

HFEA Standards for Assisted Conception Centres

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0 Introduction

These Standards for Assisted Conception Centres, (the term 'Centre' is synonymous with the term 'Tissue Establishment' used in the Directive¹), have been drafted collaboratively by the professional bodies of the assisted conception sector and the HFEA. These Standards represent an approach that involves

- a rationalisation of statutory requirements with best practice guidelines from professional bodies
- HFEA setting standards in partnership with the professional bodies

The Standards fulfil two principal objectives to provide

- a common set of requirements applying across all ART disciplines upon which compliance with legal requirements can be based
- a framework for managing quality that enables continuous improvement in the services provided to the users

and set a common language in which terms such as 'quality policy' have a clearly understood shared meaning.

The Standards are structured to follow a quality management system model, and detail the measures necessary to demonstrate compliance with legal requirements. Best practice measures agreed by the professional bodies are also incorporated. Further professional guidelines are referred to in ANNEX A.

The Standards are regularly reviewed and amended in light of experience to keep pace with developments in clinical practice and changing legislation.

1 Scope and purpose

1.1 Scope

In April 2006 the European Tissues and Cells Directive came into force, and HFEA inspections under the Directive will start from April 2007. The Standards incorporate the technical requirements of the Directive and set out the measures that Centres must meet or address.

Compliance with these Standards requires a knowledge of those professional guidelines that are specific to individual disciplines and relevant legislation (e.g. health and safety) (see ANNEX A) and guidance on topics such as consent to examination and treatment and information for users. (www.hfea.gov.uk).

The Standards are designed to be comprehensive but at a level of detail that takes account of the variation between the different types of service provided by Centres.

Standards relating to licensed research projects will be produced at a later date.

1.2 Purpose

The Standards are intended to help Centres comply with the Tissue Directive and the Human Fertilisation and Embryology (HF&E) Act and to assist them in preparing for an HFEA inspection or during self-inspection/internal audit. The application of the quality management system to assisted conception services supports the drive towards continual improvement and a consistency across the sector.

¹ Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004

The Standards will also be used by the HFEA to form a key part of the inspection process. HFEA Inspectors and External Advisors will use the standards to assess compliance against the Tissue Directive.

2 Source references

The following references are the source material used in the preparation of these Standards;

- a) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- b) Implementing Directive 2006/17/EC of the European Parliament and of the Council of 8 February 2006 as regards certain technical requirements for the donation, procurement and testing, of human tissues and cells
- c) Draft Implementing Directive 200X/XX/EC of the European Parliament and of the Council of XX Xxx 200X as regards certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells
- d) Human Fertilisation and Embryology Act 1990
- e) ISO 9001:2000 Quality management systems - Requirements
- f) ISO 9000:2000 Quality management systems – Fundamentals and vocabulary
- g) ISO 15189: Medical laboratories-Particular requirements for quality and competence

3 Terms and definitions

For the purposes of these Standards, when available the terms and definitions given in ISO 9000:2000 are used and identified with a reference, e.g. ISO 9000:2000 3.2.3. Additional definitions are based upon the EC Directives. On occasion, explanatory notes have been added to facilitate understanding of the terms and definitions. Where similar terms are used in ISO 9000 and the EC Directives explanatory notes have been added to clarify or highlight a relationship.

3.1 Centre

In these Standards, the term 'Centre' is used in two ways, that are distinct but complimentary, firstly as a 'legal entity', and secondly as an 'organisation'

an establishment licensed under the HFE Act and European Tissues and Cells Directive. The Centre may contain a number of departments within the same premises, and may include satellite or transport units on a different site.

NOTE Such an establishment is referred to in the EC Directive as a 'tissue establishment' which is defined as 'a tissue bank or unit or a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells'

a group of people and facilities with an arrangement of responsibilities, authorities and relationships (ISO 9000:2000 3.3.1)

3.2 Centre management

group of people (that includes the Person Responsible) who direct and control a Centre at the highest level.

NOTE The term 'Centre management' can also be considered equivalent to the term 'top management'. 'Top management' is defined in ISO 9000 as a 'person or group of people who direct and controls an organisation at the highest level'

3.3 competence

demonstrated ability to apply knowledge and skills (ISO 9000:2000, 3.9.12).

NOTE The term competence can be applied both to an individual or to an organisation, thus an individual can be competent to perform a particular task and an organisation such as an assisted conception centre can be competent to fulfil the requirements of these Standards by virtue of having the necessary capability

3.4 continual improvement

reoccurring activity to increase the ability to fulfil requirements (ISO 9000:2000 3.2.13)

NOTE These ongoing activities in the Assisted Conception Centre involve establishing objectives and quality indicators and using evaluation activities including audit findings and user satisfaction surveys, management reviews and other means, to find opportunities for improvement that may require corrective or preventative action.

3.5 distribution

transportation and delivery of reproductive tissues intended for human application

3.6 donor

a person providing sperm, eggs or resulting embryos to a third person where the donor is not the legal parent of any resulting child.

3.7 evaluation

processes that assess fulfilment of specified requirements

NOTE 1. the 'processes' may include assessment of user satisfaction, monitoring and resolution of complaints, staff suggestions, internal audit of the quality management system and assisted conception processes, participation in inter Centre comparisons and external reviews

NOTE 2. the 'requirements' include the requirements of this Standard and those specified by management in order to ensure that the needs and requirements of the user are met.

3.8 nonconformity

non-fulfilment of a requirement (ISO 9000:2000 3.6.2)

NOTE In the context of a Centre, any failure to protect the quality and safety of gametes or embryos during donation, procurement, testing, processing, preservation, storage and distribution processes would be regarded as major 'nonconformity' requiring immediate investigation and corrective action (see 3.16 serious adverse event and 3.17 serious adverse reaction).

3.9 patient

person or individual who is being treated within the Centre with their own gametes and either their partner's or a donor's gametes, where the patient is to be the legal parent of any resulting child.

3.10 patient partner

person or individual who is being treated with the patient and who will be the legal parent of any resulting child

3.11 procedure

specified way to carry out an activity or process (ISO 9000:2000 3.4.5)

NOTE 1. In the context of these Standards where 'procedure(s)' is prefixed as a 'documented', it means that the procedure is established, documented, implemented and maintained. The term 'documented procedure' can include a manufacturer's or supplier's guide, handbook, or instructions or other documentation provided that it is subject to document control

NOTE 2. The term 'standard operating procedures, SOPs' used in the EC directive is synonymous with 'documented procedure' and is defined as 'written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product'. The term 'documented procedure' is used in these Standards

3.12 process

Set of interrelating or interacting activities which transform inputs to outputs (ISO 9000:2000, 3.4.1).

NOTE The ISO definition embraces all types of process whereas the term 'processing' used in the EC Directive is limited to 'all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human application'.

3.13 procurement

process by which gametes or embryos are made available.

3.14 quality

degree to which a set of inherent characteristics fulfils requirements (ISO 9000:2000 3.1.2)

NOTE The designation of a product or service as a 'quality' product or service is judged on the basis of whether its 'inherent characteristics' meet the needs and 'requirements' of the user. For example, if the 'requirements' of the user for information regarding the Assisted Conception Centre (the Centre) were to include clarity of expression and availability in a particular language, then if the information provided has those requirements as 'inherent characteristics' then it would be judged as quality information and 'fit for purpose'.

3.15 quality management system

management system to direct and control an organisation with regard to quality (ISO 9000:2000 3.2.3)

NOTE 1. A management system is defined in ISO 9000 as a 'system to establish policy and objectives and to achieve those objectives'

NOTE 2. The EC Directive uses the term 'quality system' and defines it as 'the organisational structure, defined responsibilities, procedures, processes and resources for implementing quality management, including all activities which contribute to quality, directly or indirectly'. This definition indicates that every process and activity that takes place in the Centre is an integral part of the quality management system

3.16 quality policy

overall intentions and direction of an organisation related to quality as formally expressed by management (ISO 9000:2000 3.2.4)

NOTE A quality policy statement defines or describes an organisation's intentions and commitment to quality and provides a framework for setting quality objectives and planning.

3.17 record

document stating results achieved or providing evidence of activities performed (ISO 9000:2000 3.7.6)

NOTE Records provide the evidence that is required by the Centre to investigate any nonconformities that arise and also the evidence required by the HFEA to assess a Centre's conformity with these Standards.

3.18 requirement

need or expectation that is stated, generally implied or obligatory (ISO 9000:2000 3.1.2)

NOTE A requirement is a need, expectation or obligation that can be stated or implied by the Centre, its users or by an interested party such as the HFEA. For example, a stated Centre requirement in

relation to its staff might be that they read the Health and Safety Handbook, a generally implied user expectation might be to be treated in a considerate and sympathetic manner and an obligatory HFEA requirement would be that the Centre operates in conformity with these Standards.

3.19 serious adverse event

an untoward occurrence associated with the procurement, testing, processing, storage and distribution of gametes and embryos that might lead to the transmission of a communicable disease, to death or life-threatening, incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity

NOTE Any type of gamete or embryo misidentification or mix up shall be considered to be a serious adverse event

3.20 serious adverse reaction

an unintended response, including a communicable disease, in a patient or donor associated with the procurement or human application of gametes and embryos that is fatal, life-threatening, disabling, incapacitating or which might result in, or prolongs, hospitalisation or morbidity'

NOTE All centres licensed under the European Tissue and Cells Directive are required to report adverse incidents as defined in the HFEA Code of Practice. Adverse incidents are defined as any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or staff at a licensed centre. All breaches of the HFE Act and/or failure to follow the HFEA Code of Practice must be reported as adverse incidents to the HFEA. The HFEA will also investigate patient complaints that relate to adverse incidents.

3.21 third party

person or entity which provides a product (a service, software, hardware or materials) to the Centre that has the potential to affect the quality and safety of gametes or embryos

NOTE The term 'Third party' can also be considered equivalent to the term 'supplier' which defined in ISO 9000 as an 'organisation or person that provides a product *or service*'

3.22 traceability

ability to trace the history, application or location of that which is under consideration (ISO 9000:2000 3.5.4)

NOTE Traceability is defined in the EC Directive as 'the ability to locate and identify the tissue/cell during any step from procurement, through processing, testing, storage, to distribution to the recipient or disposal, which also implies the ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the recipient(s); traceability also covers the ability to locate and identify all relevant data relating to the products and materials coming in contact with those tissues/cells'

3.23 user satisfaction

user's perception of the degree to which the user's requirements have been met

NOTE This definition is based upon the definition of 'customer satisfaction' defined in ISO 9000:2000 3.1.4 as 'customer's perception of the degree to which the customer's requirements have been met'. In these Standards the customer is referred to as a 'user'. The user can be a patient, a donor, a recipient of donations or persons undergoing treatments using their own gametes.

3.24 validation

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled (ISO 9000:2000 3.8.5)

NOTE Validation is defined in the EC Directive as 'establishing documented evidence that proves a high degree of assurance that a specific process, SOPs, equipment or environment will consistently

produce an outcome meeting its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use'.

3.25 verification

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled (ISO 9000:2000 3.8.4)

NOTE The term verification is used, for example in the context of the 'receipt of reproductive tissue by the Centre', to mean that on receipt that the specified requirements for the reproductive tissue and the accompanying documentation are met.

4 Organisation and management responsibility

4.1 Organisation

4.1.1 General

The Assisted Conception Centre (hereinafter referred to as 'the Centre') shall be licensed by the HFEA and Centre management shall ensure it has an organisational structure and operational procedures appropriate to the activities for which it is licensed.

The organisational structure shall facilitate the creation of an environment in which all medical, nursing, scientific, counselling and other staff, are fully involved in order that the quality management system can work effectively, and the requirements of these Standards are met.

Centre management, or the parent organisation, shall appoint a responsible person (referred to hereafter as the 'Person Responsible') (4.1.2) subject to approval by the HFEA, and ensure that the Centre has access to a nominated medical practitioner and scientist to take professional responsibility for clinical and scientific activities.

4.1.2 Person Responsible

The Person Responsible shall at least fulfil the following conditions and have the following qualifications

- a) possession of a diploma, certificate or other evidence of formal qualifications in the field of medical, biological sciences or professional healthcare awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned,
- b) at least two years' practical experience in the relevant fields.

The Person Responsible shall have responsibility for:

- a) ensuring that the gametes and embryos intended for human application in the Centre are procured, tested, processed, stored and distributed in accordance with the EC Directives and the H F & E Act,
- b) providing information to the HFEA regarding substantial changes to its activities and seek prior written approval of such changes,
- c) notifying the HFEA of any adverse incidents and providing a report analysing the cause and the ensuing outcome,
- d) reporting annually to the HFEA, the activity of the Centre, including types and numbers of treatments, number of embryos used in each treatment episode and the fate of disposed gametes and embryos,

The Centre shall provide information to the HFEA concerning the proposed Person Responsible. Where the Person Responsible is permanently or temporarily replaced, the Centre shall immediately inform the HFEA of the name of the new proposed Person Responsible for approval.

4.1.3 Legal entity

The Centre or the organisation of which the Centre is a part shall be an entity that can be held legally responsible for its activities.

4.1.4 Integrity

Centre management shall have in place arrangements to ensure that there is no involvement in any activities that would diminish confidence in its competence, impartiality, judgement, or operational integrity.

4.2 Management responsibility

4.2.1 Management commitment

Centre management (including the Person Responsible) shall demonstrate its commitment to the establishment and maintenance of the quality management system (5.0) and the improvement of its effectiveness by:

- a) communicating to Centre personnel the importance of the needs and requirements of users and of fulfilling statutory and regulatory requirements (4.2.2),
- b) establishing the quality policy (4.2.3),
- c) ensuring that quality objectives are established (4.2.4),
- d) defining responsibilities, authorities and reporting relationships and establishing appropriate internal communication within the Centre (4.2.5),
- e) appointing a quality manager (4.2.6),
- f) conducting management reviews (4.2.7),
- g) the establishment and review of contracts with third parties (4.2.8),
- h) ensuring the availability of resources (6.1).

4.2.2 Needs and requirements of users

Centre management shall ensure that the assisted conception services provided are designed to meet the needs and requirements of the users (see also 4.2.8 Establishment and review of contracts, 8.2.1 Assessment of user satisfaction and 8.2.2 Monitoring and resolution of complaints).

4.2.3 Quality policy

Centre management shall ensure that the quality policy includes a commitment:

- a) to the provision of a service that meets the needs and requirements of the users,
- b) to meet the requirements of these Standards and to the continual improvement of the effectiveness of the quality management system,
- c) to good professional practice,
- d) to the health, safety and welfare of all staff and visitors to the Centre.

The quality policy shall be signed and issued by a person with appropriate authority, be communicated, understood and available throughout the Centre, and reviewed for continuing suitability.

4.2.4 Quality objectives and plans

Centre management shall establish documented quality objectives, including those needed to meet the needs and requirements of the users that are measurable and consistent with the quality policy.

Centre management shall have plans to achieve and maintain its quality objectives. The objectives and plans shall be regularly reviewed.

4.2.5 Responsibility, authority and communication

Centre management shall ensure that responsibilities, authorities and reporting relationships are defined, presented in an organisational chart and communicated within the Centre.

Centre management shall ensure that communication processes are established that include communication regarding the effectiveness of the quality management system and the service provided to users.

4.2.6 Quality manager

Centre management shall appoint a quality manager who, irrespective of other responsibilities, shall have designated responsibility and authority that includes

- a) ensuring that the quality management system is implemented and maintained,
- b) reporting to Centre management on the functioning and effectiveness of the quality management system, and
- c) coordinating awareness of users needs and requirements.

NOTE 1. The quality manager should have responsibility for the establishment and maintenance of the quality management system but not for all the tasks involved.

NOTE 2. The quality manager may be engaged full or part time in quality management and may or may not have other responsibilities and can be external to the Centre.

4.2.7 Management review

Centre management shall conduct a regular review of the Centre's quality management system and all its services. The review shall assess the need for changes to the quality management system and opportunities for improvement.

NOTE The minimum interval between management reviews should be twelve months but shorter intervals should be adopted when a quality management system is being established.

The review shall include, but not be limited to, consideration of changes in the volume and scope of work, personnel, premises, and the performance of third parties (suppliers) that could affect the quality management system or the service provided to users and the results of the following ongoing evaluation and improvement activities

- a) assessment of user satisfaction (8.2.1),
- b) monitoring and resolution of complaints (8.2.2),
- c) staff suggestions (8.2.3),
- d) internal audit of all elements of the quality management system, including the assisted conception processes (8.2.4),
- e) participation in inter-Centre comparisons and inter-laboratory comparisons (8.2.5),
- f) quality indicators for monitoring the Centre's performance in patient care,
- g) external reviews (8.3),
- h) identification, investigation, control, recording and notification of serious adverse events and reactions (8.4),
- i) results of continual improvement (8.5.1) including current status of corrective and preventive actions (8.5.2 - 8.5.3).

The results of the management review shall be recorded and include the decisions and actions related to improvement of the quality management system and the services provided to users and consequent resource implications.

Centre personnel shall be informed of the results of the management review.

4.2.8 Establishment and review of contracts with third parties

Centre management shall establish documented agreements with third parties when an activity takes place which has the potential to influence the quality and safety of gametes and embryos procured or processed and in particular where

- a) the Centre entrusts one of the stages of gamete or embryo processing to a third party,
- b) a third party provides goods or services that affect gamete or embryo quality and safety, including the process of distribution,
- c) the Centre provides services to another centre that is not licensed,
- d) the Centre distributes gametes or embryos processed by third parties.

Centre management shall evaluate and select third parties on the basis of their ability to meet the requirements of these Standards

The Centre shall keep a complete list of the agreements established with third parties and the agreements shall specify the responsibilities of the third parties and any agreed procedures. Copies of these agreements shall be made available to the HFEA upon request

Centres that import gametes and embryos from a country outside the EU shall ensure, where appropriate with the assistance of the HFEA, that such imports meet the quality and safety requirements set out in these Standards. Similar requirements shall apply where the Centre exports gametes or embryos to a country outside the EU.

Centres must make arrangements to ensure that, in the event of termination of activities for whatever reason, stored samples, gametes and embryos shall be transferred to other licensed Centres.

5 Quality management system

5.1 General requirements

The Centre shall establish a quality management system and continually improve its effectiveness in accordance with the requirements of these Standards.

The Centre shall

- a) identify the processes needed for quality management activities, provision and management of resources, assisted conception processes, evaluation and continual improvement and the interaction between them,
- b) ensure that the resources and information necessary to support the operation and monitoring of these processes are available and
- c) implement actions necessary to ensure the effectiveness and continual improvement of these processes.

NOTE the EC Directive requires that all 'critical' activities (processes) shall be identified and all materials, equipment and personnel involved in such processes documented. Critical is defined as 'potentially having an effect on quality and/or safety or having contact with *gametes or embryos*'. These Standards are based on the recognition that all the activities/processes defined in 5.1 a), have such potential and require to be documented according to the requirements of these Standards.

5.2 Documentation requirements

5.2.1 General

The Centre shall have quality management system documentation that includes

- a) a quality policy (4.2.3), and quality objectives and plans (4.2.4) and
- b) a quality manual (5.2.2),

- c) the documented procedures (see 3.8 NOTES 1 and 2) required by these Standards,
- d) documents needed to ensure the effective planning, operation and control of its processes, and
- e) records required by these Standards (5.2.4).

NOTE 1. The extent of the quality management system documentation can differ from one organisation to another due to;

- a) the size of the Centre and type of activities
- b) the complexity of the processes and their interactions,
- c) and the competence of the personnel.

NOTE 2 The documentation can be in any form or type of medium providing it is readily accessible

The Centre shall ensure that all documentation is available for inspection by the HFEA

5.2.2 Quality manual

The Centre shall establish and maintain a quality manual that includes

- a) a brief description of the Centre, including its legal identity, and the scope of the services provided,
- b) the quality policy (4.2.3) or makes reference to it,
- c) an organisational chart with accompanying text, that indicates responsibilities, authorities and reporting relationships within the Centre and its place in any parent organisation,
- d) an outline of the processes and documentation established for the quality management system.

5.2.3 Document control

The Centre shall establish a documented procedure to control all documents (internally generated and from external sources) required by the quality management system. This procedure shall ensure that

- a) documents are approved by authorised personnel prior to use,
- b) documents are regularly reviewed, revised as required and re approved,

NOTE Review, revision and re-approval should be conducted at a frequency that ensures that they remain 'fit for purpose'. The minimal interval between reviews should be twelve months

- c) documents are uniquely identified; identification shall include, a unique identifier, the edition or current revision date, or revision number, the number of page/total number of pages (where applicable), authority for issue, and author identification,
- d) documents remain legible and readily retrievable,
- e) there is a register of current approved versions and their distribution to ensure that only current versions are in use.

The Centre shall determine with regard to the needs of the service and in accordance with current legislation, regulations and guidelines, the appropriate retention times for documents removed from use.

Records are a special type of document and shall be controlled according to the requirements given in 5.2.4.

NOTE 1. When a Centre's documentation control system allows for the amendment of documents by hand pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialled and dated, and a revised document is re-issued as soon as practicable

NOTE 2. A document is any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts,

posters, notices, memoranda, software, drawings, plans, and documents of external origin such as regulations, standards or procedures.

5.2.4 Control of records

The Centre shall establish a documented procedure to control all records required to provide evidence of conformity to requirements of the Standards, to the effective operation of the quality management system and to the conduct of assisted conception processes. The procedure shall include the identification, collection, indexing, access, storage, maintenance, confidentiality and safe disposal of records.

The Centre shall determine with regard to the needs of the service and in accordance with current legislation, regulations and guidelines, the appropriate retention times for all records.

Records, including raw data, which are critical to the safety and quality of gametes and embryos, shall be kept in a manner that ensures access for 10 years after the expiry date, clinical use or disposal.

The records shall include the data necessary to ensure that all tissues and cells procured, processed, stored or distributed (on their territory) can be traced from patient's partner or donor to the patient and vice versa. This traceability shall also apply to all relevant data relating to the products and materials coming in contact with these tissues and cells (see also 7.3 Traceability and coding). Records that enable traceability shall be kept in a manner that ensures access for 30 years after clinical use or disposal.

NOTE 1. Access to registers and data shall be restricted to persons authorised by the Person Responsible and the HFEA for inspection purposes.

NOTE 2. Records can be in any form or type of medium providing they are readily accessible

NOTE 3. Records must be legible and indelible and may be hand-written or transferred to another system such as a computer or microfilm providing they are readily accessible

6 Resource Management

6.1 Provision of Resources

The Centre shall determine and provide the resources needed, in terms of personnel (6.2), facilities (6.3) equipment and materials (6.4) and data and information systems (6.5) to

- a) implement and maintain the quality management system and continually improve its effectiveness,
- b) enhance user satisfaction by meeting users needs and requirements and
- c) make appropriate arrangements for their management.

6.2 Personnel

6.2.1 General

The Centre shall have sufficient numbers of staff, with the competence to perform their assigned tasks, to ensure that the requirements of these Standards are met.

Personnel directly involved in activities relating to the procurement, processing, preservation, storage, and distribution of gametes and embryos shall, where appropriate, be registered in accordance with current national legislation and regulations.

NOTE see 7.7.1 for training of personnel engaged in procurement of gametes

Personnel whose assigned activities are not specifically detailed in the paragraph above shall nevertheless have the competence to undertake their assigned tasks

The Centre shall establish documented procedures for personnel management that ensure that all staff have

- a) job descriptions (6.2.5),

- b) initial basic training and update training (6.2.6),
- c) competence assessment (6.2.7),
- d) annual joint review (6.2.8),
- e) continuing education and professional development (6.2.9),
- f) personnel records (6.2.10),
- g) appropriate access to meetings and communications (6.2.11).

NOTE When the Centre is part of a larger organisation, where appropriate, some of these procedures may be undertaken by the personnel department of the parent organisation.

6.2.2 Conscientious objection

The Centre shall provide prospective employees with a full description of the Centre's activities and at interview draw their attention to the provision that any person who has a conscientious objection to participating in any particular activity carried out in the Centre shall not be under obligation to do so.

6.2.3 Criminal convictions

Centres shall require all prospective and existing staff to report promptly all criminal convictions to the Person Responsible. In deciding whether or not an individual shall take part in an HFEA licensed activity at the Centre, the Person Responsible shall take into account relevant previous convictions and breaches of regulations.

6.2.4 Job Descriptions

All personnel shall have up-to-date job descriptions that are clearly documented and understood. They shall include

- a) a job title,
- b) accountability and reporting relationships,
- c) the purpose of the job,
- d) the assigned tasks and responsibilities of the job.

A person specification may be part of the job description or be provided separately to job applicants

6.2.5 Initial/basic training and update training

Personnel shall be provided with appropriate initial/basic training and update training to carry out their assigned activities

The training programme shall ensure and document that each individual

- a) has the competence in the performance of their designated tasks,
- b) has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks,
- c) understands the organisational framework, quality system and health and safety rules of the Centre in which they work,
- d) is adequately informed of the broader ethical and legal context of their work.

NOTE Update training is required when procedures change or scientific knowledge develops. See also 6.2.5 Continuing education and professional development.

6.2.6 Competence assessment

Following initial/basic and update training, the competence of each person to perform assigned activities shall be evaluated at intervals specified in the quality management system and retraining undertaken when indicated.

6.2.7 Annual joint review

All personnel shall participate in an annual joint review that examines the needs of the Centre and of the individual in order to improve the quality of the service given to users and to encourage productive working relationships.

Staff performing annual reviews shall receive appropriate training.

6.2.8 Continuing education and professional development

A continuing education programme shall be available to staff at all levels. Staff shall take part in regular professional development programmes that include audit of practice and in professional liaison activities.

Resources shall be available for training and education that include access to library and information services and a quiet area for private study.

6.2.9 Personnel records

Personnel records shall include

- a) employment details,
- b) job description,
- c) terms and conditions of employment,
- d) a record of staff induction and orientation,
- e) a record of health and safety training
- f) a record of education and training including continuing professional development,
- g) relevant educational and professional qualifications,
- h) certificate of registration, if relevant,
- i) absence record,
- j) accident record,
- k) a record of staff annual joint reviews,
- l) occupational health record,
- m) record of disciplinary action.

The Centre shall ensure confidentiality of personnel records in accordance with local guidelines and national legislation.

NOTE If the Centre is part of a larger organisation staff records may be held by the parent organisation but should be available for inspection by the HFEA if requested.

6.2.10 Meetings and communication

The Centre shall have an effective means for communicating information to staff and receiving suggestions from staff (8.2.3). Records shall be kept of meetings and made available to all staff.

6.3 Premises and facilities

6.3.1 General

The Centre shall have premises and facilities suitable for the activities for which it is licensed that include, as appropriate, facilities for reception, clinical (6.3.2) and counselling activity (6.3.3), laboratory work (6.3.4), storage of gametes and embryos (6.3.5) and staff (6.3.6). The Centre shall provide a safe working environment for all staff.

The Centre shall have documented procedures for controlled access, health, safety and welfare, including, appropriate procedures for lone workers, cleaning and maintenance of the facilities, for waste disposal and action in case of emergencies.

6.3.2 Clinical facilities

Centres shall ensure that the clinical facilities available are

- a) appropriate for the activities for which the centre is licensed,
- b) provide for the privacy and comfort of those
 - considering donation and seeking treatment
 - examination and treatment
 - producing semen specimens
- c) have backup and emergency clinical facilities, equivalent to those which are standard practice in other medical provision and appropriate to the degree of risk involved in any planned procedure and able to cope with predictable emergencies,

6.3.3 Counselling facilities

Centres shall ensure counselling facilities that provide quiet and comfortable surroundings in which sessions can be held that are private, confidential and without interruption.

6.3.4 Laboratory facilities

The laboratory facilities shall ensure

- a) a safe working environment for staff in which they can conduct the required laboratory processes (7.7) in accordance with national legislation and guidelines,
- b) the processing of gametes and embryos, takes place in an environment with specified air quality and cleanliness, to protect their quality and safety and minimise the risk of contamination and cross-contamination between samples. The effectiveness of these measures is validated and monitored.

6.3.5 Storage facilities for gametes and embryos

Gametes and embryos shall be stored in a designated security area with controlled access. Access to the security area shall be authorised by the Person Responsible and a monitoring system shall be in place to ensure high standards of security. Only named individuals, for whom access is essential in the course of their work, shall be authorised.

The storage facilities for gametes and embryos shall

- a) be dedicated for the purpose and adequate for the volume and types of activities,
- b) provide for storage of gametes and embryos under conditions designed to ensure their quality and safety,

- c) clearly separate material prior to release from quarantine to prevent mix up and cross contamination,
- d) have physically separate areas / storage devices or segregation within the storage device for both quarantine and released storage locations for holding material against special criteria,
- e) be designed to avoid proximity to ionising radiation (radioactive material) , any known potential source of infection, chemical or atmospheric contamination,
- f) allow critical parameters such as temperature, humidity and oxygen levels to be controlled, monitored and recorded, to demonstrate conformity to specified conditions,
- g) incorporate a storage location system that minimises the amount of handling required to retrieve gametes and embryos,
- h) have emergency procedures to deal with damage to storage vessels and/or failure of storage conditions.

6.3.6 Staff facilities

The Centre, or the parent organisation, shall have staff facilities that are readily accessible and include

- a) toilet accommodation,
- b) a rest area with basic catering facilities and a supply of drinking water,
- c) a changing area and secure storage for personal effects,
- d) storage for protective clothing.

The Centre shall provide appropriate garments and equipment for personal protection and hygiene, and instructions for their use.

6.4 Management of equipment and materials

The Centre shall ensure that it has the equipment and materials required to meet the requirements of these Standards. When applicable, equipment and materials shall meet the requirements of the relevant EC Directives, 93/42/EC Medical Devices and 98/79/EC *In vitro* diagnostic medical devices.

NOTE For the purpose of these Standards, 'equipment and materials' includes all equipment , disposables, reagents, calibration and control materials used in the conduct of assisted conception processes. A major proportion of the items involved will be regulated by the Directives referred to above.

The Centre shall establish documented procedures for the management of equipment and materials that include:

- a) selection and procurement,
- b) instructions for use including action to be taken in event of malfunctions or failure,
- c) acceptance testing, verification and validation,
- d) training of personnel,
- e) calibration against traceable standards where available,
- f) maintenance, servicing, cleaning, disinfection and repair in accordance with manufacturers instructions,
- g) adverse incident reporting,
- h) inventory, stock control and records,
- i) traceability of any materials that come in contact with gametes or embryos

NOTE The reporting of adverse incidents arising from the use of equipment and materials is encouraged. Reports should be sent to the 'competent authority', the Medicines and Healthcare products Regulatory Agency (MHRA). An 'adverse incident' in this context is defined as incidents which produce, or have the potential to produce, unwanted effects involving the safety of patients, users and others. This reporting is distinct but complimentary to that required by the HFEA, see 8.4.

The Centre shall maintain records that provide evidence of conformity with the procedures for management of equipment and materials.

6.5 Management of data and information systems

The Centre shall establish documented procedures for the management of data and information systems that include:

- a) Documentation,
- b) validation and change control,
- c) security of data and safeguards against unauthorised modification,
- d) resolution of data discrepancies,
- e) maintenance and disaster recovery,
- f) storage, archiving and retrieval,
- g) secure disposal,

The Centre shall maintain records that provide evidence of conformity with the procedures for management of data and information systems.

7 Assisted conception processes

7.1 General

The Centre shall ensure that all assisted conception processes are conducted by authorised personnel in a manner that ensures the safety of patients and donors, the quality and safety of gametes and embryos, meets the needs and requirements of the user and takes into account the welfare of pre existing children and children that might be born as a result of treatment provided.

Where any aspect of the assisted conception processes are not undertaken by the Centre there shall be written agreements between the Centre and the third party (4.2.8) that include a specification of the processes and procedures to be used that is in conformity with the requirements of these Standards.

The Centre shall ensure that all aspects of the documentation of the assisted conception processes are in conformity with the general documentation requirements (5.2) of these Standards.

7.2 Confidentiality and access to health records

The Centre shall have procedures to ensure that information provided in confidence is kept confidential and only disclosed in circumstances permitted by law.

NOTE Patients should not have access to another person's records (including those of spouse or partner) without that other person's prior consent.

The Centre shall ensure that all data, including genetic information, that is collated for any purpose, and to which third parties have access, is rendered anonymous so that neither patients nor donors remain identifiable. Arrangements shall ensure that the identification details of donors and patients are not disclosed to each other.

The Centre shall establish a documented procedure for control of access to health records that ensures arrangements are in place for

- a) the prompt consideration and response to applications for access to confidential records and the proper identification of applicants,

- b) the designation of an identified individual in the Centre with responsibility to receive, check and arrange authorised access to confidential records,
- c) notification of the Information Officer in accordance with the Data Protection Act 1998,
- d) providing all individual donors and recipients who provide information about themselves, access to the record of that information and an opportunity to correct it,
- e) ensuring that individuals (data subjects) are aware of their rights under the Data Protection Act 1998 to access their own health records.

NOTE When the Centre is part of a larger organisation, where appropriate, some of these procedures may be undertaken by the appropriate department of the parent organisation.

7.3 Traceability and coding

7.3.1 Traceability

The Centre shall establish documented procedures to ensure that all gametes and embryos are traceable from procurement of gametes to patient treatment or disposal, and vice versa, to ensure

- a) the unique and accurate identification of the patient, patient partner or donor and the gametes and embryos and labelling of their containers, received and distributed (see also 7.3.2),
- b) that quarantined, non quarantined and rejected material is clearly identifiable at all stages of processing,
- c) that registers are kept of received, processed, stored and distributed or discarded gametes or embryos, enabling identification of an individual patient, patient partner or donor, individual procurement and hospital or institution from which gametes and embryos have been received,
 - identification of processing steps applied to gametes and/or embryos and, if applicable, third parties involved in processing,
 - identification of distributed gametes or embryos and hospitals or institutions to which gametes and embryos have been distributed (whether intended for application in the human body, or research purposes) and
 - investigation, post application of the gametes, if a problem with the donation is identified subsequently.
- d) records are kept of the equipment and materials used in the reception, processing, storage and discard of gametes and embryos.

7.3.2 Coding

The Centre shall use an identifying code to ensure the traceability of all gametes and embryos and provide information on their main characteristics, in accordance with the documented procedures on traceability (7.3.1)

The minimum requirements for information are for the unique identification of individuals; the identification of the Centre and for gametes and embryos a unique code, split number if applicable and expiration date where applicable.

NOTE The requirement for a European identifying code specified in the Directive awaits clarification.

7.4 Information for users

The Centre shall ensure that before any individual is given treatment or consents to the use or storage of embryos or to the donation or storage of gametes, they are given appropriate oral and written information that explains the medical, scientific, legal, and psychosocial implications of their decision.

Information given shall include issues concerning the welfare of the child.

7.5 Consent to examination and treatment,

The Centre shall comply with current professional guidelines on consent and HFEA guidance.

NOTE In the context of these Standards 'consent to examination and treatment' includes the use or storage of embryos and the donation or storage of gametes. The HFEA Guidance on consent to examination and treatment also indicates the information that should be given to the individuals regarding giving consent

The Centre shall establish documented procedures for individuals considering or giving consent to examination and treatment or donation, and storage to ensure that

- a) only personnel authorised by the Centre take consent,
- b) reasonable steps are taken to validate the identity of individuals accepted for treatment,
- c) appropriate verbal and written information is provided in conjunction with obtaining consent and its provision is recorded,
- d) individuals are given an opportunity to ask questions and receive further advice and guidance by clinical staff
- e) individuals are given the opportunity to engage in counselling, with an independent counsellor, about the implications of the proposed treatment before they consent,
- f) individuals seeking treatment or storage, or considering donation are given sufficient time to reflect upon their decisions before giving their written consent,
- g) individuals seeking treatment or storage, or considering donation confirm that information provided is true to the best of their knowledge,
- h) consent forms used by the Centre meet the requirements of the HFEA,
- i) a copy of the signed consent form shall be available for those who have given consent,
- j) an individual may specify additional conditions subject to which their gametes or embryos may be stored or used. Consent may be varied or withdrawn at any time providing that the gametes and embryos have not already been used in treatment services or research,
- k) when it is proposed that embryos are to be used in an egg sharing arrangement, the terms of the woman's consent to the storage of those embryos using her eggs must be compatible with the consent of the man whose sperm fertilised those eggs, both for the egg provider and the egg recipient,
- l) gametes are not taken from anyone without prior consent, and/or from an individual who has not given a valid consent to examination and treatment and effective consent to the use or storage of those gametes,
- m) parents cannot consent on behalf of their children to any licensed procedures, including the storage of mature gametes.

NOTE In exceptional circumstances consent to procurement of gametes may be witnessed by professional personnel out with the Centre but explanatory information should be provided with the procured gametes.

7.6 Clinical processes

7.6.1 Consultation

The Centre shall ensure that advice and recommendations for treatment are in accordance with the current guidelines on treatment.

7.6.2 Counselling

Centres shall ensure that

- a) current professional guidelines on counselling are complied with, and that when required counselling is provided by one or more counsellors and is independent of the clinical decision making process,
- b) potential users have written information about the service available and its benefits,
- c) individuals seeking treatment or donating gametes are given a suitable opportunity to participate in counselling about the implications of the proposed action before they consent,
- d) all practicable steps are taken to provide opportunities for counselling throughout the treatment, donation or storage processes and afterwards if requested,
- e) arrangements are in place for the referral of patients to specialist genetic counselling services when appropriate,
- f) where a couple or individual is undergoing infertility treatment and the possibility of donation arises, donor implications counselling shall be provided as in a) above.

7.6.3 Evaluation and screening of potential donors

Where individuals are considering donation, Centres shall ensure

- a) that those individuals have received all the required information (see also 7.5),
- b) that no pressure or undue influence is applied to donate sperm, eggs or embryos by clinic staff, friends or relatives,
- c) they understand that the donation of gametes is voluntary and unpaid, compensation being restricted to expenses and inconveniences,
- d) that any donor and their partner are given the opportunity to be seen by an independent counsellor to explore the implications of donation for all concerned,
- e) that an authorised person collects and records the donors' relevant medical and behavioural information (see 7.7.2 Donor documentation),
- f) that appropriate screening tests (Annex B) have been performed and are recorded.

NOTE 1 Unless there are exceptional reasons for doing so, sperm should not be taken for the treatment of others from donors over the age of 45 and eggs should not be taken for the treatment of others from donors over the age of 35. The exceptional reasons should be recorded in the treatment records. Gametes for the treatment of others should not be taken from anyone under the age of 18.

NOTE 2 Promotion and publicity activities in support of donation of gametes and/or embryos should comply with guidelines and shall not advertise the need for, or availability of gametes and/or embryos with a view to offering or seeking financial gain.

7.6.4 Clinical treatment

The Centre shall, where appropriate, have documented clinical guidelines that include but are not limited to

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

7.7 Procurement, distribution (including packaging and transportation), and receipt of gametes and embryos

7.7.1 General

The procurement of gametes shall be carried out by personnel who have successfully completed a training programme and specified by a clinical team engaged in the procurement of gametes. The competence of the trained personnel shall be recorded.

The Centre shall establish documented procedures for procurement, packaging, distribution and recall, and receipt of gametes and embryos that ensure

- a) that appropriate information has been provided (7.4),
- b) consent, patient, patient partner and donor identification (7.5),
- c) donor evaluation and assessment (7.6.3),
- d) the safety of the donor,
- e) that any adverse incident that might result in harm to the patient, patient partner or donor is recorded and reviewed (see also 8.4),
- f) the quality and safety of the gametes and minimises the risk of microbiological contamination and details,
- g) donor registration (7.7.2), third party procurement documentation (7.7.3), home procurement documentation (7.7.4) packaging (7.7.5) and distribution (7.7.6) labelling of packages containing procured gametes (7.7.7) transportation, labelling of shipping container and recall (7.7.8) and receipt of gametes (7.7.6) meet the requirements of these Standards.

NOTE Frozen gametes should be accompanied by documentation describing the minimum expectations for their post-thaw quality

7.7.2 Donor registration

For each donor registered at the Centre there shall be a record containing

- a) the donor identification (first name, family name, date of birth and sex),
- b) medical history, including presence of risk factors,
- c) consent, including purpose for which the gametes and embryos may be used and any specific instructions for disposal if not used for the purpose for which consent was obtained,
- d) clinical and laboratory assessment data.

7.7.3 Third party procurement documentation

Where the procurement of the gametes and embryos has taken place from a centre with which the Centre has a third party contract (4.2.8), that centre shall produce a procurement report that shall include, but not be limited to, the following

- a) the identification, name and address of the Centre to receive the gametes,
- b) patient, patient partner or donor identification,
- c) identification of the procured gametes and embryos,
- d) identification of the person responsible for the procurement session,
- e) date and time of procurement,
- f) a record of any procedures undertaken on the gametes
- g) a record of any adverse incidents,
- h) where appropriate, identification/batch numbers of any reagents and transport media used.

7.7.4 Home procurement documentation

Where the procurement of sperm has taken place at home, the record shall contain

- a) the identification, name and address of the Centre to receive the sperm,
- b) the donor identification,
- c) date and time of procurement.

7.7.5 Packaging

Following procurement all gametes shall be packaged (7.7.7) in a manner that minimises the risk of contamination and under conditions that ensure their safety and quality.

7.7.6 Distribution

When gametes are distributed from one centre to another, the transportation and shipping container used (7.7.8) shall ensure the safety and quality of the gametes, be suitable for the transport of biological materials, and comply with relevant legislation and regulations.

7.7.7 Labelling of packages containing procured gametes

At the time of procurement each package containing gametes shall be labelled. Primary containers must indicate the unique code, and split number if applicable, of the donation and the type of gamete. When the size of packaging permits the following information shall also be provided

- a) date (and time where possible) of donation
- b) identity of the donor
- c) in the case of known donations, the identity of the intended recipient

If the information under points a) – c) above cannot be provided on the primary package label, it shall be provided on a separate sheet accompanying the primary package (see also 7.3.2 Coding).

7.7.8 Transportation, labelling of shipping container and recall

The transportation of gametes and embryos shall be under conditions that ensure their safety and quality. When transportation is by a third party, the third party shall be subject to a third party contract (4.2.8), and a documented agreement in place to ensure the required conditions are fulfilled.

The transport conditions, including temperature and time limit, shall be specified and the labelling of every shipping container include a minimum of

- a) the identification of the centre from which the package is being transported (address and telephone number) and contact person in the event of problems,
- b) the identification of the centre to which the package is to be delivered (address and telephone number) and person to be contacted to take delivery,
- c) the date and time of the start of transportation,
- d) specifications concerning the conditions of transport relevant to the safety and quality of the gametes,
- e) specifications concerning the storage conditions (such as DO NOT FREEZE),
- f) warnings as follows: TISSUES AND CELLS, HANDLE WITH CARE and DO NOT IRRADIATE and
- g) in the case of autologous procurement, FOR AUTOLOGOUS USE ONLY.

NOTE Where the container has not been validated by the manufacturer/supplier for specified transport conditions then the conditions need to be monitored during transport or validated by the centre or third party undertaking the transportation

The centre originating the distribution shall have a recall procedure that defines the responsibilities and actions required when a distribution is recalled. Such a recall would be investigated using the procedure for investigation of adverse incidents (8.4). There shall be a procedure for handling returned gametes and embryos that include their reacceptance into the inventory, if applicable.

7.7.9 Receipt of gametes

Where appropriate, the Centre shall establish a procedure for the receipt of gametes from another centre to ensure that

- a) documented specifications are established against which each consignment of gametes is verified. These shall include the requirements for donor documentation (7.7.2), packaging and transportation (7.7.3), labelling of containers for procured gametes (7.7.4), labelling of shipping containers (7.7.5) and any associated documentation,
- b) verification is undertaken by authorised personnel,
- c) records are kept to demonstrate that before gametes are released all appropriate specifications have been met,
- d) consignments not meeting the specifications are segregated and quarantined,
- e) quarantined consignments are not released until b) and c) are met.

In the case of gametes intended for partner treatment, in addition to the documentation required (7.7.2) and the labelling of procured gametes (7.7.4), partner identification shall be recorded.

NOTE Receipt and recording of sperm procured at home is, where appropriate, subject to the requirements for receipt from another centre (7.7.6).

7.8 Laboratory processes

7.8.1 General

The requirements of this section relate to those laboratory processes used in the handling, manipulation, storage and release of gametes and embryos.

If the Centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patient, patient partners, donors and their gametes, these laboratories shall obtain accreditation by CPA(UK)Ltd or another body accrediting to an equivalent standard.

NOTE The pathology disciplines involved in diagnosis and investigation include Andrology, Clinical Genetics, (Cytogenetics and Molecular genetics) and Clinical Biochemistry.

NOTE If a laboratory computer is used to release results from the Centre's or a third party laboratory, an audit trail should indicate who was responsible for their release

The Centre's laboratories shall comply with current professional guidelines, legislation and regulations (ANNEX A).

Documented laboratory procedures shall include information concerning their scope and purpose, hazards to laboratory personnel and precautions, the equipment/reagents required, and the instructions to be followed and the laboratory shall ensure that personnel are competent to perform the required procedures and work to current versions of the procedures and all referenced documentation.

7.8.2 Selection and validation of laboratory procedures

The laboratory shall use procedures that meet the needs of patients, ensure the safety and quality of gametes and are appropriate to the treatment plan concerned. These should be in conformity with existing professional guidance for good practice and published evidence, where available.

Procedures shall be validated in accordance with professional guidelines and operate within legal and regulatory constraints. Validations should be based on previously published studies, or retrospective evaluation of the Centre's own data. Records of all validations shall be kept.

Significant changes in procedure shall result in the validation being repeated, and the documented procedure being revised.

Procedures shall be evaluated for hazards to laboratory staff and precautions put in place to minimise potential hazards

7.8.3 Handling and manipulation of gametes and embryos

The laboratory shall establish documented procedures that ensure

- a) no activity involving gametes or embryos is carried out without ensuring the appropriate consents are in place,
- b) processing of cells and embryos is performed using sterile technique and under conditions of appropriate air quality.
- c) gametes or embryos are handled in a manner which protects those properties that are required for their ultimate clinical use, while minimising the risk of microbial contamination,
- d) records are kept indicating each and every occasion when gametes and embryos are handled and manipulated, and by whom.

7.8.4 Storage and release of gametes and embryos

The laboratory shall establish documented procedures to ensure that

- a) all storage and handling of gametes and embryos is in accordance with licence conditions, regulations, and with relevant patient consent,
- b) all storage of gametes and embryos is carried out under controlled conditions that are validated and monitored,
- c) gametes and embryos are not be stored beyond the maximum period as laid down in statute, or the storage period consented to by the patient(s) if less than the former,
- d) gametes and embryos are packaged for storage in such a way as prevent adverse effect on the material, as well as to minimise the risk of contamination,
- e) records are kept indicating each and every occasion when gametes and embryos are handled during storage and release, and by whom,
- f) that records are kept indicating that gametes and embryos meet documented specifications (see 7.5 Consent and patient, patient partner or donor identification, 7.6.3 Evaluation and screening of potential donors and ANNEX B) for safety and quality prior to release,
- g) details the conditions for an exceptional release of material that does not conform to the requirements of these Standards,
- h) risk assessments (approved by Person Responsible) are undertaken, to determine fate of all stored material, following introduction of any new donor selection or testing criterion or new processing step enhancing safety and/or quality,.
- i) the disposal of discarded gametes and embryos is appropriate.

NOTE Exceptional release should be based on criteria that include an assessment of the urgency of the request, the availability of test results, the importance of information that is not yet available and the availability of cells and gametes for the recipient. Documentation of exceptional release should include a statement by the recipient's clinician confirming agreement to the use of tissues and cells despite the documented nonconformity. The clinician must be provided with information that becomes available after exceptional release that is relevant to the quality of the gametes and embryos.

7.8.5 Assuring the quality of procedures

The laboratory shall establish documented procedures that ensure

- a) that internal quality control procedures are in place and that there is regular critical evaluation of all processes to ensure that they continue to achieve the intended results,
- b) the maintenance of control charts for critical outcome parameters, in order to determine alert conditions/significant deviation from intended/expected outcome,
- c) that the laboratory participates in all relevant inter-laboratory (external quality assessment) schemes (8.2.5),
- d) that records of the results of quality control/assessment activities, non conformities detected and action taken are kept.

Any serious incidents that are potentially associated with non conformity of a laboratory procedure shall be investigated in accordance with 8.4.

8 Evaluation and improvement

8.1 General

The Centre shall plan and implement the evaluation and improvement processes needed and designate the responsibilities and authorities of the personnel responsible

- a) to demonstrate that the assisted conception processes are being conducted in a manner that meets the needs and requirements of users,
- b) to ensure conformity of the quality management system,
- c) to continually improve the effectiveness of the quality management system.

Evaluation activities shall include but not be limited to, evaluation of user satisfaction (8.2.1), monitoring and resolution of users complaints (8.2.2), encouraging staff suggestions (8.2.3), conducting internal audits of the quality management system (8.2.4), participation in inter Centre evaluations (8.2.5) and external reviews (8.3).

The results of evaluation and improvement activities shall be included in the input to the management review (4.2.7).

8.2 Evaluation

8.2.1 Assessment of user satisfaction

As a measure of the performance of the quality management system, the Centre shall monitor information relating to user perception as to whether the service has met their needs and requirements. Records shall be kept of the information collected and actions taken.

User complaints can be seen as the reverse of user satisfaction and the requirements for their monitoring and resolution are given in 8.2.2

NOTE Centres are encouraged to obtain both positive and negative feedback from the users of their services, preferably in a systematic way. Methods should include user surveys regarding all aspects of the service.

8.2.2 Monitoring and resolution of complaints

The Centre shall establish documented procedures for the resolution of complaints or other feedback received from users. The user can be a patient, patient partner or donor, clinicians or purchasers of services and other relevant parties.

Records shall be kept of the complaints and their investigation together with the corrective action (see 8.5.2).

8.2.3 Staff suggestions

The Centre management shall encourage staff to make suggestions for the improvement of any aspect of the Centre's service. Suggestions will be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained.

NOTE Centres are encouraged to be proactive and undertake 'staff satisfaction surveys' as a means of gauging the performance of the quality management system.

8.2.4 Internal audit

The Centre shall establish an internal audit process to determine whether the quality management system

- a) conforms to the planned arrangements for assisted conception processes, to the requirements of these Standards and to the quality management system requirements (including quality indicators) established by the Centre, and
- b) is effectively implemented and maintained.

The Centre shall establish a documented procedure to ensure that

- a) the responsibilities for the planning and conduct of audits are defined, together with
- b) the audit criteria, scope, frequency and methods,
- c) audits are carried out by trained personnel,
- d) action is taken promptly to instigate corrective action (see 8.5.2),
- e) the effectiveness of the action taken is verified in a subsequent audit,
- f) records of audits are kept that include
 - the processes, areas or items audited
 - any non conformities found
 - recommendations and time scale for action
 - record of action taken and subsequent verification of effectiveness.

NOTE 1. The audit programme shall be planned by the Quality manager (see 4.2.6). It shall take into account the importance of the processes and areas to be audited and the results of previous audits. Auditors should not audit their own areas of responsibility.

NOTE 2. The main elements of the quality management system should be subject to internal audit once every twelve months.

NOTE 3. Quality indicators established for systematically monitoring and evaluating the Centre's assisted conception processes should be a particular focus for audit (see 8.5.1 Continual improvement)

8.2.5 Participation in inter-Centre comparisons and inter-laboratory comparisons

The Centre shall participate in inter-Centre comparisons such as those organised by professional bodies and inter-laboratory comparisons (e.g. external quality assessment schemes) and by other external bodies.

The results of these comparisons should be evaluated and documented and relevant findings be used to improve the service.

In the case of inter-laboratory comparisons, the laboratory shall establish documented procedures to define the responsibilities and requirements for participation to ensure that

- a) a record of participation is maintained that includes any reasons for failure to participate,
- b) supervisory staff, together with the personnel undertaking the examinations, evaluate the returned results against agreed performance criteria and when nonconformities

are identified, participate in the implementation and recording of corrective actions (see 8.5.2),

- c) the effectiveness of corrective action is verified.

When a formal inter-laboratory comparison programme is not available, the laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated. Whenever possible, this mechanism shall utilise externally derived challenge materials such as exchange of samples with other laboratories.

8.3 External reviews

External reviews indicating nonconformities or potential nonconformities shall be reviewed and appropriate corrective or preventive action taken to ensure continuing compliance with the requirements of these Standards. A record shall be kept of corrective and preventative actions taken

8.4 Identification, investigation, control, recording and notification of serious incidents

8.4.1 Identification, investigation, control and recording

The Centre shall have a documented procedure for the identification, investigation, control and recording of serious adverse events and reactions (referred throughout section 8.4 as incidents) that ensures that

- a) the responsibilities and authorities for personnel responsible for the management of incidents are defined,
- b) the identification and investigation of incidents, that includes proactive identification through risk assessment and internal audit,
- c) the recording of incidents, including analysis of cause, corrective action taken and ensuing outcome,
- d) the cessation of assisted conception processes as required,
- e) the identification of any donor who might have contributed to the incident,
- f) the control and verifiable recall of any gametes or embryos procured or applied in association with the particular incident, within a predefined time,
- g) the identification and notification of any consignee and recipients of gametes from the same donor in the event that they may be put at risk,
- h) the control and verifiable recall of any material, and the investigation of any equipment used in association with the incident,
- i) the retention of all records in association with the adverse incident including those of gametes and embryos procured or materials applied,
- j) reporting of relevant information to:
 - all personnel within the Centre involved in assisted conception processes
 - other centres engaged in the donation, procurement, testing, processing, storage and distribution of gametes or embryos, to facilitate traceability and ensure quality and safety control,
- k) notification of the HFEA, by the Person Responsible, of adverse incidents and the subsequent provision of a confirmation/conclusion reports

NOTE 1 The investigation of incidents should include evaluation of all assisted conception processes directly related to the incident and all processes involving the management of resources, training and competence of personnel, equipment, materials, information systems and control of environment.

NOTE 2 Centres must report all adverse incidents to the HFEA by telephone within 12 working hours of the identification of the incident and submit an Incident Report form within 24 working hours.

8.4.2 Notification of adverse reactions

The initial notification/report of a serious adverse reaction to the HFEA shall include

- a) identification of the Centre
- b) report identification
- c) date of initial notification/report
- d) individual affected (patient or donor)
- e) date and place of procurement of gametes or application of gametes or embryos
- f) date of suspected serious adverse reaction
- g) details of gametes or embryos involved in the serious adverse reaction
- h) type of suspected serious adverse reaction(s) including the transmission of infectious agents

to be followed by a confirmation report including, items a) – c) above and:

- i) date of confirmation report
- j) confirmation of the type of reaction(s) OR a change in type of reaction (s)
- k) clinical outcome, if known, and classified
 - complete recovery
 - minor sequelae
 - serious sequelae
 - death
- l) outcome of investigation and final conclusions

8.4.3 Notification of serious adverse events

The initial notification/report of a serious adverse event to the HFEA shall include

- a) identification of the Centre
- b) report identification
- c) date of initial notification/report
- d) date of serious adverse event
- e) an evaluation of the event by *activity*, (procurement, testing, transport, processing, storage, distribution or other) and *specification of the source of error*, (defect in gametes or embryos, equipment or material failure or defect), human error or other) to identify preventable causes.

to be followed by a conclusion report including, items a) – c) above and

- f) date of conclusion report
- g) date of serious adverse event
- h) final analysis of cause and corrective action taken.

NOTE The Directive specifically identifies 'any type of gamete or embryo misidentification or mix up' as a serious adverse event.

8.5 Improvement

8.5.1 Continual improvement

The Centre shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, its evaluation activities, corrective and preventive actions and management review. Action plans for improvement shall be developed, documented and implemented, as appropriate, and the effectiveness of the action through a focused review or audit of the area concerned.

The Centre shall establish quality indicators for systematically monitoring and evaluating the Centre's contribution to patient care. When this programme identifies opportunities for improvement, Centre management shall address them regardless of where they occur.

8.5.2 Corrective action

The Centre shall establish a documented procedure to eliminate the cause of nonconformities that includes

- a) reviewing nonconformities,
- b) determining the causes of nonconformities,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) promptly determining and implementing action needed,
- e) recording the results of corrective action taken (see 4.2.4) and
- f) reviewing the corrective action taken.

8.5.3 Preventive action

The Centre shall establish a documented procedure to eliminate the causes of potential nonconformities in order to prevent their occurrence that includes

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) promptly determining and implementing action needed,
- d) recording the results of preventive action taken (see 4.2.4) and
- e) reviewing preventive action taken.

NOTE Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints. In addition to review of the operational procedures, preventive action might involve analysis of data, including trend- and risk-analyses and external quality assurance.

ANNEX A (informative) - Guidelines and information for good practice

A1 Introduction

There are a number of guidelines from professional organisations (see A2 Guidelines from professional organisations) and information from other sources (see A3) that constitute recommended good practice that are particularly relevant to the provision of assisted conception services, licensable by the HFEA. It is expected that Centres being assessed by the HFEA should, where appropriate, operate in conformity with this recommended good practice:

A2 Guidelines from professional organisations

The following is a list of guidelines from professional bodies that is current at the date of publication of these Standards. Individual organisations will be able to provide information on the latest editions of these guidelines.

- Guidelines on Good Practice in Clinical Embryology Laboratories, Association of Clinical Embryologists, 2004
- Laboratory Andrology - Guidelines for Good Practice, Association of Biomedical Andrologists, 2004
- Accreditation Standards And Guidelines For IVF Laboratories, Association of Clinical Embryologists , March 1999
- Guidelines For The Screening Of Semen Donors For Donor Insemination, British Andrology Society 1999, Human Reproduction 14 (7)1823-1826
- Recommendations For Good Practice On The Screening Of Egg And Embryo Donors, British Fertility Society, 2000 Human Fertility (2000) 3, 62-165
- Fertility- Assessment and Treatment for People with Fertility Problems, National Collaborating Centre for Women's and Children's Health, 2004.
- Embryo Transfer: Recommendations For Good Practice, British Fertility Society, Human Reproduction 12 Natl. Suppl. JBFS 2(2) 88-92 1997
- Guidance On The Inspection And Provision Of Counselling In Assisted Conception Centres, British Infertility Counselling Association, October 1999
- Guidelines For Nurses Carrying Out Embryo Transfers And Intrauterine Insemination, Royal College of Nursing, 2000
- Guidelines for Nurses Carrying out Egg Retrieval, Royal College of Nursing, 2000

A3 Information from other sources

The following is a list of guidelines from other sources that is current at the date of publication of these Standards. Individual organisations will be able to provide information on the latest editions of these guidelines:

A3.1 General issues

- National Minimum Standards And Regulations For Independent Health Care, Department of Health, 2002
- Standards for Better Health, Department of Health, 2004
- Code Of Professional Conduct: Standards for Conduct, Performance and Ethics, Nurses and Midwifery Council, 2004
- Good Medical Practice, General Medical Council, 2001
- Fertility: Assessment and treatment for people with fertility problems (Guideline 11), National Institute for Clinical Excellence, 2004
- Ethical Framework For Good Practice In Counselling And Psychotherapy, British Association For Counselling and Psychotherapy, 2002
- Codes of Practice For Social Care Workers And Employers, General Social Care Council, 2002

A3.2 Consent

- Reference Guide To Consent For Examination Or Treatment, Department of Health, 2001
- Seeking Patients' Consent: The Ethical Considerations, General Medical Council, 1998

A3.3 Safe sedation

- Implementing And Ensuring Safe Sedation Practice For Healthcare Procedures In Adults, Academy of Medical Royal Colleges, 2002

A3.4 Good manufacturing practice

- Guide To Good Manufacturing Practice For Medicinal Products, 91/356/EEC, 1991
- Rules And Guidance For Pharmaceutical Manufacturers And Distributors, HMSO, 1997

A3.5 Laboratory practice

- The Control Of Substances Hazardous To Health Regulationsⁱ, Statutory Instrument No 437, 1999
- Safety In Health Service Laboratories: Safe Working And Prevention Of Infection In Clinical Laboratories, Health Service Advisory Committee, 1991

A3.6 Tissue storage and donation

- Use Of Human Organs and Tissue: A Draft Interim Statement For Consultation By The Department of Health, Department of Health, 2002
- A Code Of Practice For Tissue Banks Providing Tissues Of Human Origin For Therapeutic Purposes, Department of Health, 2001
- Guidance On The Microbiological Safety of Human Organs, Tissues And Cells Used In Transplantation, Department of Health, 2000
- Code of Practice, Human Tissue Authority

A3.7 Communicable diseases

- Protection Against Blood-borne Viruses In The Workplace: HIV And Hepatitis, Advisory Committee On Dangerous Pathogens, 1995
- Guidance For Clinical Health Care Workers: Protection Against Blood-borne Viruses, Department of Health, 1998
- Revised Advice On Laboratory Containment Measures For Work With Tissue Samples In Clinical Cytogenetics Laboratoriesⁱⁱ, Advisory Committee On Dangerous Pathogens, 2001
- HIV Infected Health Care Workers: A Consultation Paper On Management And Patient Notification, Department of Health, 2002
- Note For Guidance On Minimising The Risk Of Transmitting Animal Spongiform Encephalopathy Agents Via Human And Veterinary Medicinal Products, Medicines Central Agency, 2001
- Transmissible Spongiform Encephalopathy Agents: Safe Working And The Prevention Of Infection, Advisory Committee On Dangerous Pathogens, 1998
- Protecting Health Care Workers and Patients From Hepatitis B, Department of Health, 1993 And Scottish Office, 2003
- Hepatitis B Infected Health Care Workers, National Health Service Scotland, 2000
- Hepatitis C Infected Health Care Workers, Scotland Health Department, 2002
- Guidance On The Management Of AIDS/HIV Infected Health Care Workers And Patient Notification, National Health Service Scotland, 1999

A3.8 Clinical trials

- European Directive on Clinical Trials (2001/20/EC)

A3.9 Legislation

- Human Fertilisation and Embryology Act 1990
- Care Standards Act 2000
- Adoption and Children Act 2002
- Data Protection Act 1998
- Human Rights Act 1998
- Health and Safety at Work Act 1974
- Health and Social Care Act 2001
- Medicines Act 1968
- Medical Act 1983
- The Control of Substances Hazardous to Health Regulations 1999
- The Private and Voluntary Care (England) Regulations 2001
- The Human Tissue Act 2004

ⁱ These guidelines contain specific guidance on containment levels for handling of samples where there is infection with various biological agents.

ⁱⁱ This guide contains guidance on the containment levels that are expected to be used for handling known, suspected or unknown contaminated samples.

ANNEX B (normative) - Selection criteria and laboratory tests required for patients and donors of reproductive cells

B1 Patient and partner - direct use

Donor selection criteria and laboratory testing do not need to be applied in the case of direct use of partner's gametes

In all uses of gametes and embryos processed for treatment but not to be stored, the Centre shall demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes.

B2 Patient and partner treatment and storage and gamete donation

Reproductive cells that are processed and stored, and reproductive cells that will result in the cryopreservation of embryos, must meet the following criteria:

B2.1 The clinician responsible for the treatment or donation must determine and document, based on the patient's medical history and therapeutic indications, the justification for the treatment or donation and its safety for the recipient and any children that might result.

B2.2 The following biological tests must be carried out to assess the risk of cross contamination

Infection	Test
HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HbsAG Anti-HBc
Hepatitis C	Anti-HCV-Ab

B2.3 Blood samples must be obtained at the time of procurement.

B2.4 Where HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or where the patient or partner is known to be a source of infection risk, a system of separate storage must be devised.

B2.5 HTLV-I antibody testing must be performed for patients, patient partners or donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

B2.6 In certain circumstances, additional testing may be required depending on the patients, patient partners or donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g. Rh D, malaria, CMV, T. cruzi).

B2.7 Positive results will not necessarily prevent use of partner gametes in accordance with national rules.

B3 Donations of gametes or embryos

The use of reproductive cells other than for partner donation must meet the following criteria:

B3.1 Donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases

(such as sexually transmitted infections), or health risks to themselves (e.g.; superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor).

B3.2 The donors must be negative for HIV 1 and 2, HCV, HBV and syphilis on a serum or plasma sample, tested using the biological tests indicated in B 2.2. A validated testing algorithm must be applied to exclude the presence of active infection with *Treponema Pallidum*. A non-reactive test, specific or non-specific, can allow tissues and cells to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific Treponema confirmatory test is non-reactive. A donor whose specimen tests reactive on a Treponema-specific test will require a thorough risk assessment to determine eligibility for clinical use.

Sperm donations must be quarantined for a minimum of 180 days, after which repeat testing is required. (If the blood sample is additionally tested by nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required.)

Sperm donors must additionally be negative for Chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT).

B3.3 HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

B3.4 In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CMV, T. cruzi).

B3.5 For autologous donors, if the removed gametes are to be stored, the same minimum set of biological testing requirements shall apply. Positive test results will not necessarily prevent the gametes being stored, processed or re-implanted, if appropriate segregated storage facilities are available to ensure no cross contamination or mix ups.

B3.6 Genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information must be provided, in accordance with the national requirements. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

Annex C (informative) - Cross references between these Standards, the Human Fertilisation and Embryology Act (1990) and EC Directives

The section will be in the form of a table, between Standards/HF&E Act and EC Directives or two separate Annexes, one for the HFE Act and one for the EC Directives.

TO FOLLOW

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