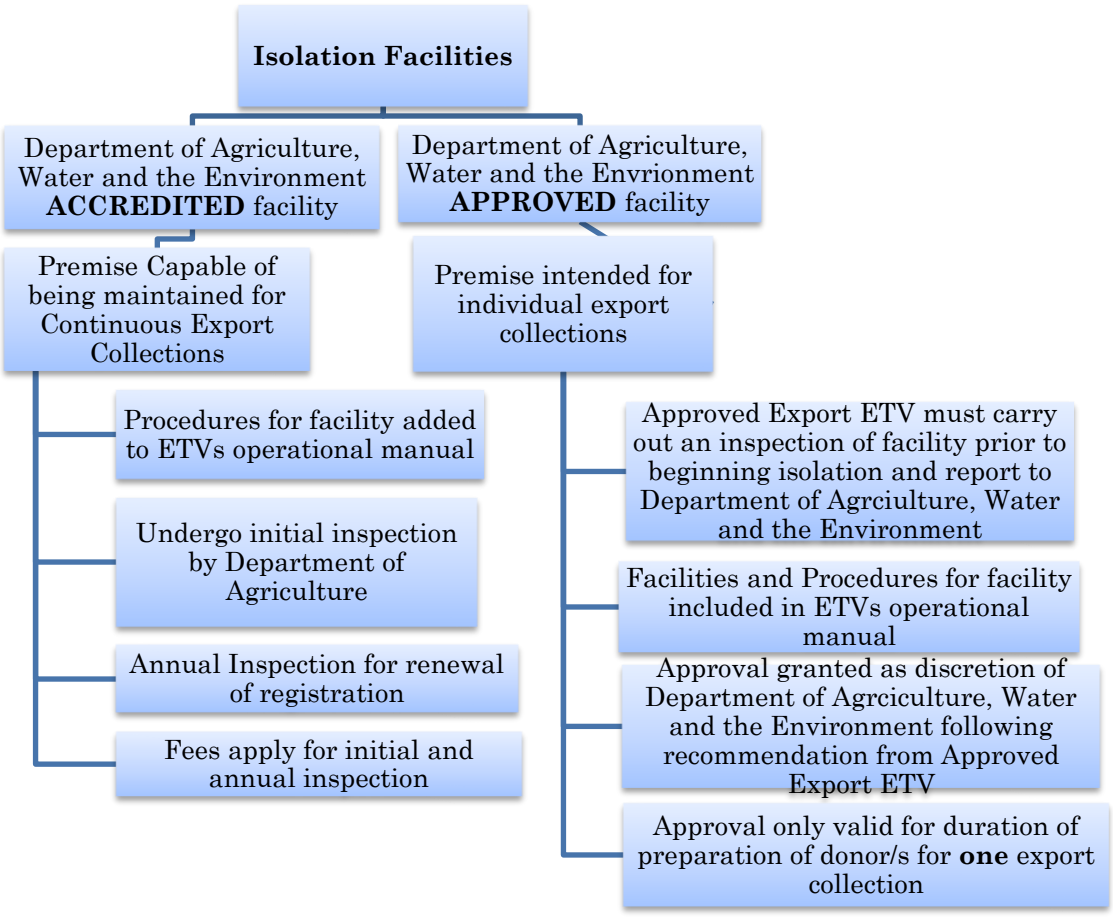
the result, with recommendations, in writing to the Department of Agriculture, Water and the Environment – Reproduction Exports Team.

2) The approval may be granted under the discretion of the Department of Agriculture, Water and the Environment Certifying Veterinary Officer, following recommendation from the Department of Agriculture, Water and the Environment approved ETV.

3) The facility and procedures must be added to the operational manual.

4) The approval is valid only for the duration of the preparation of donor/s for one export collection.

Figure 6 Isolation facility



6.3 Minimum standards for isolation facilities

The minimum standards for an isolation facility for donors of export embryo/s are determined by the importing countries protocol. The minimum standards for the auditing of isolation facilities by the Department of Agriculture, Water and the Environment are:

1) Unless otherwise determined by the importing country, animals held in isolation must be separated from other animals by double fencing with 3 metres between each fence.

2) Animals held in isolation must use separate facilities (water troughs, feed troughs) from those used by other animals. Facilities, such as crushes and loading ramps, need to be cleaned and disinfected with an appropriate disinfectant prior to use.

3) Fencing used for isolation facilities must be species proof and adequate to prevent any incursion or excursion of animals.
4) Fodder and drinking water supplied to animals held in isolation must be so derived that it does not constitute a quarantine risk.
5) Equipment used for husbandry practices must be either new or cleaned and disinfected prior to use.
6) The isolation facility to be sited to prevent drainage or surface run-off from surrounding areas which contain or have recently contained other animals.

7 Processing laboratory and storage facility

Embryo/s for export must be processed (examined, washed, treated, and placed in identifiable and sterile straws) in a laboratory facility, either permanent or mobile, approved by Department of Agriculture, Water and the Environment.

The laboratory must not operate in an area subject to restrictions or quarantine measures unless the disease in question has been listed by the International Embryo Technology Society (IETS) in Category One or has been determined to be of insignificant risk for transmission by embryo/s.

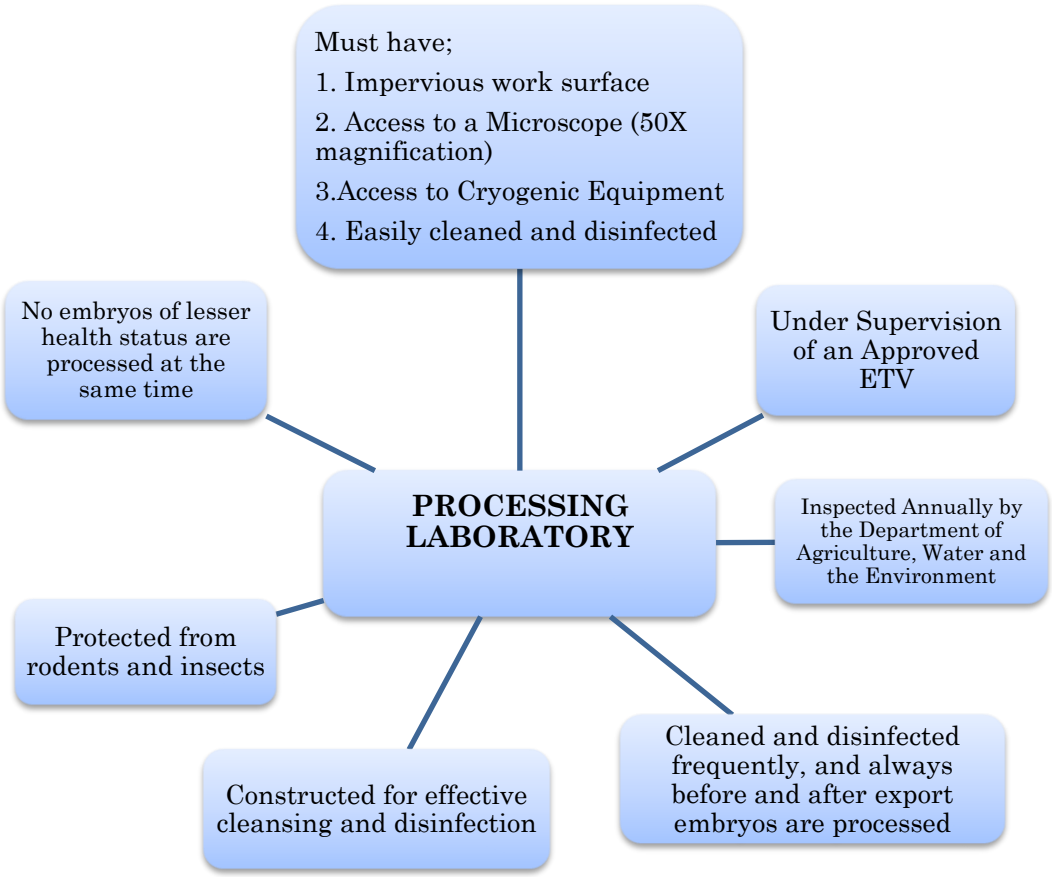
A permanent laboratory may be part of a specifically designed collection and processing facility, or a suitably adapted part of an existing building. It may also be on the premises where the donor animals are isolated. In either case, the laboratory should be physically separated by a permanent wall from the animal enclosure and from the collection area.

Both mobile and permanent laboratories must have a clear and permanent separation between dirty areas (animal handling) and clean, processing areas (mobile or permanent laboratories). Temporary partitions between the collection area and processing area are unacceptable.

7.1 Requirements for the processing laboratory

1) Each laboratory facility must have:
    a) impervious work surfaces
    b) access to a microscope capable of 50X magnification
    c) access to cryogenic equipment
    d) working facilities which can be easily cleaned and disinfected.
2) The laboratory must be under the direct supervision of the Department of Agriculture, Water and the Environment approved ETV and be annually audited by a Department of Agriculture, Water and the Environment Official Veterinarian.
3) While embryo/s for export are being handled prior to storage in straws, no embryo/s of a lesser health status should be processed.
4) The laboratory should be protected against rodents and insects.
5) The processing laboratory should be constructed with materials which permit effective cleansing, disinfection, and vermin control. Cleaning and disinfecting should be done frequently, and always before and after each occasion on which embryo/s for export are processed.

Figure 7 Processing laboratory



7.2 Permanent laboratory

A permanently sited laboratory must have the following clearly defined workspaces:

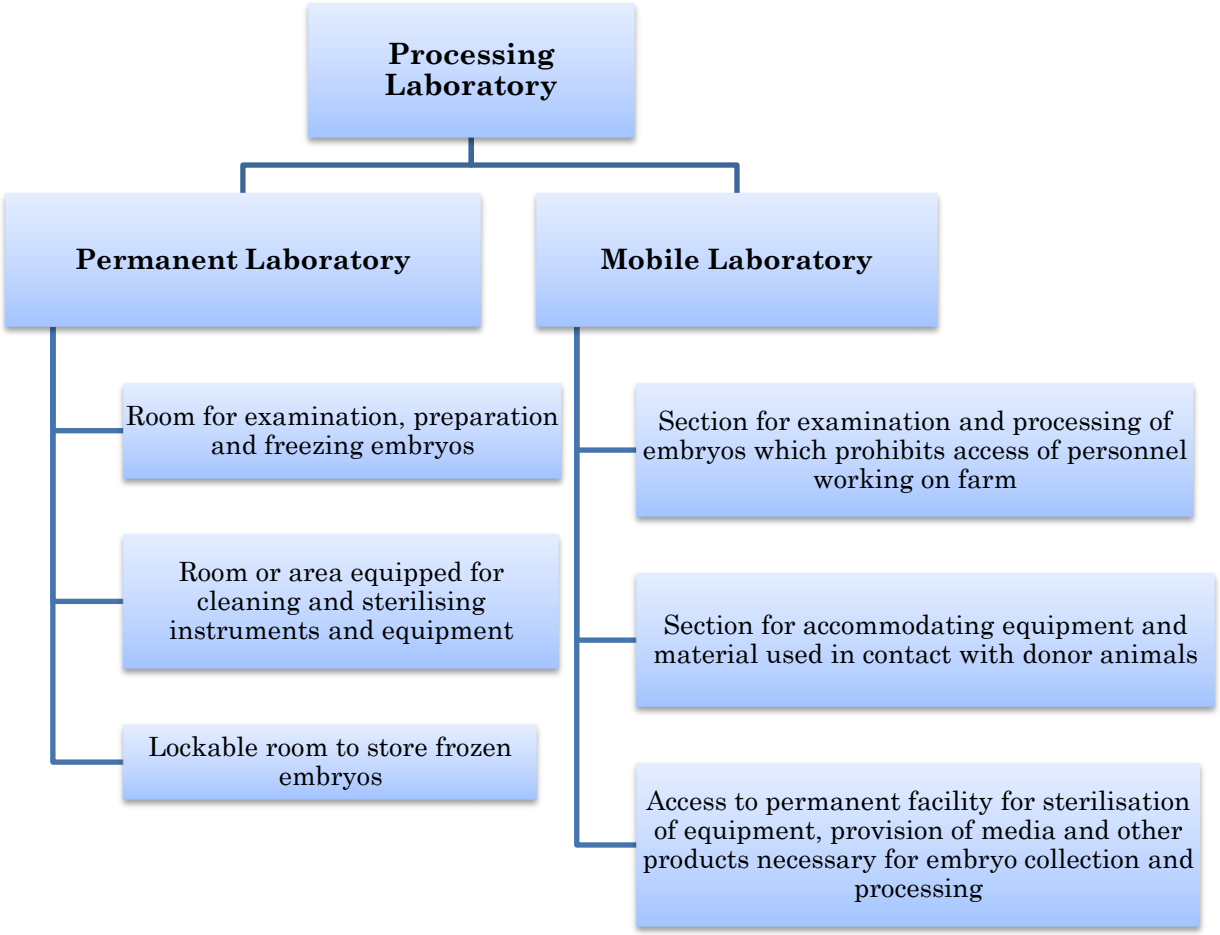
1) a room for the examination, preparation and freezing of embryo/s.
2) a room, or area equipped for cleaning and sterilising the instruments and equipment used in embryo collection and processing.
3) a lockable room to store frozen embryo/s. The frozen embryo/s may be stored in the embryo processing laboratory if the processing laboratory is a lockable room and the processing laboratory is not used to process non-export embryo/s.

7.3 Mobile laboratory

A mobile laboratory must have:

1) a section for examination and processing of embryo/s which prohibits access of personnel working on the farm.
2) a section for accommodating equipment and material used in contact with donor animals.
3) access to a permanent facility for the purposes of sterilisation of equipment and the provision of media and other products necessary for embryo collection and processing.

Figure 8 Types of processing laboratory



7.4 Storage facility

1) With respect to storage, embryo/s collected for export must be stored by an embryo collection team under the supervision of a Department of Agriculture, Water and the Environment approved ETV in the premises approved by the Department of Agriculture, Water and the Environment for this purpose.

2) In order to be approved, the storage premises must:

   a) be comprised of at least one lockable room intended for genetic material storage. The export genetic material must be stored in a clearly demarcated area and in such a way that precludes access and there is no risk of contamination. The storage room should be kept locked. The export genetic material may be stored in the processing laboratory if it is a lockable room and not used to process non-export embryo/s. Some importing countries, such as the EU, have additional minimal requirements for the storage of embryo/s for export.

   b) have permanent records of all incoming and outgoing embryo/s, an inventory of the embryo/s and their location within the storage area must be available.

   c) have the capability to maintain embryo/s for export of equivalent health status in the same container and to be maintained separately from embryo/s not destined for export or not of equivalent health status in separate containers.

3) The laboratory and storage facility should be under the direct supervision of the approved ETV and must be audited annually by a Department of Agriculture, Water and the Environment auditing veterinarian, unless otherwise stipulated by the importing country.

8 Compliance with certification requirements

Although export embryo animal health protocols are becoming more uniform, the importing country has the sovereign right to determine the requirements that need to be met for embryo entry.

To this end, there will be variations with respect to the health certification requirements i.e. what constitutes acceptable isolation of donors, the need and nature of donor testing for specified disease agents and the processing and treatment requirements for embryo/s.

The intent of this program is to ensure that the procedures required by the importing country are performed according to established international standards. Endorsement and application of the official export stamp to all export veterinary health certificates for embryo/s will remain a Department of Agriculture, Water and the Environment responsibility.

The Department of Agriculture, Water and the Environment's main consideration is the health status of the embryo/s to be exported. Any doubts as to the integrity of the certification process could lead to rejection of the export consignment. Consequently, the ethics and professionalism of an approved ETV must be of the highest level. Any activity, e.g. errors in identification, morphological classification, or qualification of embryo/s, that might jeopardise the credibility of the approved ETV, may justify the withdrawal of approval. Any doubts as to the integrity of the protocoling of donors, preparation, collection, and processing could lead to rejection of the export consignment and may justify withdrawal of ETV approval.

To ensure compliance with the export protocol the Department of Agriculture, Water and the Environment requires that approved ETVs and teams under their supervision adhere to the steps outlined below:

1) Prior to initiating any preparation or collection procedures the approved ETV must be familiar with, and comply with, the importing country requirements for embryo/s. The approved ETV is responsible for obtaining the most recent export embryo requirements for each country to which embryo/s produced by their team will be exported. The Department of Agriculture, Water and the Environment MICOR website can be consulted and is regularly updated; however, importing countries may change their requirements without notice and may not inform the Australian Department of Agriculture, Water and the Environment. If discrepancies are detected between the import permit or import conditions obtained from MICOR, they should be immediately forwarded to the Department of Agriculture, Water and the Environment – Reproductive Material Import and Export Team (Reproduction Hub – ReproHUB) at genetics@agriculture.gov.au.
2) Prior to commencing collection procedures, it is the responsibility of the approved ETV to ensure that both the donor herd/flock and the premises of collection conform to the requirements of the protocol of the importing country or countries to which embryo/s are intended for export.
3) Conduct pre-isolation/pre-admission tests if required. The sampling of donors for serological testing and performance of any other procedures required by the importing

country will also be the responsibility of the approved ETV. The testing and procedures can be performed by veterinarians or technicians responsible to the approved ETV.

4) Start donor isolation in the Department of Agriculture, Water and the Environment approved or accredited isolation facility, unless otherwise stated in the importing country's protocol.

5) Carry out pre-collection tests and treatments as required by the importing country's protocol. The testing, treatments and procedures can be performed by veterinarians or technicians responsible to the approved ETV.

6) Ensure that collection and processing of embryo/s for export follows the standards set out in the current edition of the *IETS Manual* – Chapters 4, 6 and 8. (Current Edition).

7) Ensure that processed embryo/s are identified and stored as recommended in Chapter 9 of the *IETS Manual* (Current Edition).

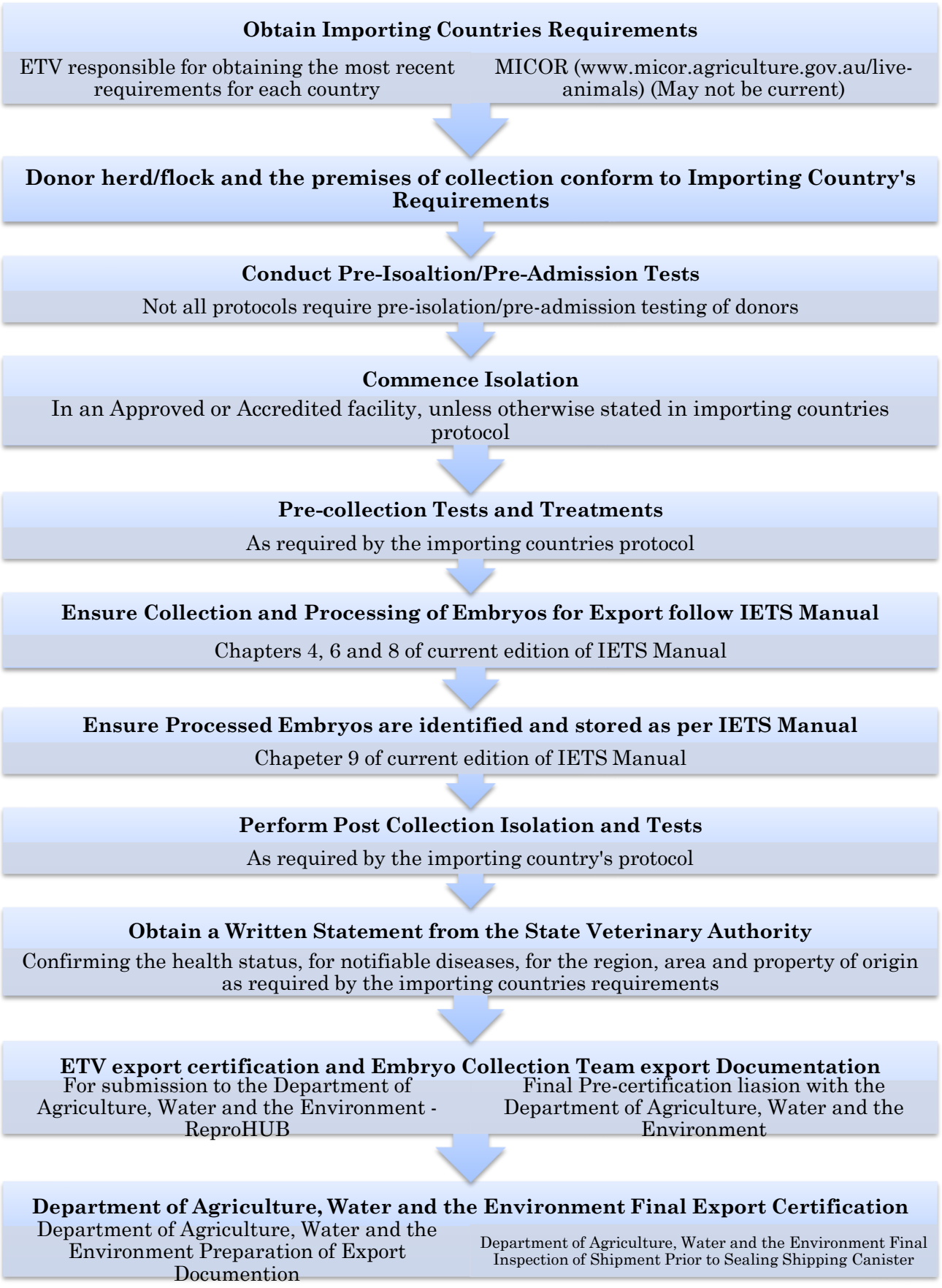
8) Perform post-collection isolation and testing as required by the importing country's protocol. The testing and procedures can be performed by veterinarians or technicians responsible to the approved ETV.

9) Have the State Veterinary Authority confirm in writing the health status, in reference to notifiable diseases, of the region, area and property of origin as required by the importing country's protocol.

10) Preparation of ETV export certification documentation and embryo collection team export documentation for submission to the Department of Agriculture, Water and the Environment – Reproductive Material Import and Export Team (Reproduction Hub – ReproHUB) for assessment. Embryo/s presented to the Department of Agriculture, Water and the Environment for final export certification must have a well-documented health status as required by the protocol of the importing country.

11) The Department of Agriculture, Water and the Environment – ReproHUB prepare the final official export veterinary health certificate and documentation. The Department of Agriculture, Water and the Environment will then complete the final inspection of the embryo/s straws prior to sealing the shipment with an official seal and signing the final official export veterinary health certificate.

Figure 9 Steps to ensure compliance with certification requirements



9 Preparation of donors

Embryo transfer programs require intensive management. To produce export quality embryo/s, Department of Agriculture, Water and the Environment approved ETVs and their embryo collection teams must implement all necessary precautions to eliminate pathogens. Approved ETVs should be informed by reading the current IETS Manual. Specifically, the donors of embryo/s for export must be:

1) Selected from a herd with an adequate health status and resident in the herd of origin, as required by the importing country's protocol.
2) Isolated in the Department of Agriculture, Water and the Environment accredited, or approved facility, unless otherwise stated in the export protocol, for the period required by the importing country's protocol.
3) Tested to confirm freedom from diseases listed in the importing country's protocol.
4) Clinically assessed by the approved ETV, or by a veterinarian responsible to the approved ETV and certified to be free of clinical signs of contagious and infectious diseases transmissible to ruminants, or as specified by the importing country's protocol.
5) Isolated as per the importing country's protocol during the post-collection period until all post-collection tests are performed to confirm the donor's health status.
6) Only subjected to protocol and testing procedures that are clearly documented in ET-facility protocol or job-sheets, that specify the test/procedure, the veterinarians, or technicians responsible, and the date. Such documentation must include inseminations, plus the collection, processing and freezing of embryo/s.
7) Certified by the owner with a signed statement that to the best of their knowledge the donors are free of any known genetic defects and not associated with such defects in close relatives. Owners also need to certify the freedom from non-notifiable diseases as per the importing country's requirements.

10 Production of embryo/s for export

Embryo transfer programs require intensive management and success depends on the ability to perform a series of technical steps with rigor. There is also a need to minimise the influence of factors having a negative effect on the result of the birth of live, healthy offspring.

Sound sanitary procedures are vital at all stages and without them, the health of donors may be jeopardised, pregnancy rates may be low, and infection may be transmitted when (or after) the embryo/s are transferred to recipients.

When embryo transfer is performed on the farm, the client should be made aware of the importance of health and good hygiene for the success of super-ovulatory treatments, fertilisation, viability of the embryo/s, qualification of embryo/s (or the resultant offspring) for sale, and pregnancy and birth rates following transfer.

Embryo transfer facilities and laboratories must be carefully designed and operated to avoid the introduction of disease. Equipment, including clothing, should be routinely processed as appropriate i.e. instruments coming into contact with the uterus or embryo/s must never be used for more than one animal without re sterilisation, and clothing must be completely disinfected or changed between farms.

Personnel working in the embryo transfer field must be knowledgeable and conscientious in carrying out procedures in a manner that will prevent disease transmission from animal to animal, or from farm to farm. Staff must not wear the same overalls used during collection when processing the embryo/s. Animals must be rigorously screened before entry and if there is a resident embryo transfer herd/flock, new entrants should be kept in isolation for a period before joining the main herd/flock.

This section outlines some specific requirements for media and equipment that should be adhered to when processing embryo/s for export. It also identifies specific aspects of embryo handling and storage necessary to reduce the possibility of contamination.

10.1 Media

Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryo/s should be free from pathogenic agents. Media and solutions used in the collection, freezing and storage of embryo/s/ova should be sterilised by approved methods, in accordance with the *IETS Manual* (Current Edition), and should be handled in a manner that will ensure sterility is maintained. Antibiotics should be added to the collection wash and storage media as recommended in the *IETS Manual* (Current Edition).

10.2 Equipment

All equipment used to collect, handle, wash, freeze and store embryo/s should be disposable, or sterilised as recommended in the *IETS Manual* (Current Edition).

10.3 Important points

1) Only embryo/s from one donor should be processed simultaneously.

2) During the processing of export embryo/s, there must not be any contact with other embryo/s used for other purposes, or of a lesser health status.

3) All equipment contacting the donors, or embryo/s during collection and processing, must be disposable or must be properly disinfected or sterilised prior to each use as described in the current *IETS Manual*.

4) Products of animal origin used in the collection fluid, processing media and in transport medium shall be obtained from sources, which present no animal health risk, or are to be so treated prior to use so that such risk is prevented.

5) Only a cryogenic agent which was not previously used in conjunction with other animal products may be used.

6) Unwarranted access to laboratories must be restricted with explicit laboratory policies and signage.

7) Depending on the import requirements of the country, embryo/s may be required to be washed and/or trypsin treated by one of the following methods (*IETS Manual* Chapter 6):

    a) For routine washing: Embryo/s in groups of 10 or fewer are transferred through at least ten changes of media; each of the ten washes must be a 100 fold dilution of the previous wash, and a fresh, sterile micropipette must be used for each transfer; to be eligible to be washed together, embryo/s must originate from the same donor.

    b) When inactivation or removal of certain viruses is required, the standard washing procedure should be modified to include additional washes with trypsin, as described in the current *IETS Manual*. If embryo/s are to be trypsin treated, then the following washing/trypsin procedure is carried out instead of the washing procedure set out above: Embryo/s will be transferred through 5 washes containing bovine serum albumin instead of serum, then through 2 washes of 0.25% trypsin, pH 7.6 7.8, for a total time in the trypsin of 60 90 seconds, and finally through 5 washes that contain serum or an approved serum substitute; each of the washes must be a 100 fold dilution of the previous one, and a fresh sterile pipette must be used for each of the transfers; only embryo/s from the same donor may be washed and treated together.

8) After the last wash, embryo/s must be examined microscopically at 50X magnification to ensure the zona pellucida is intact and free from any adherent material.

9) Identification of frozen embryo/s must meet international standards as outlined in the *IETS Manual*.

10) Embryo/s are to be frozen in such a manner to minimise holding time in media.

11) The embryo/s are to be stored in a new or a sterilised lockable canister, under the supervision of the Approved ETV.

12) Storage of embryo/s is subject to annual inspection by a Department of Agriculture, Water and the Environment auditing veterinarian unless shorter intervals are stipulated by the importing country.

Figure 10 Important points for embryo processing

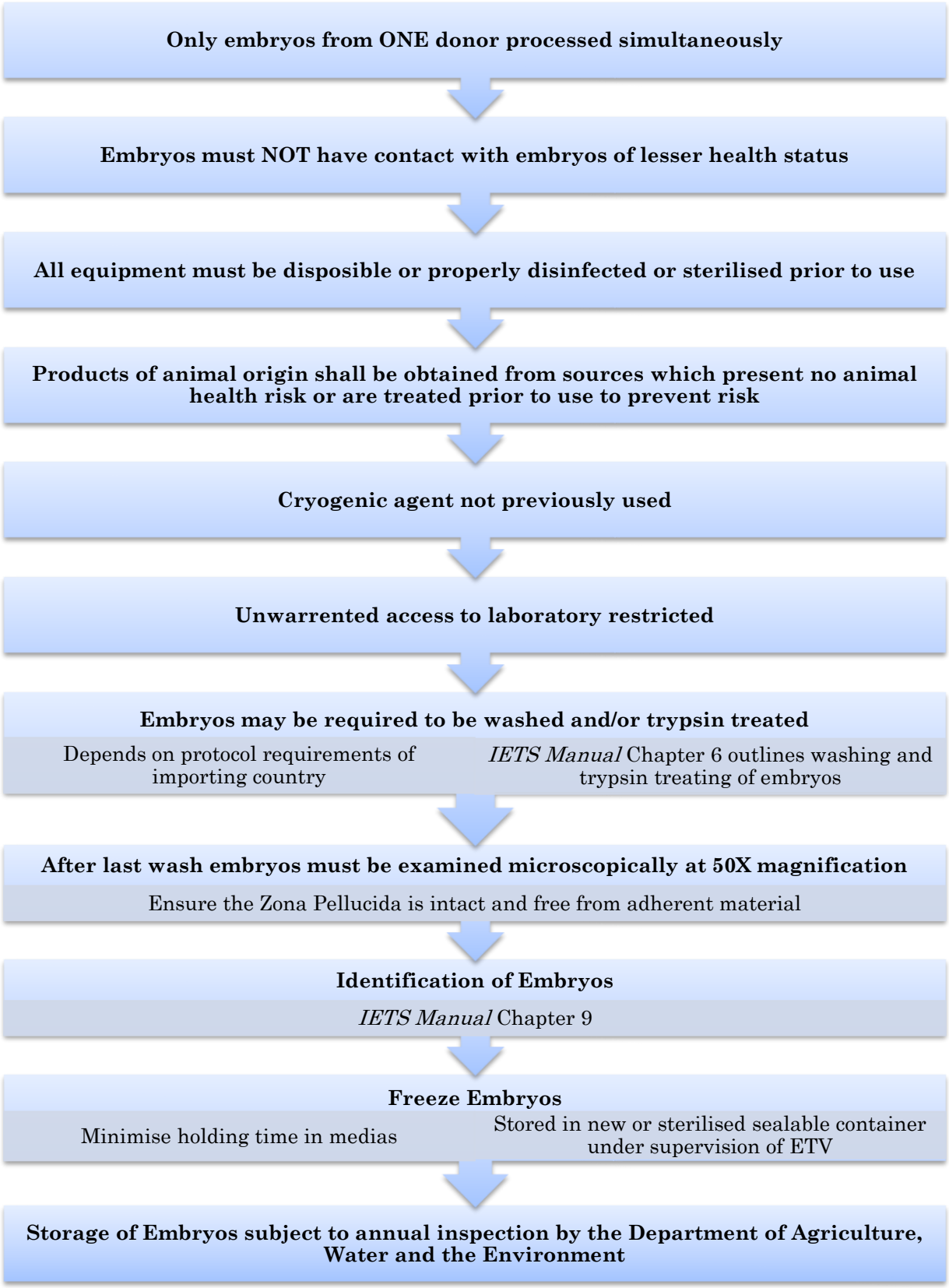
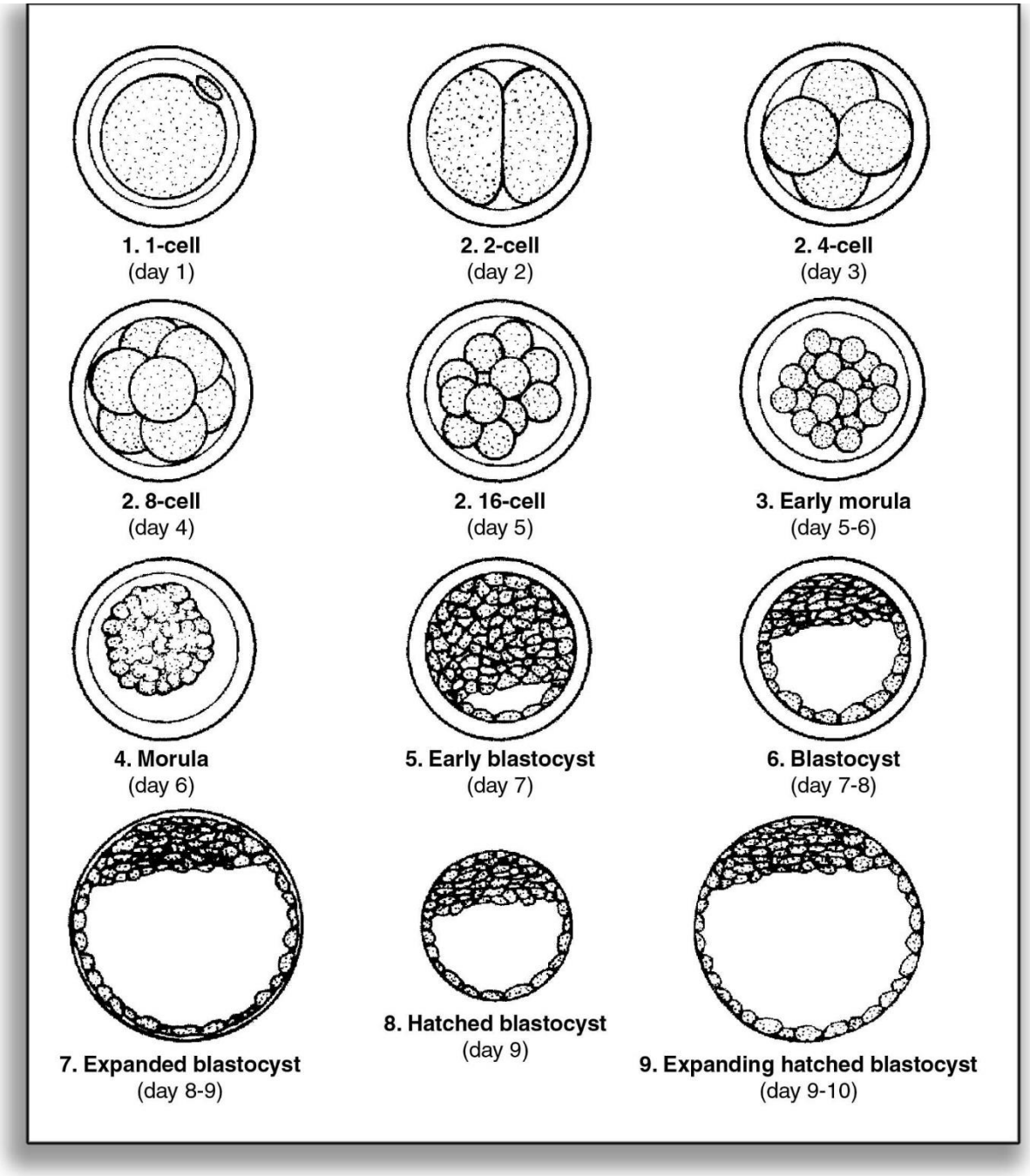


Figure 11 IETS embryo identification



Source: IETS Manual, Chapter 9, current edition

11 Embryo identification

Clear and consistent embryo identification is one of the greatest concerns currently confronting the movement of embryo/s. The importance of the link between the embryo and its Health Certification, and between the embryo and its origin cannot be over stressed. The former link assures that the embryo has satisfied the requirements of the importing country as attested in the Health Certificate. The latter confirms the pedigree of the embryo and its eligibility for registration in the respective herd book/flock book.

The standardised system for labelling straws developed by the IETS has international acceptance and, unless otherwise specified by an importing country, is mandatory for any embryo/s certified for export from Australia.

Importing countries may have specific requirements such as identification of the country of origin of the embryo/s on the straw using three letters at the beginning of the code. The approved export ETV is responsible for identifying and complying with this requirement of embryo identification during the collection and processing procedures.

12 Storage and transport

1) Export embryo/s/ova should be frozen in sterile straws/ampoules in fresh liquid nitrogen.
2) Only embryo/s from the same donor should be stored together in the same straw.
3) Ampoules/straws must be sealed at the time of freezing and should be labelled according to the IETS Manual. The liquid nitrogen container should be sealed prior to being forwarded to Department of Agriculture, Water and the Environment.
4) Export embryo/s must be stored in sterilised, or new liquid nitrogen containers under strict hygienic conditions at a storage facility, approved by Department of Agriculture, Water and the Environment, where there is no risk of contamination.
5) Export embryo/s must be transported under hygienic conditions, in a lockable container and stored in an approved storage facility until their export; the serial number of the container must match the number on the Health Certificate.
6) An official government seal will be added after the pre-export inspection of the consignment, prior to export, and the seal number recorded on the Health Certificate.

13 Maintenance of samples

For all export collections, representative samples of collection fluids, washing fluids, degenerated embryo/s and unfertilised ova resulting from the activities of each approved export ETV, must be maintained for official, random examination for bacterial and viral contamination.

Such examination will be used as the basis for auditing the quality assurance program to confirm the efficacy of, and adherence to, established guidelines of the embryo washing procedures by an approved ETV and as a quality-control check.

For each category of sample or fluid, plastic cryotubes, or 0.25 ml or 0.5 ml straws should be filled to achieve the final volume required for each fluid category as outlined below. The straws or tubes must be labelled and preserved.

These samples must be identified in a manner similar to the embryo/s (with basic identification unit and freeze date). However, the unique straw number and number of embryo/s per straw will be replaced by the word "sample" for degenerated embryo/s and unfertilised ova. For collection liquids and washes, the terms "flush" and "washing" will be used.

All the samples must be stored at < 70°C until requested for analysis or authorised for destruction. The samples will be randomly selected by Department of Agriculture, Water and the Environment auditors for testing to confirm the absence of pathogenic organisms, the efficacy of the washing procedure and quality control. The Embryo Collection team is responsible for the cost of testing. The Department of Agriculture, Water and the Environment randomly select samples, from the inventory submitted by the embryo collection team, to be submitted to an accredited laboratory for the following testing:

- Aerobic bacterial culture
- Mycoplasma culture
- Virus isolation / PCR for pestivirus.

The Department of Agriculture, Water and the Environment may authorise the pooling of each sample type, that is all flush samples together, all wash samples together and all embryo/s/ova together.

Once the results of the quality control submissions have been reported, the Department of Agriculture, Water and the Environment will usually authorise the discarding of all remaining retained samples in the inventory up to and including the most recent collection date which has been screened.

Samples may also be requested by the importing country for courtesy testing associated with a specific export consignment.

13.1 Collection of fluid

Collection fluid is tested as it gives some indication of the disease agents to which the embryo(s) might have been exposed within the reproductive tract of the donor (i.e. it is an indicator of the health status of the donor). A minimum of 1 mL of collection fluid must be retained. Pathogens found in the collection fluid can be removed by the prescribed washing procedure.

13.2 Wash fluid

The rationale for testing the last few washes is that it provides some indication of what the recipient may be exposed to when the embryo is transferred. The last four washes (7, 8, 9 and 10) should be pooled and an entire volume of the last 4 washes must be retained.

13.3 Embryo/s and/or ova

Testing the degenerated embryo/s and unfertilised ova collected from a donor provides some indication of what the embryo/s have been exposed to and whether proper washing has been carried out. It is assumed that the health status of these embryo/s/ova represents the health status of the transferable embryo/s from the same donor.

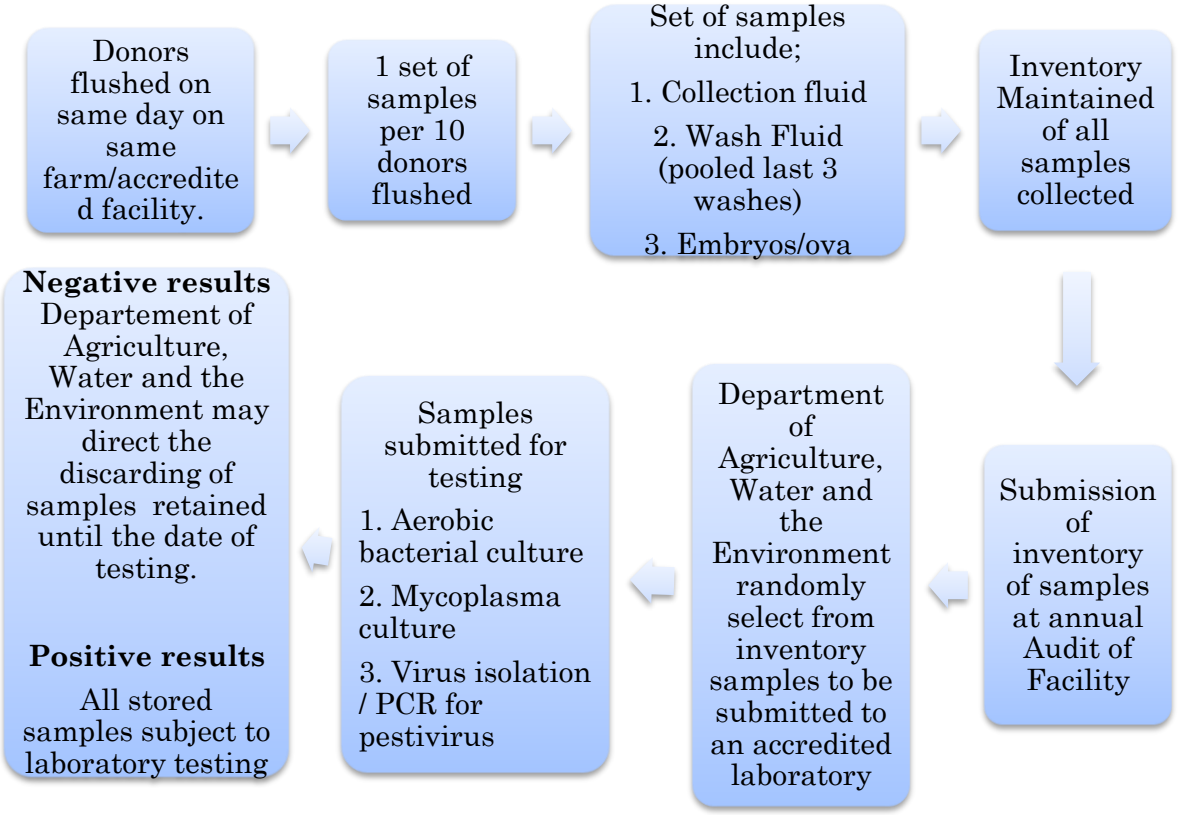
A maximum of three degenerated embryo/s and unfertilised ova collected should be preserved (where no degenerative or unfertilised ova are collected, at least one embryo must be kept for this purpose).

13.4 Sampling ratio

In order to prevent excessive costs of laboratory testing, statistically significant sampling is acceptable by Department of Agriculture, Water and the Environment. Following well documented procedures for collection and processing of embryo/s for export, and under Department of Agriculture, Water and the Environment auditor's discretion the following sampling procedure is recommended:

1) Only one random sample (1 collection fluid, 1 washing fluid and 1 degenerated embryo) is to be stored for up to 10 donors from collections carried out on the same day and at the same facility.
2) Every 2 years, from the stored samples inventory, the Department of Agriculture, Water and the Environment auditor, will select for laboratory testing:
    a) 3 samples out of 10
    b) 5 samples out of 20
    c) 7 samples out of 50
    d) 9 samples out of 75
    e) 10 samples out of 100 or more
3) The laboratory report of testing is to be submitted to the Department of Agriculture, Water and the Environment – ReproHUB team for review.
4) Negative Results to all of the tests performed on submitted samples: the Department of Agriculture, Water and the Environment Veterinary Officer will authorise all samples up to the date of testing to be discarded. Samples can only be discarded on receipt of authorisation in writing from the Department of Agriculture, Water and the Environment.
5) Positive Results to any of the tests performed on submitted samples: the Department of Agriculture, Water and the Environment will require each individual (stored) sample to be subjected to laboratory testing.

Figure 12 Maintenance of samples



Number of sample sets auditor will select;

a) 3 samples out of 10

b) 5 samples out of 20

c) 7 samples out of 50

d) 9 samples out of 75

e) 10 samples out of 100 or more

14 Record keeping

An approved export ETV must keep an inventory of all activities with respect to embryo collection and must retain the records for a period of two years following the export of the embryo/s.

The records must include:

1) the registered name and registration number, or identification equivalent, breed and age of the female from which embryo/s were recovered.
2) the property of origin certification, dates of commencement and completion of isolation of donors and dates of tests performed and the results of tests.
3) a record of insemination for each embryo recovery; this record will include the registered name, registration number, breed, and stud code of the male whose semen was used, along with the collection date, or freezing code.
4) records of dates and places of collection, processing and storage of embryo/s collected, as well as names of the team members.
5) identification of the embryo/s as established by the IETS.
6) a record of the number of transferable embryo/s recovered, including stage and grade as established by the IETS as well as the method used for washing the embryo/s.
7) the identification code of samples.
8) the inventory of frozen embryo/s with details of their disposition (location of storage, or export country).
9) copies of health certificates.

15 Department of Agriculture, Water and the Environment audits of ETV facilities/procedures

The Department of Agriculture, Water and the Environment's responsibility, with regard to export of embryo/s, is the provision of export health certification and export permits consistent with Australian legislation and importing country requirements. This responsibility is fulfilled by Department of Agriculture, Water and the Environment through setting technical standards and by auditing those standards.

A sound auditing mechanism is essential to maintain confidence in the approval program, and to monitor the performance of veterinarians and their teams engaged under this program. All areas of preparation of donor animals, collection, processing, and storage of embryo/s for export are subject to audit by the Department of Agriculture, Water and the Environment. An accredited facility will be audited at least annually (twice per year for facilities producing embryo/s for export to EU).

These visits may take the form of an audit of record keeping, embryo identification, laboratory facility and storage facility.

Department of Agriculture, Water and the Environment annual audit of facilities will examine:

1) If embryo/s collected for export originated from qualified donors.
2) If embryo/s were properly collected, examined, washed, stored, and identified.
3) If declarations provided by the Department of Agriculture, Water and the Environment Approved ETV conform to Department of Agriculture, Water and the Environment and importing country requirements.
4) Raw material control including quality control of raw materials and storage.
5) Process control including layout of establishment, analysis of production processes, embryo identification and traceability, and embryo failure procedures.
6) Finished product (embryo) control including storage, release procedures, control of product in transit, and product rejection log.
7) Cleaning and sanitation of equipment and the establishment including medical waste disposal procedures.
8) Pest control, including field and establishment
9) Inspection, measuring and testing equipment including equipment/instrumentation calibration and maintenance.
10) Quality records and documentation control including schedule of quality records, schedule of references, controlled documents and amendments.

15.1 Audits and quality assurance aspects

The third-party approval for ETVs operates as a compliance program. There are some issues which must be considered in this compliance program.

1) Department of Agriculture, Water and the Environment must be assured that the veterinarian is technically competent to carry out the complex procedures involved in the collection and processing of embryo/s for export.
2) The Department of Agriculture, Water and the Environment approved ETV and the facilities they supervise must demonstrate well documented work in relation to each stage of preparation of donors, collection and processing of embryo/s, transport and storage of embryo/s and certification of embryo/s for export.
3) The facilities must keep very good records in relation to the production of embryo/s for export for minimum two years after export.
4) Operational manual: The Department of Agriculture, Water and the Environment approved and accredited facilities, and the approved ETVs that supervise these facilities, must be able to prove that there is a quality system in place for their operations that will assure that only embryo/s which meet the Department of Agriculture, Water and the Environment export requirements, and therefore the importing country's requirements, will be produced and presented for export. The emphasis here is that the quality system for the operation is in place and working. The best and easiest method to ensure that this is the case is to develop operational manual.
    a) As an initial step in this process, the embryo collection team must follow standards of *IETS Manual* and *OIE Terrestrial Animal Health Code*. The manual and code are an effective working document for the team and is the basis on which Department of Agriculture, Water and the Environment audits the system.
    b) Guidelines for the Operational Manual are available in the Appendices of this document.

15.2 Department of Agriculture, Water and the Environment auditing of accredited facilities

1) This accreditation of facilities requires an annual audit, or two audits per year if the ETV is producing embryo/s for export to the EU.
2) There must be at least one audit of the facility before it can be accredited.
3) The audits (post-accreditation, annual) should be carried out at the base/office of the embryo collection team.
4) The other audits may be conducted at a mutually convenient location. Such audits may only be possible, subject to the Department of Agriculture, Water and the Environment auditor's discretion and only if the facility operates with an operational manual.
5) During the preparation for an embryo collection facility audit, auditors should familiarise themselves with details of the accreditation program, OIE Terrestrial Code and IETS standards. The Department of Agriculture, Water and the Environment has checklists for the departments representatives to use when auditing activities within the facilities under the supervision of an approved ETV.

6) During the audit, auditors must collect and analyse objective evidence that is relevant and sufficient to draw conclusions about the audited quality system. Auditors must maintain confidentiality and document their findings on their check list.

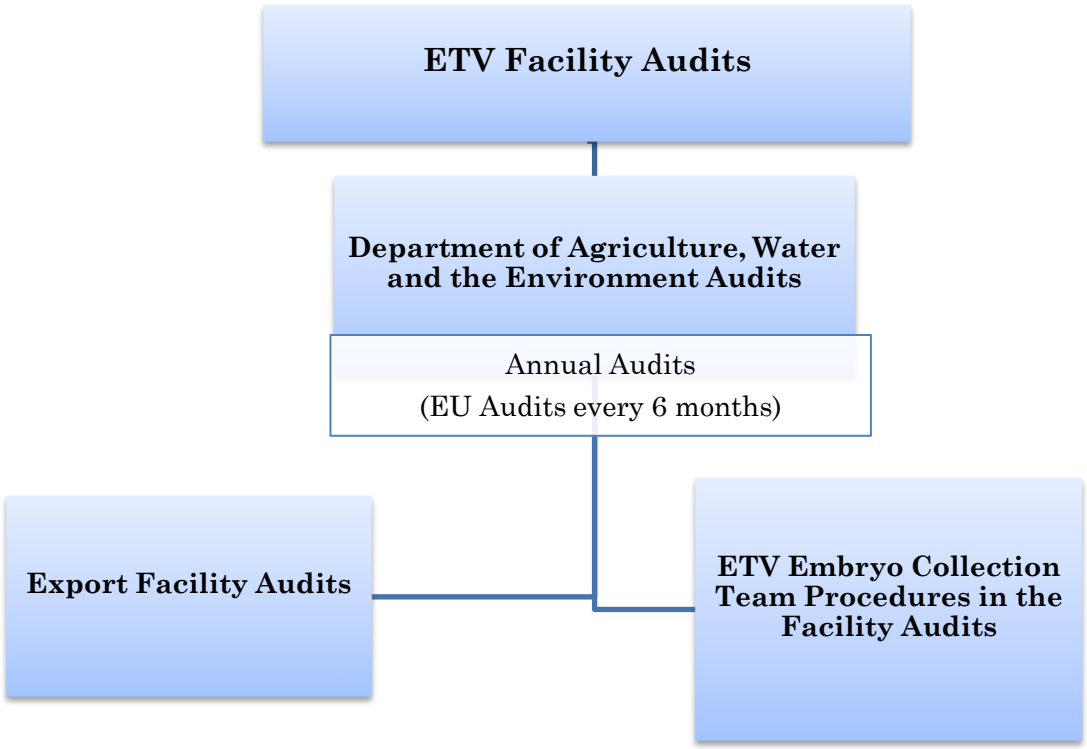
7) After the audit, auditors should prepare a report in which they will draw conclusions and recommendations regarding the accreditation of the audited embryo collection team.

8) The Department of Agriculture, Water and the Environment accredited export facilities under the supervision of approved ETVs will be charged a standard fee for service based on the time spent by an auditor for the preparation of the audit, the time of the audit itself and time spent for the preparation of the audit report.

15.3 Audit conclusion

1) Audits by the Department of Agriculture, Water and the Environment will be rated in 4 categories:
    a) Acceptable
    b) Minor defects
    c) Major defects
    d) Critical defects – critical non-conformity.
2) Following the completion of the audit, the auditor must write a report which will include:
    a) short summary of the audit
    b) discussion of advisory findings
    c) plan to deal with nonconformities and requested action
    d) any type of nonconformity which may undermine the program reportable to the Manager of Animal Programs Section.

Figure 13 Auditing ETV facilities



16 ETV technical management committee review of on-going approval

The review of an ETVs adherence to the on-going approval requirements is fulfilled by the ARV ETVTMC. They in-turn report back to the Department of Agriculture, Water and the Environment.

The approval of ETVs for the 3 year period is dependent on compliance to the annual audits of the facilities that the approved ETVs supervise and the audit of export consignment health certifications signed by approved ETVs.

16.1 ETVTMC review of ETV on-going approval requirements

The ETVTMC responsibility, with regard to the approval of ETVs, is to ensure ETVs maintain commercial expertise in embryo transfer in the species for which they are approved. This responsibility is fulfilled by the ETVTMC through setting on-going approval requirements and reviewing those requirements.

A sound reviewing mechanism is essential to maintain confidence in the expertise of the approved ETVs. On-going approval requires meeting the on-going approval requirements set by the ETVTMC in a triennial review of ETVs.

1) ETV On-going Approval requirements:
    a) **Registered Veterinary Surgeon** in the state/s with which the ETV practices. (Please note National recognition of Veterinary Registration may apply in some states).
    b) **IETS data submission:** Provide evidence to the Department of Agriculture, Water and the Environment of submission of IETS data. This data is to be provided to the IETS data retrieval committee and contains information on donors flushed and embryo/s collected/frozen/transferred for exportation and domestic use by the embryo collection team under their supervision. ETVs can directly access the IETS database to enter their data via www.iets.org/data-retrieval/. The IETS need to be contacted to obtain a login and password for the database. (Please note that IETS member login and password does NOT grant access to the database).
    c) **On-going competence requirements:** Approved ETV has supervised or conducted a minimum of 40 collections from bovine donors and processed 200 embryo/s in the past 3 years. For small ruminants the minimum number of embryo collections is 20 and the number of processed embryo/s is 100 in the past 3 years. These embryo/s do not need to be exclusively for export and can include the collecting and processing of embryo/s for immediate transfer, or the collecting and processing of embryo/s for cryo-preservation (domestic or export).
2) The approval of ETVs requires a review every 3 years.
3) The following reviews are carried out by the ETVTMC.

a) It is the responsibility of the approved ETV to submit their IETS data to the IETS data retrieval committee annually and to retain evidence of submission of the data.

b) At annual audits of facilities by the Department of Agriculture, Water and the Environment, or any time during the 3 years of approval, the approved ETVs must present annual evidence of submission of their retrospect ET data to the IETS data retrieval committee. The Department of Agriculture, Water and the Environment representative must sight this evidence then sign the Department of Agriculture, Water and the Environment approved ETV *IETS Data Submission Evidence Declaration* for the ETV.

c) The approved ETV must complete the on-going competence component on the *ETV on-going Approval Declaration*.

d) It is the responsibility of the approved ETV to submit their *ETV on-going approval declaration* with supporting documentation to the ETVTMC for review every 3 years via the AVA online learning management system.

4) After review, the ETVTMC will report to the Department of Agriculture, Water and the Environment the outcome of the approved ETV meeting the on-going approval requirements.

5) The ETV will be charged an On-going Approval fee by the AVA-ARV.

16.2 Review conclusion

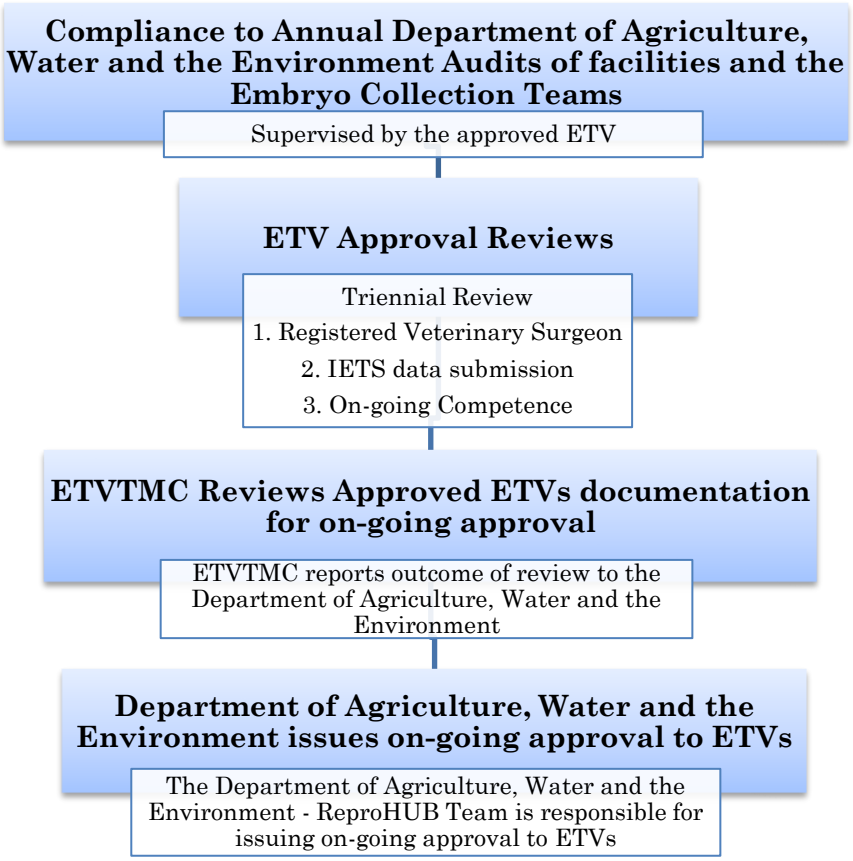
1) Review of on-going approval of ETVs by the ETV Technical Management Committee will be rated as ‘compliance’ or ‘non-compliance’.

2) Following the completion of the review the ETV TMC must report to the Department of Agriculture, Water and the Environment:

a) a summary of the compliance or non-compliance,

b) reasons for non-compliance and recommendations for on-going export approval of the ETV.

Figure 14 Review of ETV approval



17 Non-compliance

Defects may be identified during the annual audit or during on-going audits of documentation before export or during triennial review of the ETV on-going approval requirements.

17.1 Minor defects

A minor defect is any deviation from good practice which does not jeopardise program integrity.

Action: It will require written advice to the auditee with a request to improve current practices and the auditee must provide the auditors with an updated operational manual demonstrating how practices have been rectified to correct the minor defect.

17.2 Major defect – controllable noncomformity

A major defect is one where there is a major deficiency in a preparation procedure, deficiency in veterinary science application or record keeping, but which in the auditors opinion is not a deliberate attempt to compromise the integrity of the program, e.g.

- unsatisfactory submission of samples
- unsatisfactory description of samples
- major omission in record keeping
- major inaccuracy in record keeping

Action:

1) It is a defect which requires a full report to all parties involved in the accreditation of the facility and the approved ETV supervising the facility. The defect requires immediate rectification.
2) A request for corrective action must be issued by the auditor at the time of the audit.
3) The issue must be discussed with the approved ETV and all parties involved in the accreditation of the facility to ensure that the nonconformity is understood.
4) A deadline for rectification must be set and agreed.
5) A follow-up audit (additional audit) to check that the nonconformity has been rectified should be scheduled.
6) The additional audit will be conducted on a full cost recovery basis.
7) Continued non-compliance (finding of additional audit) will result in the approved ETV being excluded from the program and their approval terminated and the termination of the accreditation of the facility. The Department of Agriculture, Water and the Environment will notify the ARV ETVTMC of the termination of the ETVs approval

17.3 Critical defect – critical nonconformity

A critical nonconformity is one which in the opinion of the auditor has the potential to very seriously compromise the program or the accreditation facility or the approval of the ETV, including findings where there has been incompetence, malpractice, deceit or error resulting in or with the potential to cause the breakdown of the program's integrity e.g.

- non disclosure of positive test results
- substitution of animals or samples
- failure to keep essential records
- false certification and/or altered signature (different handwriting)
- failure to rectify previous major defects found at audit.

Action:

1) A critical nonconformity will result in a full investigation by the Department of Agriculture, Water and the Environment Compliance Branch with possible suspension or termination of the accreditation of the facility and the approval of the ETV
2) Pending the results of the Department of Agriculture, Water and the Environment Compliance investigation, the relevant State CVO and the relevant Veterinary Board must be notified. The Department of Agriculture, Water and the Environment will notify the ARV ETVTMC if the ETVs approval is terminated.

17.4 Non-compliance to on-going requirements

If the on-going approval requirements have not been met at the ETVTMC review of approved ETVs every 3 years;

Action:

1) A grace period of 12 months is allowed for the approved ETV to meet the on-going approval requirements (submission of IETS data and continued competency)
2) If evidence of meeting the on-going approval requirements are not submitted to the ARV ETVTMC within the grace period, the Department of Agriculture, Water and the Environment will be notified. The Department of Agriculture, Water and the Environment will terminate the ETVs approval.
3) On termination of the ETVs approval, in order for the veterinarian to be an Embryo Collection Team Veterinarian (approved ETV) the individual will need to re-submit an application and, complete the full examination and approval process.

List of appendices

1) ARV Application form for Department of Agriculture, Water and the Environment Embryo Transfer Veterinarian Approval (ETV)
2) ARV Application form for Department of Agriculture, Water and the Environment Embryo Transfer Approval (ETV) for an additional species
3) Model Worksheets for ETV Approval Application
4) IETS Freeze Code application form
5) Department of Agriculture, Water and the Environment ETV Declaration
6) ARV ETVTMC Pre-Approval Auditors Checklist
7) ARV On-going ETV Approval Documentation
8) IETS Data Retrieval Documents
9) Operational Manual Guidelines
10) Checklist for Approved Isolation Facilities

Glossary

Term	Definition
approved ETV	An embryo transfer veterinarian approved by the Australian Department of Agriculture to collect and process embryos for exportation.
ARV	Australian Reproduction Veterinarians – a special interest group within the AVA providing a link between members and government bodies, breed societies and the artificial breeding industry.
AVA	Australian Veterinary Association – the professional association representing veterinarians in Australia.
Embryo Collection Team	A team of adequately trained personnel in the techniques and procedures of embryo transfer which are under the direct supervision of a Department of Agriculture Approved ETV.
Embryo Transfer Veterinarian Technical Management Committee	Committee formed to provide assurances that those ETVs approved by the Australian Department of Agriculture have the knowledge and competencies in embryo and/or oocyte collection, handling, processing and testing procedures to meet those standrads set out in the OIE Terrestrial Code and IETS Manual.
ET	Embryo Transfer. In the context of this document it is defined as superovulation, collection and processing of embryos, which includes the evaluation and appropriae handling of embryos for immediate transfer and cryo-preservation.
ETV	Embryo Transfer Veterinarian.
ETVTMC	Embryo Transfer Veterinarian Technical Management Committee.
facility	A Department of Agriculture approved or accredited facility under the supervision of an approved ETV for the isolation of donros and collection of embryos for exportation.
IETS Manual	International Embryo Technology Society Manual with guidelines for general prodcedures for embryo transfer, minimum standards for hygienic handling of embryos and recommended standardisation methods of labelling of frozen embryos for the international trade of embryos.
IETS	International Embryo Technology Society (formerly the International Embryo Trasnfer Society). www.iets.org
MICOR	MICOR (Live Animals) is a Department of Agriculture website the sets out the known importing country requirements that Australian exporters must comply with to export animal reproductive material.
OIE	The World Organisation for Animal Health (OIE = Office International des Epizooties) www.oie.int
Processing Laboratory	A Permanent or Mobile Laboratory approved by the Department of Agriculture to process embryos for export.
ReproHUB	The Reproductive Material Import and Export Team Reproduction Hub is a team within the Australian Department of Agriculture's Veterinary Export and Meat Group. The team oversee the approval of ETVs and the approval and accreditation of facilities for the collection of embryos for exportation. The ReproHUB is responsible for reviewing approved ETVs certification documentation and preparing the final official export veterinary health certificate.
SIG	Special interest group within the Australian Veterinary Association (AVA).
Storage Facility	A Department of Agriculture approved facility to store embryos collected for export.