



**British Fertility Society**



# Quality Manual

Incorporating HFEA Standard  
Licence Conditions

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# Quality Manual Skeleton

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## Introduction

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This skeleton quality manual has been prepared by a collaboration between the British Fertility Society, Association of Clinical Embryologists and the Human Fertilisation and Embryology Authority (HFEA). A quality manual is a fundamental part of the Quality Management System (QMS) and is designed to encompass the ethos of clinical governance including education and training, clinical audit, clinical effectiveness, research and development, openness and risk management.

It is mandatory for Fertility Clinics licensed by the HFEA in the UK to have a Quality Management System in place to enable continual improvement of service.

This manual is a tool that centres can adapt to reflect their own service provision. The aim is to provide a skeleton to compliment or develop a Centre's QMS. The aims of each section describe what the outcome should be and practical examples have been given. The examples are not exhaustive and Centres should develop their own Standard Operating Procedures (SOPs) to support their quality manual.

Where possible aims and examples have been mapped to the relevant HFEA standard licence conditions included in the 8<sup>th</sup> HFEA Code of Practice (CoP). Examples suggest where implementation of quality standards outlined in this manual might be mapped to comply with HFEA standard licence conditions. Users should be aware that not all requirements of standard licence conditions or of the 1990 Human Fertilisation and Embryology Act (as amended) or HFEA Directions are mapped to this manual. Implementing a Quality Management System on the basis of this manual would not mean that a Centre would be fully compliant with all HFEA requirements.

HFEA Standard licence conditions in this template are denoted by the letter T and a number, and these references are linked to a list of HFEA standard licence conditions appended at the end of the document. A standard licence condition highlighted in bold indicates that it has been mapped to the quality manual template. This should help Centres comply with mandatory HFEA requirements. The manual and the activities undertaken in its implementation can form part of the evidence of compliance shared with the HFEA in the course of an inspection.

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## Section 1 Quality Management System

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### General Requirements

#### Aim:

- The Centre should set up a system which should establish its aims and how they are to be achieved. The system should be developed, resourced, installed and integrated into the daily working of the Centre. [T32]

#### Purpose:

- A Quality Management System ensures that patients receive an agreed standard of care throughout their treatment and that Centres continually improve the way the service is delivered, ensuring consistency throughout. [T32]

#### Examples:

- Having an organisational chart showing roles and responsibilities [T11]
- Ensuring consistency throughout the Centre by having processes clearly defined and audited [T36]
- Ensuring all staff are aware of the quality policy and how it will be achieved.
- Providing evidence of continual improvement in services for patients, outcome data and the introduction and audit of new processes.

#### Risks:

- Patients receiving inconsistent advice and care from inappropriately trained staff
- Key processes not being undertaken as Centre staff are unaware it is their responsibility
- Continual improvement not evident

### Documentation Requirements

#### Aims:

- Centres should be able to provide evidence that they have maintained control over activities that can affect the way patients are treated throughout their contact with the Centre. [T72, T24]
- Centres should have a Quality Manual, standard operating procedures for all activities, guidelines and training and reference manuals.[T33, T43, T44]

- There are key documented processes required within a QMS which are not linked to any specific process or area and it is a responsibility of the management team to ensure that staff are aware of the importance of these documents and how they should use them.

These include:

1. Document control
2. Control of records [ T37, T38, T39, T40 T102, T103, T104]
3. Conducting audits [T36]
4. Non conformity control
5. Corrective actions [T36, T24, T21]
6. Preventive actions [T121]

**Examples:**

- Centres should have a clear SOP on document control [T34]
- An audit plan should be made annually as part of the management review
- Risk management and risk assessment strategies should be in place which demonstrate how the Centre is continually aiming to improve
- There should be a documented system in place that ensures the identification of all gametes and embryos[T70]

**Risks:**

- Patients could receive out of date information if there is no control of documents
- If reasons for corrective actions that have been taken are not clear and documented there is an increased chance of patients being treated incorrectly
- Key areas escape audit which may result in a lack of improvement to the service

**Quality Manual**

**Aims:**

The Quality Manual (QM) should describe how the Centre consistently provides care to patients satisfaction and meets statutory and regulatory requirements. It has several uses since it:

- Communicates the Centre’s purpose; past, present and future
- Explains how the quality system has been set up and maintained
- Demonstrates the links between different processes within the Centre
- Explains clearly who does what, when and where [T11]

- Explains how the Centre complies with external standards of the parent organisation e.g., the NHS, and other external agencies, e.g., the HFEA, which leave an impact on the Centre

**Example:**

- The QM should contain all information showing linkage between every activity within the Centre including the scope of activities undertaken, how they are achieved, by whom, with what training, resources and facilities are required, and how these can be supplied.

**Risks:**

- Not having a QM is non-compliant with the HFEA Licensed Condition [T33]
- If a Centre does not have a QM there is no realistic overview of how the Centre operates, and key areas may not be addressed.

## Control of Documents

**Aims:**

- Centres should have a documented procedure outlining how documents should be created, reviewed, approved, distributed, archived, and disposed of and who is responsible. Centres can include documents from external sources by incorporating them into their QMS and labelling them accordingly. Their distribution within the Centre should follow the same process as for in-house documents.[T34]
- It should be clear how staff can up-date documents when new evidence is available or changes to procedures need to be made. Changes to documents need to be identified and each Centre should have a method in place to do this including updating the revision status of the document. Within the QMS there should be evidence of any document having become obsolete.

**Examples:**

- All documents should have an author, a reviewer (usually a member of the management team) and be approved by the Quality Manager with a clear date of implementation and review.
- All documents should be logged in the QMS indicating where the document can be located. [T33]
- A member of staff – the Quality Representative should have responsibility for removing documents from the controlled location and replacing them in the newly reviewed/revised document.

**Risks:**

- Inadvertent use of invalid information
- Documents not being available where they are needed if location is not indicated on the QMS
- Unintended use of obsolete documents which have out of date information.

## Control of Records

### Aims:

- To have records, which are documents that state the results achieved or provide evidence of activities performed.
- To demonstrate that records are under control, Centres should be able to show that any record can be retrieved or when it was destroyed, that records are up to date and kept in good condition. Records can be used to demonstrate the effectiveness of the QMS and how the Centre is continually trying to improve. There are some specific areas where there is benefit in keeping records [T37 , T38, T39, T34]
- Individual patient records should be compiled and record all activities and contact between patients and the Centre

### Examples:

- Patient complaints
- Service reports
- Records of corrective and preventive action taken [T36]
- Management review records
- Undertaking audits against Centres objectives [T36]

### Risks:

- Improvement not happening if records are not kept and distributed following reviews, complaints and audits.

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## Section 2 Management Responsibility

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### Aims:

- Management must provide evidence of its commitment to the development and implementation of the Quality Management System. Managers must inform others of their intentions and how they are going to undertake tasks required to demonstrate the Centre is continually striving to improve its effectiveness.
- The Person Responsible (PR) must have successfully completed the Authority's entry programme [T8, T9]
- The PR must ensure restricted access to confidential identifying information registers and data to authorised personnel [T45, T8/T9]

### Examples:

- Managers must ensure that the quality policy is established and that the criteria set within it are being met.
- Managers must establish quality objectives, ensure they are established in each area and make staff aware of the objectives set and their role in achieving them. [T35]
- Managers must appoint a member of staff who is part of the management team and is responsible for ensuring the management system is established and maintained by all staff. [T12]

### Risks:

- Feedback from patients may reflect the lack of leadership within the Centre if there is no management commitment
- High staff turnover could result from Managers not being committed to improving standards whether by lack of decision-making or actions.

## Customer Focus

### Aim:

- Centres should have strategies in place for determining the requirements of patients, General Practitioners, referring Clinicians and any other Customers and how the Centre is going to meet them. In order to understand which services the Centre should supply, staff should consider who the patients are, what services they need and how these should be delivered to meet their expectations.

**Examples:**

- Undertake patient satisfaction surveys on a regular basis through questionnaires or observational studies.
- Review of literature and attendance by staff at Continual Professional Development sessions [T15].
- The Centre should have a SOP in place to ensure that all information is kept confidential and only disclosed in circumstances permitted by law [T43].
- An SOP to control access to patients' health records must be in place [T44].

**Risks:**

- Losing patients from the Centre due to their expectations not being met.
- Breach of the HFEA Code of Practice if there is no evidence of patient satisfaction being met.

## Quality Policy

**Aim:**

- Management is required to have a quality policy, which defines the overall intentions and direction of a Centre. The quality objectives are based on how the Centre will achieve the quality policy and should use words which demonstrate commitment.

**Examples:**

- We will listen to our customers
- We will train and develop our staff
- We will work with suppliers to achieve the best for our patients

**Risks:**

- Management with no commitment to their quality policy do not have a framework on which to build the quality objectives; thus staff may not be aware of their role in improving service given to patients.

## Quality Objectives

**Aims:**

- These define how the Centre will achieve the quality policy it has established and can be seen as a set of guiding principles which are measurable to ensure improvement.

- All objectives set should be achievable within the defined time frame.

**Examples:**

- If a Centre states in the Quality Policy that they will ‘listen to our patients and staff’ – they should set a measurable objective to provide evidence that this is done. This can be achieved by patient questionnaires, responding to suggestions and complaints by patients and evidence that all staff have an annual appraisal [T35].

**Risks:**

- Without quality objectives there can be no improvement and no means of measuring how well the Centre is performing.

## Quality Management System Planning

**Aims:**

- Management must ensure that provisions are in place to measure, monitor and analyse processes, determine their sequence and interaction and determine criteria and methods to ensure their effective operation and control. In addition, resources and information must be provided to support the operation and monitoring of these processes [T72, T73].

**Examples:**

- Internal audits can be set up to ensure that SOPs are being monitored and that each SOP links to the next step in the process [T36]
- Key Performance Indicators (KPIs) can be set to ensure the processes in place are effective [T35]
- Management annual reviews should highlight resources that may be required when quality policy and objectives are being discussed, and any changes should be planned and managed.

**Risks:**

- Management may assume that SOPs are being followed, however if audits are not undertaken there is no evidence that they are, which may result in patients receiving a different standard of care to that which the Centre aims to deliver.

## Responsibility, Authority, Communication

**Aim:**

- Managers must determine who does what, when and how, including guidance as to which areas and functions staff are responsible and who has the authority to take action when needed with clear lines of communication familiar to all staff [T11].
- Managers may assign responsibilities to others and can delegate authority, however the manager must remain responsible and accountable for the way that authority is used.

**Examples:**

- Clearly defined organisational diagram [T11]
- Job descriptions for all members of staff, which are familiar to all members of the team [T13]
- Standard Operating Procedures to ensure that staff are correctly trained and use these procedures as part of their job [T33]

**Risks:**

- In the absence of delegation of authority and assignment of responsibilities, individuals may assume duties that they should not be undertaking and have had no training to do, whilst other tasks may be duplicated leading to a situation where all the good jobs get done twice and the things people don't like doing are left undone.
- Can lead to tension between staff and result in less than optimum standards of care for patients.

## Management Representative

In many Centres, Quality Managers (QM) or Quality Representatives (QR) have been appointed and given the authority and responsibility for managing the QMS, but are not responsible for ensuring that the QMS produces the desired standards and improvements the Centre wishes.

**Aim:**

- The Manager within each area should work with the QM/QR to ensure the Quality Policy and Quality Objectives are being achieved as part of everyday working practices.

**Examples:**

- The QM/QR should raise document/process changes and ensure all steps are followed for document review and implementation and that staff are aware of document/process changes [T15, T34]

- The QM/QR should undertake internal audits and report their findings to the Area Manager/Management who should take appropriate measures to ensure findings are acted upon. [T36]
- The QM/QR should be responsible for producing data which Managers may rely on to determine progress.

**Risks:**

- Each area may devise their own aims without realising they are not meeting the quality objectives set by management.

## Internal Communication

**Aims:**

- There should be an agreement within the management group about who should communicate information within the Centre and how this should be undertaken. There should be a standard process for disseminating information, particularly for quality policy, document control, control of records, results of audits, corrective and preventive actions as well as nonconformity control.

**Examples:**

- Management should have strategies in place to ensure they have staff attention – through a group meeting or acknowledgement of the receipt of an email.
- Have a strategy in place to assess staff understanding of the information disseminated [T15]
- Have a strategy in place to ensure staff acceptance and that action had been taken.

**Risks:**

- The right information may fail to be transmitted
- Essential information may not be fully understood
- The information to be communicated will not have the outcome desired

## Management Review

**Aims:**

- Management should ensure that there is an annual review of the Quality Management System to ensure it is working, i.e., that the quality policy is being met through objectives being achieved effectively and efficiently. Records from management reviews should be maintained and contain

information on who participated in the review, evidence of current performance levels, identifiable strengths, weaknesses, opportunities and threats and a conclusion detailing actions, responsibilities and timescales.

**Examples:**

Review and have evidence of:

- Patients' satisfaction with the service
- Adherence to Policies Standard Operating Procedures being followed [T36]
- Quality objectives set the previous year being achieved [T36]

**Risks:**

- Continuous improvement may not be being achieved in the way management have stated that it should be.
- Patients and staff may be put at risk.

## Review Inputs

**Aim:**

Review the data from audits, patient feedback, supplier reviews, external audits (e.g. HFEA) in order to establish current performance.

**Examples:**

- Establish current performance from KPIs/Audits – identify projects to improve overall performance.
- Use corrective action data to ensure there is adequate analysis of risk management cases with clear actions being undertaken [T36].
- Review preventive action to ensure identification of potential problems including staff training and resources.

**Risks:**

- Without adequate review, continuous improvement is not possible, recurrence of risk issues is likely and prevention of future risky behaviour may not occur.

## Review Outputs

**Aims:**

- The purpose of reviewing current outputs is to make decisions and initiate actions to improve the effectiveness of the processes used to achieve the desired outcomes.

**Examples:**

- Review of KPIs to ensure desired outcomes are being met [T36].

**Risks:**

- Pregnancy rates may be less than patients are led to expect.

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## Section 3 Resource Management

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### Provision of Resources

#### Aims:

- Plan the acquisition of resources prior to deployment, following which plans are made for how resources should be used and evaluated/maintained and how and when the resources should be disposed of or terminated
- Provide and deploy resources for the effective running of the organisation [T2, T12, T14 T17, T21].
- Provide resources to improve quality management systems [T2],
- Provide resources to enhance patient satisfaction.
- Put processes in place for the actions which need to be undertaken when current resources do not meet immediate needs
- Ensure there are resources available to carry out treatment or Third Party Agreements are in place for others to supply the facility/resource. [T1]

#### Examples:

There are certain changes that have resource implications; these include:

- Unplanned loss of capability due to staff leave, equipment failure [T24] etc.
- Increase or reduction in activity.
- Changes in external standards, regulations [T36], statutes, market and patient expectations.
- Changes in availability of resources including personnel and consumables.
- Specific resources which should be defined [T31] including their quantity, delivery and quality.

#### Risks:

- Not having the resources to cope with demand.
- Plans or objectives will not be achieved unless the appropriate resources are provided.
- Having resources surplus to requirements resulting in financial loss and a risk to the effective functioning of the facility.

### Human Resources

- Personnel carrying out activities for the purpose of providing treatment services must be registered with the appropriate professional body (T14)
- The Centre must have access to a nominated registered medical practitioner, within the UK, to advise on, and oversee, medical activities (T16)

## Training, Awareness and Competence

### Aims:

- Centres should ensure that individuals are competent in the tasks required of them to achieve the desired outcome
- Centres should have processes in place to enable staff to acquire competence in skills through setting of standards.

### Examples of methods of ensuring competence:

- Provide training to satisfy those needs [T15]. Within the laboratory, there are special requirements for the use of embryos for training purposes [T93, T94, T95, T96, T97, T98]
- Evaluate the effectiveness of the training provided [T15]
- Ensure employee awareness of the importance and relevance of their activities [T15]
- Maintain appropriate training records [T15].
- The PR must have successfully completed the HFEA's PR entry programme and be responsible for all issues listed in [T9].

### Risks:

- Non-competent staff can be wasteful of time and resources if not functioning to deliver services required by the centre.
- Failure to train staff to achieve competencies for required outcomes leads to deficiencies in service with decreased effectiveness.

## Premises and Facilities

### Aims:

- To ensure the availability of permanent facilities and equipment required by a Centre.
- To provide a service or resource other than financial and human.

**Examples of premises and facility requirements:**

Suitable facilities to carry out licensed activities include:

- Office, consulting and treatment facilities [T17].
- Equipment, hardware and software including the replacement of worn or out of date equipment.[T17, T22, T23, T24, T25, T26, T27, T28, T29, T30, T31]
- Necessary supporting services; eg., maintenance contracts, independent pathology services, security services and IT [T26].
- Alterations, additions or new premises be required to undertake licensed treatment in which case the PR must contact the HFEA [T18, T19]
- Laboratories used for investigations which must be appropriately accredited [T21]

**Risks:**

- Without appropriate resources results will not be achieved.
- A malfunction in equipment can affect results.

## Work Environment

**Aims:**

- Ensure that the physical, social and psychological factors of the work environment are managed effectively so that they provide optimum conditions for employee productivity.
- Ensure that a Centre identifies and manages the work environment appropriately for treatment or service requirements.

**Examples of methods to ensure an appropriate work environment:**

- Constantly monitoring to include human and physical factors [T24, T20, T112].
- Regular documented building maintenance checks carried out and recorded [T17].
- Use of Health & Safety registers with details of corrective works commissioned.
- Employee surveys
- Air quality in fertility laboratories conforming to standards set by EU Tissue Directive and the HFEA in terms of background air quality, air filtration systems and the use of biological safety cabinets for all procedures involving the manipulation of gametes and embryos [T20].
- Oxygen monitoring systems to ensure a safe environment where liquid nitrogen vessels are used.

**Risks:**

- An unfavourable environment influences individual behaviour by causing fatigue, distraction and health problems.
- A de-motivated workforce will not produce desired results.

### General Requirements for Planning Service Delivery

#### Aims:

The centre should document the following to ensure that all activities occur consistently under controlled conditions:

- Quality objectives and requirements
- Processes, documents and resources specific to the clinic procedures
- Specific verification, validation, monitoring and inspection activities
- Records of evidence that these aims have been fulfilled

#### Examples to meet the standard include:

- A process flow diagram to identify the sequence of procedures required to deliver a service to the patient.
- Detailed SOPs should be in place to map the patient journey, and identify quality requirements.
- If new services are launched, the management team should review and plan for any additional steps to be incorporated to maintain the integrity of the quality system
- A mechanism should be in place to highlight resource needs

#### Risks:

- Lack of documentation may lead to inconsistency and increase in errors
- The resources required are not in place to meet service needs
- New services or procedures not being implemented consistently

### Patient Related Processes

#### Aims:

- For each patient/donor the Centre must maintain a record which must be clear and readable [T46, T47]
- The records must be kept for at least 30 years in accordance with HFEA/NHS Legislation [T48]
- Documented evidence must be present for the treatments undertaken [T49] including lab tests, whether they are part of investigations or prior to storage of gametes or embryos [T50, T51]

- A set of requirements should be developed with the aim of achieving satisfaction by understanding and meeting needs and expectations of patients within the regulatory framework.

**Examples:**

- Contracts with the patient e.g., costed treatment plans
- Treatment plans for the patient
- Documented procedures should be in place to ensure that the sequence of procedures in the patient journey is completed consistently to the defined requirements. [T36]
- Examples of how the patient related procedures can be monitored include:
  1. Inspection of laboratory protocols:
  2. Quarterly performance measures:
  3. Departmental/ Unit meetings
  4. Management review meetings
- Patient requirements should be recorded accurately either electronically or in the patient notes [T46, T47, T48, T49]
- Donor selection and laboratory tests must meet all requirements set out in (T52,T53,T54,T55)
- Information giving and obtaining informed consent is vital, as is what to do if a patient or partner wishes to withdraw consent, particularly in relation to legal parenting. [T61, T62, T63, T64, T65]

**Risks:**

- Increase in customer complaints
- Lack of consistency between operators and treatments
- Failure to meet regulatory requirements

## Purchaser Related Processes

**Aims:**

- A set of requirements should be developed to meet the needs and expectations of purchasers.
- A process should be in place to evaluate whether purchaser requirements are met prior to the start of treatment.

**Examples:**

- Defined and documented treatment plans

- Review and confirmation of documents required prior to treatment (e.g., welfare of the child assessment) [T56]
- Review and confirm consents [T57]
- Review and confirm screening blood test results [T52, T50]

**Risks:**

- Increased complaints
- Increased risk of failure to commence treatment

## Communication During Service Delivery

**Aims:**

- Processes need to be documented to ensure effective lines of communication for patients; from initial enquiry to completion of treatment.
- If written information is used, a system should be in place to ensure all documents used to communicate information are monitored regularly. [T34]
- To ensure informed consent is obtained, appropriate information must be provided [T57,T58]
- To have agreed processes in place with the regulator

**Examples:**

- The centre must determine which information is required and the best way to distribute it [T58, T59]
- Contracts/consents in place and completed [T57]
- Patient feedback and complaints mechanisms clearly defined including specific time lines for responses. [8Th Code of Practice interpretation of mandatory requirements, 28A]
- Personnel obtaining consent must be trained and ensure that all patients have the opportunity to receive proper counselling about the implications of treatment [T59, T60]
- A documented procedure must be in place for risk management, incident reporting and methods to report corrective and preventative actions [T118]
- Result of changes recorded and communicated to relevant personnel and the patient [T15]

**Risks:**

- Failure to improve service continually by failing to identify customer suggestions and complaints
- Ineffective methods of communication leading to an inconsistent service and increased customer complaints

- Failure to communicate with your regulator may result in loss of license to operate.

## Design and Development of Service

### Aims:

- Clinics should control design and development activities, by a simple flowchart or checklist or by more complex planning documentation
- For new procedures or projects the centre should create a clear development plan to identify responsibilities and timelines. The documentation should include plans for validation checks and review [T17, T18, T19, T23, T24, T25, T28, T72, T73].
- The scope of the plan should include all aspects of the service and involve effective communication methods with a multi-disciplinary approach.
- The documentation should include plans for validation checks and review

### Examples:

- Definition of the patient pathway
- Improvement of the protocols, following research, audit and feedback
- Processes for the implementation of new services/procedures

### Risks:

- Ineffective implementation of new services and procedures
- Failure to meet regulatory requirements

## Design and Development Inputs

### Aims:

The centre should determine the inputs required for the plan to be achieved. The following inputs can be identified, documented and reviewed:

- Functional and performance requirements
- Statutory and regulatory requirements
- Information from previous plans
- Other requirements e.g., costs, traceability, safety,

The inputs should be documented and reviewed.

**Risks:**

- Insufficient information to proceed with the most effective treatment option
- Failure to meet regulatory requirements and incorporate best practice

## Design and Development Outputs

**Aims:**

- The output is the result of the design and development inputs and process i.e., the treatment plan and process.
- The Centre should ensure that outputs :
  1. Meet the input requirements [T36]
  2. Provide appropriate information of processes and procedures [T33, T31]
  3. Contain or reference product acceptance criteria e.g., quality assurance and quality checks and KPIs [T31, T35]
  4. Identify safety issues
- The centre should ensure all aspects of the treatment are adequately documented to ensure inputs have the desired output. The design output is the treatment plan and process. However, it can also include quality checks and identification of non conformances.

## Design and Development Review

**Aims:**

- The centre should ensure procedures are in place to determine if the design and development activities meet the input requirements and the patients' needs.
- Systematic reviews should be in place to evaluate the activities and identify any problems. The review and any subsequent actions should be fully documented and include when the review was carried out and any follow up actions. The review can include risks, treatment pathways, consultation meetings, patient review meetings and lessons learnt from other situations. [T36]

**Risks:**

- Failure to identify problems and implement corrective and preventative actions to improve the service

## Design and Development Verification

### Aims:

- The Centre should ensure that there is a formal check at the end of the design and development stage to ensure the original requirements are met. This includes checking, for example, the patient and regulatory requirements. Any problems should be rectified and documented. Checks could include KPIs such as clinical pregnancy rates [T35].

### Risks:

- Failure to identify problems and implement corrective and preventative actions will compromise the service

## Design and Development Validation

### Aims:

- The centre should ensure that following verification, validation occurs. Validation can include process validation and feedback, follow up, patient satisfaction surveys and long term care or audits to measure compliance [T72, T73, T24, T25, T28, T36]

### Risks:

- Failure to identify problems and implement corrective and preventative actions will compromise the service

## Control of Design and Development Changes

### Aims:

- The centre needs a mechanism to ensure changes to plans such as treatment regimens are documented to maintain a record of the changes and their effects on outcomes [T46, T47, T48]. If a new service is being implemented and the design is changed, full details must be documented. [T33, T34]

### Risks:

- Lack of traceability if deviations from SOPs occur

## Purchasing

### Aims:

- The centre should ensure that products supplied which may have impact on the service meet the requirements set. A defined process for purchasing should be developed, for example:

## Purchasing Process

### Aims:

Purchasing Controls are implemented to ensure:

- Suppliers are evaluated, selected and monitored on their ability to supply products to meet requirements for all quality and safety issues. [T111, T112, T113, T114, T116]
- Selection and the method of evaluation are defined
- Evaluation results and actions are recorded
- Centres have up to date lists and copies of Third Party Agreements especially if gametes/embryos are procured. [T115, T117]

### Examples of evaluation criteria:

- Product and service quality
- Audit of suppliers' manufacturing site
- Capability
- Price
- Local representation available for users when required

### Risks:

- The products being supplied may not be of sufficient quality and cause a decrease in the service offered.

## Purchasing Information

### Aims:

Purchasing documents should include, where appropriate:

- Comprehensive, specific information about the product to be ordered [T114]

- Whether training will be required and how it will be delivered and evaluated [T14]
- Quality management system requirements [T32]

**Risks:**

- Incorrect products may be supplied

## Verification of Purchased Product

**Aims:**

- The Centre should establish a mechanism to check that the purchased product meets specified purchase requirements. The type and extent of the verification depends on:
  1. The type of product
  2. Supplier history and company portfolio

**Risks:**

- Product may not meet original specified requirements

## Control and Validation of Production and Service Provision

**Aims:**

Operations and services should be controlled through:

- Availability of information regarding customer requirements and treatments
- Availability of departmental protocols and SOPs [T33]
- Use and maintenance of suitable equipment [T23]
- Availability and maintenance of measuring equipment [T24, T25, T26]
- Implementation of inspection activities [T24]
- Implementation of monitoring activities [T24]
- Implementation of defined processes for delivery of treatment plans (Clinical SOPs) [T33]
- Post treatment obligations (e.g., follow up consultations)

**Risks:**

- Lack of consistency between treatments
- Equipment may function at suboptimal levels or fail

## Identification and Traceability

### Aims:

Procedures should ensure that:

- Patient records are fully identifiable [T100] and all gametes are recorded and traceable throughout the treatment [T46]
- Customer treatment plans and notes are individually identified with name and ID number [T46]
- Equipment is identified with serial numbers and records of maintenance [T99]
- Medication is identified with batch number and, where applicable, expiry date
- All medication supplied to the patient is recorded for traceability purposes. [T46]
- All staff and visitors are identified with an appropriate badge while on the premises
- All consumables batch numbers are recorded for traceability [T99], can be easily recalled if required [T122] and each container used is clearly labelled [T101]
- UKAS Logo is used correctly
- All gametes and embryos are fully traceable and there is a documented procedure [T99, T70, T122]

## Customer Property

This includes:

- Intellectual property: all information as supplied by the patient or purchaser
- Patient property during treatment
- Embryos can only be produced with the intention to use them, or store them for the treatment of a particular woman [T66]

## Preservation of Product

All gametes and embryos are handled and preserved during processing and storage to ensure viability is maintained. This should be addressed within a SOP [T33, T72].

Storage of gametes and embryos must be carried out under controlled conditions. Embryos and gametes must be kept for the statutory period only and with appropriate written consent [T75, T76, T77, T78, T79, T80, T81, T82, T83, T84]

### Risks:

- Inability to demonstrate full traceability throughout every aspect of a patient's treatment
- Risks to the security of patients' property

## **Control of Measuring and Monitoring Equipment**

### **Aims:**

- Controls should be in place to ensure that the capability of measuring and monitoring equipment is consistent with required standards. All critical equipment should be calibrated to determine how accurate it is against a reference standard. [T24] All results need to be recorded and if a non conformity occurs corrective action be taken [T25, T26, T27]
- Verifications, inspections and tests ensure that the product meets customer expectations.

### **Risks:**

- Equipment fails to operate optimally
- Inadequate service records

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## Section 5 Measurement, Analysis and Improvement

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### Monitoring and Measurement

#### Aim:

- To ensure monitoring, measurement, analysis and improvement activities are planned and implemented throughout a Centre to ensure continuing improvement.
- To have in place standards against which to judge results. [A standard or target performance indicator defines what should be done; measurement determines what is being done.]

#### Examples:

- Prepare documents that describe the Centre's plans for achieving quality [T33] ensuring the documents contain both quality assurance and quality control.
- Identify if the service has the ability to satisfy patient needs
- Assess quality risks in processes and end products (e.g., pregnancy rates) [T36]
- Identify if service plans are being implemented, and risks contained.[T36].

### Customer Satisfaction

#### Aims:

- To make patient satisfaction the main motive behind quality assurance, and a key performance indicator.
- To ensure Human Fertilisation and Embryology Authority patient, GP and referring Clinician's perceptions are met.

#### Examples on how customer satisfaction is monitored:

- Collect and analyse data on customer perceptions through questionnaires, GP/Clinician meetings.
- Follow up consultation with all patients
- Patients can feedback to the Centre where they received treatment or to the HFEA.
- Regular patient satisfaction questionnaires. These are distributed towards the end of treatment but at the patients' discretion as to whether they wish to complete them anonymously.
- User Satisfaction questionnaires designed for referring clinicians

- Review of complaints.
- Informal communication between staff and patients which is communicated to the multidisciplinary meetings.

**Risks:**

- Fewer patients would be referred to the service if action is not taken on areas of concern highlighted by patients.
- Failure to monitor and respond to patient satisfaction may jeopardise the service
- Users with out of date information

## Internal Audit

**Aims:**

- To have a documented process in place for carrying out audit and evaluating the results objectively to determine the extent to which agreed standards or criteria have been met [T36].
- To define the scope, frequency and method of audit [T36].
- To record audit results and ensure that timely corrective action is taken. Follow up action includes the reporting of corrective action implementation.
- To ensure that any clinical audits undertaken are reviewed within the quality management system on receipt of the relevant report.

**Examples:**

- Internal audits conducted periodically to determine that the quality system conforms to the relevant standard (e.g., ISO9001) and is effectively implemented and maintained
- [Interpretation of mandatory requirements at 23A of the 8th HFEA Code of Practice : The Centre management must regularly review the Centre’s quality management system and all its services, identifying the need for changes and opportunities for improvement]

**Risks:**

- The service would not be able to tell if the systems put in place had achieved a Centre’s objectives and fulfilled the functions for which it had been designed.
- When audits are not undertaken it would be difficult to establish where corrective action should be undertaken.

## Monitoring and Measurement of Processes

### Aims:

- To document the output of a Centre's service by inspection, testing and monitoring of processes.

### Examples of process monitoring include:

- Pre-cycle stimulation meeting held weekly to ensure all steps completed before ovarian stimulation begins
- Witness checks in laboratory at each stage of the laboratory process carried out by two members of staff [T36]
- Monthly pregnancy rate (biochemical and clinical pregnancy rate)[T36]
- Percentage of fertilised eggs and cleaved embryos [T36]
- Conditions in the laboratory including air quality and results of microbiological screen [T36]
- Monitoring of cleanliness [T36]
- Internal and external quality control e.g., National External Quality Assessment Service (NEQAS)

### Risks:

- Where processes are not measured, valuable time and resources may be wasted
- Reactive changes may be implemented where a considered approach is required but only if the information is available.

## Monitoring and Measurement of Measuring Equipment

### Aims:

- To detect adverse events before they occur so that action can be taken to prevent non-conformity, taking into account the requirements of the patient, the regulator and the Centre.
- To ensure there is a documented procedure for every critical activity which records identifying information about all of the materials and equipment used [T22].

### Examples:

- Receipt and testing of consumables including all batch numbers.
- Inspection of laboratory protocols [T34]
- Records of equipment used for processing of gametes and embryos
- Laboratory performance indicators [T35]

- Quarterly performance measures
- Calibrating equipment [T24]

**Risks:**

- If a centre does not identify the monitoring and measurements to be undertaken, it would have little knowledge of whether requirements had been met.

## **Control of Nonconforming Product**

**Aims:**

- To reduce nonconformities caused by factors that should not be present in a process.
- To identify a service or treatment which does not conform to requirements, and prevent it happening again [T36].

**Examples of non-conformances include but are not limited to:**

- Inadequate or inappropriate materials and services
- Equipment that is not functioning correctly or is out of service or out of calibration
- Out-of-date supplies, medication or drugs, which have not been disposed of properly
- Failure to meet legislative or regulatory requirements (e.g., HFEA, Healthcare Commission, occupational health and safety regulations)
- Failure to meet procedures, standards or practice guidelines
- Deficiencies in the quality management system or procedures

**Risks:**

- Factors that cause nonconformity on one occasion, unless removed could cause non-conformity again.

## **Analysis of Data**

**Aims:**

- To collect and analyse data which monitors the suitability and effectiveness of the Quality Management System
- To collect data which measures the effectiveness of the Quality Management System and identifies improvements that can be made.

**Examples of data to be collected include:**

- Waiting time for clinic from referral
- Numbers of cycles started per treatment type and outcomes of each cycle
- Patient satisfaction
- Staff satisfaction
- Air quality in laboratories where gametes are collected

**Risks:**

- Such data are essential in ensuring effective quality management.
- Quality management is only as good as the data provided

## Improvement

**Aims:**

- The Centre should have in place systems to manage the processes of the Quality Management System.
- To make recommendations for improvement and creating change that results in improved service delivery
- Some simple questions should be asked when striving for improvement, these include:
  1. Are we doing it right?
  2. Is this the right thing to do?
  3. Is there a better way of doing it?

**Examples of methods employed to achieve this include:**

- The use of the quality policy.
- The Centre's objectives.
- Internal audits.
- Analysis of data.
- Corrective and preventive action.
- Management review meetings.

**Risks:**

- If a service is not delivered right, the service suffers.
- Undesirable changes occur that become tolerable over time

## Corrective Action

### Aims:

- To ensure action is taken to eliminate the causes of any breaches of SOPs or HFEA Code of Practice which may have resulted in an adverse outcome to the patient. [T36]
- To address issues within a risk management strategy ensuring that action taken reduces the likelihood of a recurrence
- To communicate effectively the implications or non compliances to staff ensuring they understand the action required of them and that there is monitoring to ensure the actions are implemented.

### Examples of action taken include:

- Identifying and reviewing non-conformities
- Determining the cause of non-conformities
- Evaluating the need for action to prevent recurrence
- Determining and implementing action needed
- Recording the results of action taken
- Reviewing the effectiveness of the action taken
- Notification of serious adverse reactions to HFEA [T118, T119, T120, T121]

### Risks:

- If corrective action is not undertaken there may be recurrence of the non conformity.

## Preventive Action

### Aims:

- To ensure preventive action takes place during the planning and design of processes within a Centre.
- To have pro-active risk assessment processes in place to ensure that incidents do not occur.
- To ensure that when introducing new processes, procedures or ways of working, all potential risks should be identifiable and the probability of an incident occurring ranked.

### Examples of preventive action taken to eliminate the causes of potential non-conformities and prevent occurrence:

- Identifying potential non-conformities and their causes
- Evaluating the need for action to prevent occurrence

- Determining and implementing action needed
- Recording the results of action taken [T36]
- Reviewing the effectiveness of the action taken
- Evaluating potential non-conformities which may occur
- Undertaking audits against evidence-based Standard Operating Procedures [T36]
- Undertaking a risk assessment using a risk matrix as stated on the HFEA website
- Should the Centre have to terminate activity for any reason all gametes and embryos in storage should be transferred and all patients should be notified of situation [T10]

**Risks:**

- The results and reputation of a centre would be at risk

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## HFEA Standard Licence Conditions

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### Licensing

- T1. **The activities authorised by the licence must be carried out only on the premises specified in this licence and under the supervision of the person responsible (PR). However, where authorised by a licence, procurement, testing, processing or distribution of gametes or embryos intended for human application can also be carried out on relevant third party premises, provided that such premises, and the activities undertaken there, are covered by the terms of a written third party agreement.**
- T2. **Suitable practices must be used in the course of activities authorised by this licence and in other activities carried out in the course of providing treatment services that do not require a licence.**
- T3. Any member or employee of the Authority, on production of a document identifying the person as such, if so required, must at all reasonable times be permitted to enter those premises and inspect them (including inspecting any equipment or records and observing any activity).
- T4. In support of an inspection, the Authority must be provided, within 28 days of a request in writing being made, with such information as specified in the written requests or in Directions.
- T5. A copy of the Certificate of Licence (the first page of this licence) must be displayed at the licensed premises in a position or positions in which it can easily be read by persons who are receiving treatment services or providing gametes or embryos for use for the purpose of activities governed by the Human Fertilisation and Embryology Act 1990 (as amended), or who may wish to do so.
- T6. No centre may undertake any licensable activities, treatment service or methods of carrying out licensable activity (“new activities”) that is not specified in this licence. Where the centre wishes to undertake new licensable activities, it must notify the Authority in writing and the centre must not undertake new licensable activities until the licence, where applicable, is varied to specify the new activities.
- T7. Where the PR is unable to carry out their duties, whether permanently or temporarily, (eg, where the PR is suspended pending investigation or is on extended sick leave) the holder of the licence must inform the Authority immediately and apply to the Authority for a licence variation to nominate a substitute PR. This nominated substitute PR must not commence their post unless and until the Authority decides that they are suitable.

## Person Responsible (PR)

- T8. **The PR must have successfully completed the Authority's PR Entry Programme.**
- T9. **The PR must have responsibility for:**
- a. **ensuring the requirements imposed by section 31ZD of the Human Fertilisation and Embryology Act 1990 (as amended), in relation to the provision of information to donors about resulting children, are complied with**
  - b. **ensuring that the activities are carried out on suitable premises**
  - c. **ensuring the centre's staff co-operate fully with inspections and investigations by the Authority or other agencies responsible for law enforcement or regulation of healthcare**
  - d. **ensuring fees are paid to the Authority within the timescale specified in Directions or in writing**
  - e. **ensuring data provided to the Authority about activities and data, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing**
  - f. **ensuring requests for information and/or documents from the Authority are responded to promptly, and**
  - g. **notifying the Authority immediately if s/he becomes aware of any decision or proposal to close their centre.**
- T10. **In the event of termination of activities, for whatever reason, the PR must ensure that all stored gametes, embryos or admixed embryos are transferred to another licensed centre or centres. The PR must ensure that all relevant information including traceability data and information concerning the quality and safety of gametes and embryos, is transferred with any stored gametes, embryos or admixed embryos, or that records containing this information are made accessible as required.**

## Personnel

- T11. **The centre must have an organisational chart which clearly defines accountability and reporting relationships.**
- T12. **Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals.**
- T13. **All personnel must have job descriptions that accurately reflect their tasks, and responsibilities.**

- T14. Personnel carrying out licensed activities or other activities carried out for the purposes of providing treatment services that do not require a licence must, where appropriate, be registered in accordance with the appropriate professional and/or statutory bodies, (eg, General Medical Council, Health Professions Council, Nursing and Midwifery Council).
- T15. Personnel must be provided with initial/basic training. Training must be updated as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development must be provided. The training programme must ensure and document that each individual:
- a. has demonstrated 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 & Safety rules of the centre in which they work, and
  - d. is adequately informed of the broader ethical, legal and regulatory context of their work.
- T16. The centre must have access to a nominated registered medical practitioner, within the UK, to advise on and oversee medical activities.

## **Premises and Facilities**

- T17. A centre must have suitable facilities to carry out licensed activities, or other activities carried out for the purposes of providing treatment services that do not require a licence.
- T18. Prior to making any alterations or additions to an existing premises within the same building the PR must contact the Authority and, if applicable, submit a written application for a variation of the licence. If activities, not subject to a third party agreement, are to take place in premises in a different building an application must be made for an additional licence.
- T19. Prior to moving to entirely new premises, either within the same building or in a new building, the PR must contact the Authority and submit an application to vary the licence.
- T20. In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP\_ Annex 1 and Directive 2003/94/EC). It must be demonstrated and documented that the chosen environment achieves the quality and safety required.

**NOTE: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for processing tissue for use in transplantation are different than those listed above.**

- T21. If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by Clinical Pathology Accreditation (UK) Ltd or another body accrediting to an equivalent standard. The pathology disciplines involved in diagnosis and investigation include andrology, clinical genetics, (cytogenetics and molecular genetics) haematology, bacteriology, virology and clinical biochemistry.**

## **Equipment and Materials**

- T22. For every critical activity, identifying information about all of the materials and equipment must be documented.**
- T23. Activities must be carried out using equipment and materials designated for the purpose and maintained to suit their intended purpose and must minimise any hazard to patients and/or staff.**
- T24. All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available.**
- T25. New, repaired and recommissioned equipment must be tested and validated before use. Test results must be documented.**
- T26. Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises must be performed regularly and recorded accordingly.**
- T27. Procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure.**

- T28. **Sterile instruments and devices must be used for the procurement of gametes and embryos. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.**
- T29. **When reusable instruments are used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.**
- T30. **Wherever possible only CE marked medical devices must be used.**
- T31. **The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and, when applicable, the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament under the Council of 27 October 1998 on In vitro Diagnostic Medical Devices.**

## **Quality Management**

- T32. **The centre must put in place a quality management system and implement this system to continually improve the quality and effectiveness of the service provided in accordance with the conditions of this licence and the guidance on good practice as set out in the HFEA's Code of Practice.**
- T33. **The following documentation must form part of the quality management system:**
- a. **a quality manual**
  - b. **standard operating procedures (SOPs) for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence**
  - c. **guidelines**
  - d. **training and reference manuals, and**
  - e. **reporting forms.**
- T34. **A document control procedure must be established that records the history of document reviews and ensures that only current versions of documents are in use.**
- T35. **Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.**
- T36. **Trained and competent persons must audit the activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence**

against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.

## **Records and information**

- T37. **Proper records must be maintained in such form as the Authority may specify in Directions.**
- T38. **Records must be legible and indelible and may be hand written or transferred to another validated system, such as a computer or microfilm.**
- T39. **Such information must be recorded as the Authority may specify in Directions about the following:**
- a. **the persons for whom services are provided in pursuance of the licence,**
  - b. **the services provided for them**
  - c. **the persons whose gametes are kept or used for the purpose of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used**
  - d. **any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence**
  - e. **any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo,**
  - f. **such information as the Authority may specify in directions as to the persons whose consent is required under schedule to the Human Fertilisation and Embryology Act 1990 (as amended), the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions must be included in the records maintained in pursuance of the licence, and**
  - g. **such other matters as the Authority may specify in Directions,**
- T40. **Information must not be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for records of the class in question.**
- T41. **The Authority must be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.**
- T42. **Where gametes or embryos are supplied to a person to whom another licence applies, that person must be provided with such information as the Authority may specify in Directions.**

## **Data Protection and Confidentiality**

- T43. The centre must have standard operating procedures (SOPs) to ensure that all information is kept confidential and only disclosed in circumstances permitted by law.
- T44. The centre must have in place an SOP for the control of access to health data and records, including arrangements for:
- a. establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient/donor files or records, and the transfer of information
  - b. establishing and maintaining procedures to resolve all data discrepancies
  - c. preventing unauthorised disclosure of information whilst guaranteeing the traceability of gamete, embryo or tissue (cell) donations
  - d. considering and responding to applications for access to confidential records and correctly identifying applicants, and
  - e. receiving, checking and arranging authorised access to confidential data and records.
- T45. Access to registers and data must be restricted to persons authorised by the PR and to the Authority for the purpose of inspection and control measures.

## **Patient/Donor Records**

- T46. For each patient/donor the centre must maintain a record containing:
- a. patient/donor identification: first name, surname, date of birth, age and sex
  - b. how, and by whom, the patient/donor has been reliably identified
  - c. the services provided to them
  - d. medical history
  - e. welfare of the child assessment
  - f. consent, including the purpose or purposes for which their gametes or embryos created using their gametes may be used, and any specific instructions for use and/or disposal, and
  - g. clinical and laboratory data and the results of any test carried out.
- T47. All records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.

- T48. Patient/donor records required for full traceability must be kept for a minimum of 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the Authority.

#### **Patient Selection Criteria and Laboratory Tests**

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

- T50. Prior to the storage of patient gametes or embryos the centre must::

- a. Carry out the following biological tests to assess the risk of cross contamination
  - HIV 1 and 2: Anti-HIV – 1, 2
  - Hepatitis B: HBsAg/Anti-HBc
  - Hepatitis C: Anti-HCV-Ab
- b. Devise a system of storage which clearly separates:
  - quarantined/unscreened gametes and embryos,
  - gametes and embryos which have tested negative, and
  - gametes and embryos which have tested positive.
- b. Perform HTLV- 1 antibody testing for patients 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
- c. In certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, Cytomegalovirus (CMV), T.cruzi)

Positive results will not necessarily prevent the use of the partners' gametes.

**NOTE:** Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for screening patients prior to the storing of their tissue for use in transplantation are different than those listed above.

- T51. The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:
- a. the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and

- b. blood samples must be obtained at the time of donation.

## Donor Selection and Laboratory Tests

- T52. Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below, namely:
- a. 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 donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (eg, superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor)
  - b. the donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:
    - HIV 1 and 2: Anti-HIV – 1, 2
    - Hepatitis B: HBsAg/Anti-HBc
    - Hepatitis C: Anti-HCV-Ab
    - Syphilis: see (d) below
  - c. the centre must devise a system of storage which clearly separates:
    - quarantined/unscreened gametes and embryos,
    - gametes and embryos which have tested negative, and
    - gametes and embryos which have tested positive.
  - d. a validated testing algorithm must be applied to exclude the presence of active infection with *Treponema Pallidum*. The non-reactive test, specific or non-specific, can allow gametes 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. The donor whose specimen test reacted on a *Treponema*-specific test will require a thorough risk assessment to determine eligibility for clinical use
  - e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the Nucleic Acid Amplification Technique (NAT)
  - f. all donors must be screened for CMV

- g. HTLV-1 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, and**
- h. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the gametes donated (eg, RhD, Malaria, T.cruzi).**

**T53. The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:**

- a. the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge,**
- b. blood samples must be obtained at the time of donation, and**
- c. donor sperm must be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.**

**T54. Where donor gametes and/or embryos created with donor gametes are to be used in treatment the following conditions apply:**

- a. where the gametes were provided by a person who gave consent as required by paragraph 5 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) (a 'gamete donor') and who last provided information as to their identity before 1 April 2005 (donors who did not consent to their identity being known) and/or where embryos, were created using those gametes those gametes and/or embryos may not be used, except:**
  - i. in the case of gametes supplied by the donor before 1 April 2005, where the woman to be treated or, where she is receiving treatment together with another person, that person, is the parent of a child conceived as a result of treatment services provided before 1 April 2006 using gametes provided by the donor of those gametes**
  - ii. in the case of embryos created using donor gametes before 1 April 2005, where the woman to be treated or, where she is receiving treatment together with another person, that person, is the parent of a child conceived as a result of treatment services provided before 1 April 2006 using embryos donated by those who provided the gametes from which those embryos were created, or**
  - iii. in the case of embryos, where the embryos were created before 1 April 2006 using gametes supplied by a donor before 1 April 2005 together with the gametes of the**

woman to be treated or, where she is receiving treatment together with another person, with the gametes of a donor together with the gametes of that person, and not transferred to the woman to be treated before that date.

b. in the case of treatments falling within the exemptions at (i) to (iii) above, the gametes or, as the case may be, embryos, may be kept in storage and used in accordance with the consent of the gamete providers until the expiry of the maximum permitted storage period.

T55. Potential donors that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability

b. a serious illness, or

c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

#### **Welfare of the Child, Provision of Information, Counselling and Consent**

T56. A woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.

T57. Gametes or embryos must not be used in the provision of treatment services (except in the use of gametes in the course of providing basic partner treatment services or non-medical fertility services) or placed in storage unless effective consent is in place from each gamete provider in accordance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

T58. Prior to giving consent gamete providers must be provided with information about:

a. the nature of the treatment

b. its consequences and Risks:

c. any analytical tests, if they are to be performed

d. the recording and protection of personal data and confidentiality

e. the right to withdraw or vary their consent, and

f. the availability of counselling.

T59. The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.

T60. A woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of her being provided

with treatment services of that kind, and have been provided with such relevant information as is proper.

- T61. A woman must not be provided with treatment services where there is an intended second parent unless she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.
- T62. The reference in licence conditions T60 and T61 above to the intended second parent is a reference to:
- a. any man with respect to whom the agreed fatherhood conditions in Section 37 of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61, and
  - b. any woman with respect to whom the agreed female parenthood conditions in Section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61.
- T63. In the case of treatment services using donated gametes, or embryos using donated gametes, the person receiving treatment and any intended second parent, must be provided with information about:
- a. the importance of informing any resulting child at an early age that they were born as a result of such treatment, and
  - b. suitable methods of informing such a child of that fact.
- T64. In cases where the nominated second parent withdraws their consent to be treated as the parent of any child born to a named woman, the PR must:
- a. notify the woman in writing of the receipt of the notice from the second parent, and
  - b. ensure that no treatment services are provided to the named woman until she has been notified of the second parent’s withdrawal of consent.
- T65. If a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this.

- T66. **The centre may not attempt to produce embryos in vitro unless there is an intention to store or use the resulting embryo(s) or unless there is a specific reason why it is necessary to do so in connection with the provision of treatment services for a particular woman.**
- T67. The centre must not attempt to produce embryos in vitro by embryo splitting for treatment purposes.
- T68. Where the sperm is procured at home, the centre must record this in the gamete provider's records.
- T69. No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by Directions.
- T70. **There must be a documented system in place that ensures the identification of all gametes and embryos from procurement to use or disposal.**

### **Processing and Use of Gametes and Embryos**

- T71. Centres must have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place. A record must be kept in each patient's/donor's medical records. These records must include the name, status and signature of the person performing the activity and the name, status and signature of the person who witnesses the procedure.
- T72. **The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.**
- T73. **Before implementing any significant change in processing, the modified process must be validated and documented.**
- T74. There must be a documented system in place for ratifying that gametes and/or embryos meet appropriate specifications of safety and quality for use and for their transportation/distribution.

### **Storage of Gametes and Embryos**

- T75. **Centres must ensure that all storage processes are carried out under controlled conditions.**

- T76. **Gametes of a person must be placed in storage only if –**
- a. **received from that person,**
  - b. **acquired in circumstances in which by virtue of paragraph 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person’s consent to the storage is not required, or**
  - c. **acquired from a person to whom a licence or third party agreement applies.**
- T77. **Embryos taken from a woman must be placed in storage only if –**
- a. **received from that woman, or**
  - b. **acquired from a person to whom a licence or third party agreement applies.**
- T78. **Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.**
- T79. **No gametes or embryos must be kept in storage for longer than the statutory storage period and, if stored at the end of the period, must be allowed to perish.**
- T80. **The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.**
- T81. **The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.**
- T82. **Regulations may provide that licence conditions T80 and T81 must have effect as if for ten years there were substituted –**
- a. **such shorter period, or**
  - b. **in such circumstances as may be specified in the relevant Regulations, such longer period, as may be specified in the relevant Regulations.**
- T83. **Gametes or embryos which are or have been stored must not be supplied to a person otherwise than in the course of providing treatment services, unless that person is a person to whom a licence applies.**
- T84. **With respect to treatment involving storage of eggs and any other subsequent activities the following licence conditions apply:**
- a. **That before a woman gives consent to the storage and/or use of cryopreserved eggs in treatment services she must be given an oral explanation supported by relevant written material explaining,**
    - i. **all risks associated with the cryopreservation and thawing of eggs, and**
    - ii. **that counselling is available.**
  - b. **That the centre must not mix, in the same treatment cycle:**
    - i. **fresh eggs with eggs that have been cryopreserved**

- ii. **embryos that have been created using cryopreserved eggs with embryos created using fresh eggs, or**
- iii. **cryopreserved embryos that have been created using cryopreserved eggs with cryopreserved embryos that have been created using fresh eggs.**

T85. A documented risk assessment must be undertaken to determine the fate of all stored gametes and embryos following the introduction of any new donor/patient selection or testing criterion or any significantly modified processing step that enhances safety or quality.

## Embryo Testing

T86. Embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

- a. a serious physical or mental disability
- b. a serious illness, or
- c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

T87. Embryos that are known to be of a particular sex and are known to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop:

- a. a gender-related serious physical or mental disability
- b. a gender-related serious illness, or
- c. any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

T88. With respect to any embryo testing programme involving blastomere/polar body biopsy the centre must ensure that:

- a. embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, are not transferred with any other (non- biopsied) embryos in the same treatment cycle
- b. no embryo or material removed from it is subjected to a test that supplies genetic information about the embryo, which is not expressly authorised by the Authority
- c. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test, that supplies genetic information about the embryo, which is not expressly authorised by the Authority, and
- d. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.

- T89. With respect to any preimplantation genetic diagnosis (PGD) programme the centre must ensure that PGD is only being carried out for those genetic conditions, chromosomes or traits (or combinations of these) that are expressly authorised by the Authority.
- T90. With respect to any preimplantation genetic screening (PGS) programme the centre must ensure that:
- a. PGS for aneuploidy is only carried out for the chromosomes, or combination of chromosomes authorised by the Authority
  - b. any information derived from tests on an embryo, or any material removed from it or from gametes that produced it, is not used to select embryos of a particular sex for social reasons
  - c. before the people seeking treatment give consent to preimplantation screening of embryos for aneuploidy they must be given an oral explanation supported by relevant written material:
    - i. of the risks associated with the preimplantation screening for aneuploidy
    - ii. of the unproven nature of the procedure, in particular that more robust clinical and laboratory trials are needed to assess whether or not PGS can significantly increase live birth rates for different specific indicators and it is likely that the method of fluorescent in situ hybridisation (FISH) on embryos, using a limited number of chromosomes, is not effective at increasing live birth rates
    - iii. that embryos that have been biopsied may not be available for cryopreservation and for use in subsequent treatment cycles
    - iv. of the misdiagnosis rates associated with the preimplantation screening for aneuploidy, including that the misdiagnosis rates can be positive or negative
    - v. that the more chromosome tests that are used, the higher the technical failure rate, and the lower the chance of finding suitable embryos for transfer
    - vi. that there is no guarantee against a miscarriage occurring, despite PGS for aneuploidy being performed
    - vii. of the costs of treatment both financially and emotionally in the context of the chance of not taking home a baby following preimplantation screening for aneuploidy, and
    - viii. that counselling is available.
  - d. they monitor the latest literature and professional guidance in order to validate the use of PGS for each category of patients to which they offer it. Validation should be also be based on data from previously published studies and retrospective evaluation of their own data.
- T91. Centres may use non-invasive procedures, for example metabolomics, to test and select for the viability of embryos. However, centres must not use these procedures to test for specific gene, chromosome or mitochondrion abnormality without prior authorisation from the Authority.

## Use of Embryos for Training Staff

- T92. No embryo appropriated for the purpose of training staff in embryological techniques must be kept or used for the provision of treatment services.
- T93. **Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques and in those activities that are expressly authorised by the Authority.**
- T94. **Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, where both gamete providers have consented to the use of embryos, created using their gametes, for the purpose of training.**
- T95. **The centre must establish, implement and comply with documented procedures to ensure that clinical and training roles are separated.**
- T96. **The centre must establish, implement and comply with documented procedures to ensure that the number of embryos used in training is kept to a minimum.**
- T97. **Prior to giving consent, each gamete provider must be provided with the necessary information including:**
- a. **the nature of the training for which embryos will be used**
  - b. **that the decision whether to donate will not affect their treatment in any way**
  - c. **that they can vary or withdraw the terms of their consent until the point the embryos are used in training, and**
  - d. **whether any information will be fed back to the them.**
- T98. **The information referred to in licence condition T97 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes.**

## Traceability and Coding

- T99. **The centre must establish, implement and comply with documented procedures to ensure that:**
- a. **all gametes and embryos, and**
  - b. **all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa.**
- T100. **The documented procedures referred to in licence condition T99 include the following information:**
- a. **the unique and accurate identification of each patient/donor**
  - b. **the unique and accurate identification of each set of gametes and embryos**

- c. **date of procurement**
- d. **place of procurement**
- e. **type of treatment**
- f. **description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and**
- g. **description of all processing steps applied to the procurement, use and storage of gametes and embryos.**

- T101. **The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, possessing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying.**
- T102. **The centre must record such information as is necessary to facilitate the traceability of gametes and embryos and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.**
- T103. **The centre must keep data necessary to ensure traceability for a minimum of thirty years (and for such longer period as may be specified in Directions) in an appropriate readable storage medium.**
- T104. **Records not covered by licence condition T103 and test results that impact on the safety and quality of the embryos and gametes, must be kept so as to ensure access to the data for at least 10 years after the expiry date, clinical use or disposal.**

### **Import, Export and Transportation/Distribution of Gametes and Embryos**

- T105. All gametes and embryos must be packaged and transported in a manner that minimises the risk of contamination and preserves the required characteristics and biological functions of the gametes or embryos. The packaging must also prevent contamination of those responsible for packaging and transportation.
- T106. The packaged gametes/embryos must be shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos.
- T107. The transport conditions, including temperature and time limit, must be specified and the labelling of every shipping container must include as a minimum:
- a. a label marked "TISSUES AND CELLS" and "HANDLE WITH CARE"

- b. the identification of the establishment from which the package is being transported (address and telephone number) and a contact person in the event of problems
- c. the identification of the tissue establishment of destination (address and telephone number) and the person to be contacted to take delivery of the package
- d. the date and time of the start of transportation.
- e. the type of gametes/embryos plus their identification code
- f. specifications concerning conditions of transport relevant to the quality and safety of the gametes or embryos
- g. specifications concerning storage conditions such as “DO NOT FREEZE”
- h. in the case of all gametes and embryos, the following indication: “DO NOT IRRADIATE”, and
- i. when a product is known to be positive for a relevant infectious disease marker, the following indication: “BIOLOGICAL HAZARD”.

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

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

### **Receipt of Gametes and/or Embryos**

- T109. The centre must put in place, maintain and implement a procedure for the receipt of gametes and/or embryos from another centre or third party premises to ensure that:
- a. the consignment of gametes and/or embryos is verified against SOPs and specifications. These must include information relating to the transport conditions, packaging, labelling, patient/donor documentation, and any other associated documentation and samples. These must also include the technical requirements and other criteria considered by the establishment to be essential for the maintenance of acceptable quality, and
  - b. the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant patient/donor and procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.
- T110. The following data must be registered at the centre:

- a. consent including the purpose(s) for which the gametes and/or embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the consented purpose
- b. patient/donor identification and characteristics: age, sex and presence of risk
- c. all required records relating to the procurement and the taking of the patient/donor history
- d. gametes and embryos obtained and relevant characteristics
- e. the results of laboratory tests and of other tests, and
- f. a properly documented review of the complete patient/donor evaluation against the selection criteria by an authorised and trained person.

### **Third Party Relations**

- T111. **The centre must establish a written agreement with those third parties who provide goods or services that influence the quality and safety of gametes and embryos, 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 assurance, including the process of distribution, and**
  - c. **the centre distributes gametes or embryos processed by third parties.**
- T112. **The centre must evaluate and select third parties on the basis of their ability to meet the requirements of these licence conditions and the guidance set out in the HFEA Code of Practice.**
- T113. **Agreements with third parties must specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification.**
- T114. **The centre must ensure that the following core requirements are included in any third party agreement, namely:**
  - a. **full address and contact details of the third party, and nature of the service to be provided**
  - b. **identification of person(s) responsible for managing arrangement between the centre and the third party**
  - c. **provision setting out how often the agreement will be reviewed and by whom**
  - d. **summary of the responsibilities of the third party and agreed procedures with regard to each party's respective responsibilities,**
  - e. **any specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety, and**
  - f. **description of how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.**

- T115. The centre must keep a complete list of agreements referred to in licence condition T111 that they have established with third parties. Copies of these agreements must be made available to the Authority upon request.
- T116. The centre must ensure that it is made a condition of any third party agreement referred to in licence condition T111 that the third party will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice.
- T117. Where the third party procure gametes and/or embryos on behalf of a licensed centre, the third party agreement must require the procuring establishment to produce a report to the licensed centre which must include, but not be limited to, a record of the following:
- a. where the procurement took place
  - b. patient/donor identification data including how and by whom identified
  - c. description and identification of the procured gametes/embryos including samples for testing
  - d. identification of the person responsible for the procurement process
  - e. date, time and location of procurement and SOP used
  - f. details of any incidents, including any serious adverse events and/or reactions, that occurred during the procurement process
  - g. where appropriate, the environmental conditions at the procurement facility, and
  - h. where appropriate, the identification/batch numbers for any reagents and transport media used.

## **Identification, Investigation, Reporting, Recording and Notification of Serious Adverse Events and Reactions**

- T118. The centre must establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions that occur on any premises to which a licence relates and any relevant third party premises.
- T119. The documented procedures referred to in licence condition T118 must enable the centre to communicate to the Authority, without delay:
- a. all relevant available information about suspected serious adverse events and reactions, and
  - b. the conclusion of the investigation to analyse the cause and ensuing outcome in relation to serious adverse events and reactions.

**T120. The PR must notify the Authority of any suspected serious adverse events and serious adverse reactions by providing the information set out below and such other information as the Authority may specify in Directions:**

- a. identification of the centre**
- b. identification of the premises concerned**
- c. report identification**
- d. date of notification, and**
- e. date of serious adverse event/serious adverse reaction**

**In relation to serious adverse events the following information is also required:**

- f. 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) to (e) above.**

**In relation to serious adverse reaction(s) the following additional information is also required:**

- g. date and place of procurement of gametes or application of gametes or embryos**
- h. unique donation identification number**
- i. date of suspected serious adverse reaction**
- j. details of gametes or embryos involved in the suspected serious adverse reaction, and**
- k. type of suspected serious adverse reaction(s).**

**T121. The centre must thereafter notify the Authority of the conclusion of the investigation into the serious adverse event/serious adverse reaction by providing at least the information set out below and any such other information as the Authority may specify in Directions:**

- a. identification of the centre**
- b. identification of the premises concerned**
- c. report identification**
- d. date when the serious adverse event/serious adverse reaction was confirmed**
- e. date of the serious adverse event/serious adverse reaction, and**
- f. corrective measures taken.**

**In relation to serious adverse reaction(s) the following additional information is also required:**

- g. date when the serious adverse reaction was confirmed**
- h. unique donation identification number**
- i. confirmation of the type of reaction(s) or a change in the type of reaction(s),**
- j. clinical outcome, if known:**
  - i. complete recovery**
  - ii. minor sequelae**

iii. **serious sequelae, or**

iv. **death**

k. **root cause analysis**

l. **outcome of investigation and final conclusions, and**

m. **recommendations for preventive and corrective actions.**

**T122. The centre must ensure that an accurate, rapid and verifiable procedure is in place, which will enable it to recall from distribution any product that may be related to a serious adverse event or reaction.**

**28A. Interpretation of mandatory requirements: The law requires NHS and private centres to have, and adhere to, a complaints procedure.**