


15. Procuring, processing and transporting gametes and embryos

This guidance note contains:

 Refer to principles 3, 6, 7, 8, 10 and 11

Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

HFEA guidance

- Documented procedures: general ●
- Patient selection and procurement ●
- Home insemination ■
- Home procurement ●
- Reception at the centre ●
- Processing and disposal of gametes and embryos ●
- Packaging, distribution and recall of gametes and embryos ●■
- Quality and safety of gametes and embryos

● Section includes mandatory requirements

■ Section includes interpretation of mandatory requirements

Other legislation, professional guidelines and information



Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Requirements for holding a licence for gametes and embryo preparation processes

- 11 In respect of gametes and embryos preparation processes, licence conditions shall require compliance with—
- the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and
 - the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

Relevant provisions of the third Directive	
Reception of gametes and embryos at the tissue establishment	Annex II, Part A
Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating procedures)	Annex II, Part C
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F



Mandatory requirements (cont)

NOTE: Directive 2006/86/EC (the third Directive) implements Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

Directions

0001 – Gamete and embryo donation.

0009 – Keeping gametes and embryos in the course of carriage between premises

For a copy of the relevant Directions visit www.hfea.gov.uk



HFEA guidance

Documented procedures: general



Mandatory requirements

Licence conditions

- T70 There must be a documented system in place that ensures the identification of all gametes and embryos from procurement to use or disposal.
- T74 There must be a documented system in place for ratifying that gametes and/or embryos meet appropriate specifications of safety and quality for use and for their transportation/distribution.

15.1 The centre should, where appropriate, have documented procedures that cover:

- (a) superovulation
- (b) egg retrieval
- (c) sedation
- (d) resuscitation
- (e) sperm aspiration
- (f) gamete and embryo transfer
- (g) insemination
- (h) follow-up after treatment, including management of complications, and
- (i) management of ovarian hyper-stimulation syndrome.

See also guidance note:

- **31 – Record keeping and document control**



See also references to specific documented procedures in the following sections of this guidance note:

- [Home procurement](#)
- [Reception at the centre](#)
- [Processing and disposal of gametes and embryos](#)
- [Packaging, distribution and recall of gametes and embryos](#)
- [Quality and safety of gametes and embryos.](#)

Patient selection and procurement



Mandatory requirements

Licence conditions

- T49 The clinician responsible for the patient must document the justification for the use of their gametes or embryos created with their gametes in treatment, based on the patient's medical history and therapeutic indications.



Interpretation of mandatory requirements

15A

Procurement of gametes is a licensable activity which must be undertaken at licensed premises or in accordance with a third party agreement.

- 15.2** In addition to meeting the requirements in licence conditions, the centre should, at the time of procurement, label each package containing gametes and embryos in a way that is not susceptible to unauthorised or undetectable alteration. If the size of the packaging permits, the identity of the patient, patient's partner or donor should also be noted.
- 15.3** The centre should not obtain gametes for treatment from anyone under the age of 18 unless:
- those gametes are intended for the patient's own treatment or that of their partner
 - the centre can satisfy itself that the patient is capable of giving effective consent to the use of the gametes for that purpose, and
 - the patient has given effective consent to the use of their gametes for that purpose.

Home insemination



Interpretation of mandatory requirements

15B

The centre may supply cryopreserved sperm only to a person covered by a licence. Sperm supplied for home insemination must therefore be thawed or thawing. The use of a dry shipper or any other container that would preserve the sperm in a frozen or preserved state when it leaves the treatment centre is prohibited.

- 15.4** Sperm should be supplied for insemination at home (or another unlicensed site) only in exceptional circumstances. When this occurs, the treatment centre should:
- record this fact and explain the relevant exceptional circumstances in the medical records, and



15.4 (cont)

- (b) complete the relevant DI (Donor Insemination) treatment form in the usual way, except that the date of supply or posting should be entered as the date of insemination and a note made that the sperm was supplied for home insemination.

15.5 Provided that the woman has attended the treatment centre for assessment, sperm for insemination at home (or another unlicensed site) may be either handed to her in person or sent to her by courier.

See also:

- [DI Treatment Forms – available at www.hfea.gov.uk](http://www.hfea.gov.uk)

Home procurement



Mandatory requirements

Licence conditions

T68 Where the sperm is procured at home, the centre must record this in the gamete provider's records.

15.6 A centre should normally store or use only sperm that has been obtained directly from the provider, another licensed clinic or a centre with which the licensed centre has a transport arrangement, or that has been imported in line with HFEA Directions.

15.7 The centre may use sperm produced by a man at home (or another unlicensed site). The centre should follow protocols to ensure, as far as possible, that:

- (a) the identity of the sperm provider is confirmed
- (b) the sperm provider confirms he produced the sperm
- (c) the date and time of the sperm production is confirmed (and is no more than two hours before the centre received the sperm)
- (d) the sperm has not been interfered with, and
- (e) the sperm receptacle is clearly labelled with the sperm provider's full name and unique identifier.

The centre's documented procedures should ensure that this information is recorded in the patient's medical records.

15.8 If embryos have been created using partner sperm produced at home (or another unlicensed site) and donation is being considered, the centre should consider the fact that the sperm was not produced at a licensed treatment centre and tell prospective recipients.

15.9 The requirements for receipt from another centre also apply to sperm procured at home or another unlicensed site (see 'Reception at the centre' below).

See also guidance note:

- [16 – Imports and exports](#)



Reception at the centre

Mandatory requirements (cont)

Licence conditions

- T109 The centre must put in place, maintain and implement a procedure for the receipt of gametes and/or embryos from another centre or third party premises to ensure that:
- the consignment of gametes and/or embryos is verified against SOPs and specifications. These must include information relating to the transport conditions, packaging, labelling, patient/donor documentation, and any other associated documentation and samples. These must also include the technical requirements and other criteria considered by the establishment to be essential for the maintenance of acceptable quality, and
 - the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant patient/donor and procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.
- T110 The following data must be registered at the centre:
- consent including the purpose(s) for which the gametes and/or embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the consented purpose
 - patient/donor identification and characteristics: age, sex and presence of risk
 - all required records relating to the procurement and the taking of the patient/donor history
 - gametes and embryos obtained and relevant characteristics
 - the results of laboratory tests and of other tests, and
 - a properly documented review of the complete patient/donor evaluation against the selection criteria by an authorised and trained person.

15.10 In addition to the requirements in licence conditions, the documented procedures against which each consignment of gametes and embryos is verified should include requirements for:

- patient, patient's partner and donor verification
- packaging and transport
- labelling of containers for procured gametes, and
- labelling of shipping containers and any associated documents.

15.11 The documented procedure for the receipt of gametes or embryos from another centre should also ensure that records are kept to demonstrate that before gametes or embryos are released, all appropriate specifications have been met.

15.12 The centre's documented procedures should ensure that the relevant legal requirements are met for registering patients, patients' partners and donors.



Processing and disposal of gametes and embryos



Mandatory requirements

Licence conditions

- T72 The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.
- T73 Before implementing any significant change in processing, the modified process must be validated and documented.

15.13 The centre should take account of the special status of the human embryo when the development of an embryo is to be brought to an end. Terminating the development of embryos and disposing of the remaining material should be approached with appropriate sensitivity, having regard to the interests of the gamete providers and anyone for whose treatment the embryos were being kept.

See also guidance note:

- **10 – Embryo testing and sex selection**

Packaging, distribution and recall of gametes and embryos



Mandatory requirements

Licence conditions

- T105 All gametes and embryos must be packaged and transported in a manner that minimises the risk of contamination and preserves the required characteristics and biological functions of the gametes or embryos. The packaging must also prevent contamination of those responsible for packaging and transportation.
- T106 The packaged gametes/embryos must be shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos.
- T107 The transport conditions, including temperature and time limit, must be specified and the labelling of every shipping container must include as a minimum:
- a label marked “TISSUES AND CELLS” and “HANDLE WITH CARE”
 - the identification of the establishment from which the package is being transported (address and telephone number) and a contact person in the event of problems
 - the identification of the tissue establishment of destination (address and telephone number) and the person to be contacted to take delivery of the package
 - the date and time of the start of transportation.
 - the type of gametes/embryos plus their identification code
 - specifications concerning conditions of transport relevant to the quality and safety of the gametes or embryos
 - specifications concerning storage conditions such as “DO NOT FREEZE”



Mandatory requirements

T107 (cont)

- h. in the case of all gametes and embryos, the following indication: “DO NOT IRRADIATE”, and
- i. when a product is known to be positive for a relevant infectious disease marker, the following indication: “BIOLOGICAL HAZARD”.

If any of the information under the points above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. The sheet must be packaged with the primary container in a manner that ensures that they remain together.

T108 The container/package must be secure and ensure that the gametes or embryos are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.



Interpretation of mandatory requirements

15C

When a third party transports gametes or embryos, they must be subject to a third party agreement, and a documented agreement must be in place to ensure that the required conditions are fulfilled.

The centre originating the distribution must have a recall procedure that defines the responsibilities and actions required when a distribution is recalled. Such a recall should be investigated using the procedure for investigating adverse incidents. There must be a procedure for handling returned gametes and embryos that includes their reacceptance into the inventory, if applicable.

15.14 If a container used to ship packaged gametes or embryos has not been validated by the manufacturer or supplier for specified transport conditions, these conditions should be monitored during transport, or validated by the centre or third party responsible for transport.

15.15 The centre's documented procedures should ensure that the following are recorded:

- (a) packaging and labelling procured gametes for distribution
- (b) transporting gametes and embryos
- (c) labelling shipping containers, and
- (d) recalling gametes and embryos.

See also guidance notes:

- [24 – Third party agreements](#)
- [27 – Adverse incidents](#)

Quality and safety of gametes and embryos

15.16 The centre should establish and use documented procedures to ensure that:

- (a) procedures involving the manipulation of gametes or embryos (for example, sperm preparation, separation of eggs from cumulus cells, and fertilisation of eggs) are performed in a controlled environment with appropriate air quality
- (b) the risk of bacterial or other contamination is minimised
- (c) appropriate measures are in place for handling contaminated samples



15.16 (cont)

- (d) gametes or embryos are handled in a way that protects those properties that are required for their ultimate clinical use
- (e) where permitted, the mixture of gametes or embryos that have been subject to different laboratory procedures before transfer (eg, IVF and ICSI) is recorded and the reasons for their mixture are clearly set out, and
- (f) all blood products with which gametes or embryos may come into contact, except those of the woman receiving treatment, are pre-tested for HIV, hepatitis B and hepatitis C.

15.17 If it is impractical to carry out a procedure involving the manipulation of gametes or embryos in a Grade C environment, it should be done in an environment of at least Grade D air quality. If the environmental air quality drops below Grade D during a procedure involving the manipulation of gametes or embryos, those gametes or embryos should be used in treatment only if the centre can assure itself that this poses no extra risk to the woman to be treated or to any resulting child.

15.18 Air quality monitoring should be used as a routine measure of quality assurance (for example, through particle counts or the use of settle plates, recording any cultures observed). The process of validating air quality should include:

- (a) documenting culture conditions, and
- (b) mapping temperature and using control charts to predict the effects of any change in procedures.

15.19 Where possible, cryopreserved gametes should be accompanied by documents that indicate their expected post-thaw quality.

15.20 The centre should not use for treatment gametes or embryos exposed to a material risk of contamination or damage that may harm recipients or resulting children. If in any doubt about these risks, the centre should seek expert advice.

See also:

- [HFEA Summary of air quality information, 2006](#)
You can find these forms at www.hfea.gov.uk



Other legislation, professional guidelines and information

- Rules and Guidance for Pharmaceutical Manufacturers and Distributors (2002).