Site visit inspection report on compliance with HTA minimum standards

Luton and Dunstable Hospital

HTA licensing number 22605

Licensed for the

- **procurement, testing, storage and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007**

14 May 2013

Summary of inspection findings

The HTA found the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although the HTA found that the Luton and Dunstable Hospital (the establishment) had met the majority of the HTA standards, six shortfalls were found in relation to governance and quality systems. The shortfalls relate to the requirement for independent audits to be conducted every two years to verify compliance with protocols and HTA standards, for an organisational chart to be in place defining the lines of accountability for those working under the licence, and for risk assessments to be carried out in relation to all licensable activities. The establishment's standard operating procedures (SOPs) should be subject to appropriate document control and they should be amended to include sufficient information to safeguard the quality and safety of the tissues being stored under the authority of the licence. The establishment should also implement systems for distributing regulatory alerts and for ensuring that Serious Adverse Events and Reactions (SAEARs) are reported to the HTA.

The HTA was unable to contact the Designated Individual in the lead up to the inspection, and he was unavailable on the day of the inspection itself. Since the inspection, the HTA has received a formal application to change the DI.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone	**E***		**E***	**E**	**E***		
Tendons	**E***		**E***	**E**	**E***		
Chondrocytes	**E***		**E***	**E***	**E***		

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by the Luton and Dunstable Hospital. The establishment, which is part of the Luton and Dunstable Hospital NHS Foundation Trust, is licensed for the procurement, testing, storage and distribution of human tissues and cells

under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The establishment has been licensed by the HTA since August 2010 and has been inspected on one previous occasion.

The Luton and Dunstable Hospital currently purchases and stores around 50 samples a year from another HTA-licensed organisation for use in orthopaedic surgery. The majority of samples held by the establishment are femoral heads, although bone struts and tendons are also occasionally stored. Samples received into the establishment are logged in its Bone Register and stored in a dedicated freezer located within a secure area of the hospital that is manned on a 24 hour basis. The freezer is fitted with an audible alarm and is subject to continuous monitoring to ensure that appropriate storage conditions are maintained. Records associated with sample storage, such as the data sheets from the freezer's chart recorder and the establishment's logs of daily manual temperature checks, are stored in accordance with the requirements set out in the HTA's "Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment" which forms the Annex to Directions 003/2010.

The establishment also has procedures in place relating to the procurement of chondral tissue for use in Autologous Chondrocyte Implantation (ACI) for the repair of damaged knee cartilage. In these cases, samples would be distributed to one of a number of companies, which process the tissue samples into an Advanced Therapy Medicinal Product (ATMP). The ATMP has been granted Marketing Authorisation by the European Medicines Agency, and therefore its manufacture and distribution for end use fall outside the remit of the HTA other than with regard to continued traceability and SAEARs reporting. The licensable activities relating to this work are therefore restricted to procurement and testing. At the time of the inspection, although no samples had been procured by the establishment for this purpose, the systems and documentation relating to this activity were reviewed to assess their suitability should this activity commence.

The establishment also stores demineralised bone products purchased from another HTA-licensed establishment. As storage of acellular products for end use is not currently regulated, the systems used for the storage of these samples were not assessed as part of this inspection.

This report describes the establishment's second routine site visit inspection which took place on 14th May 2013. The inspection included interviews with key members of staff working under the licence, including the Senior Orthopaedic Lead, who is also the Person Designated, and a Team Leader/Theatre Lead. An interview was also conducted with one of the hospital's Consultant Orthopaedic Surgeons, who had been identified by the establishment as a possible replacement for the incumbent DI. A review of documentation relevant to the establishment's activities and a visual inspection of the areas of the establishment where licensable activities take place were also conducted as part of the inspection.

An audit of the five samples held in storage at the time of the inspection was performed. Storage locations were cross-checked with records, including the establishment's Bone Register, to ensure that they contained all relevant documentation and that the information contained therein was accurate. Although a minor transcription error was noted in the e-procurement system in relation to one of the samples, this was readily resolved using

associated records and the error did not impact on sample traceability. No further discrepancies were found.

Inspection findings

The HTA found the Licence Holder to be suitable in accordance with the requirements of the legislation.

The HTA was unable to contact the DI in the lead up to the inspection. As a result, arrangements for the inspection were made with the nominated Person Designated and other members of staff working under the licence. Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the DI has a statutory duty to ensure that the conditions of the licence are complied with. The DI must also be in a position to secure that suitable practices are used in the course of carrying out licensable activities, and that these activities are carried out by suitable persons. Failure to exercise these duties, or to respond to formal requests for information, may result in the HTA taking regulatory action. On enquiry, it was explained to the HTA that the DI felt that his operational commitments compromised his ability to fulfil the role of DI and that steps had been taken by the establishment to identify a suitable replacement. The prospective new DI was available on the day of the inspection to assist the inspection team, and he provided appropriate assurances that his current role would not preclude him from discharging the statutory duties of a DI. Shortly after the inspection a formal DI change request was received by the HTA. The change request was authorised by the HTA prior to completion of the inspection report.

The establishment should be mindful of the legal responsibilities of the DI and the fact that, although day-to-day operational matters relating to licensed activities can be delegated to staff working under the licence, responsibility for ensuring regulatory compliance rests with the DI. If, in the future, a change of DI becomes necessary, this should be communicated to the HTA in a timely fashion to mitigate any risk of the establishment operating without a DI. In addition to ensuring regulatory compliance, this will help ensure that staff working under the licence are appropriately supported as they carry out licensable activities.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.	At the time of the inspection, an organisational chart setting out the lines of accountability and reporting relationships for staff working under the licence was not in place.	**Minor**
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	Although the establishment has put in place SOPs for the majority of licensable activities, those relating to autologous chondrocyte implantation lack sufficient information to ensure the integrity of any samples procured as part of this procedure. SOPs should be updated to reflect the current facility being used by the orthopaedics team, and process critical fridges and freezers should be identified accordingly. All parameters that are critical for ensuring the quality and safety of the samples, such as storage temperatures and times, should be set out in the SOPs themselves so that this information is readily available to those carrying out this work. The SOP relating to the storage and use of human tissue products does not make reference to the procedures that should be followed when tendons are received into the establishment.	**Minor**
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.	Although the establishment has an effective document control system in place for Trust-level documentation, SOPs relating to licensable activities are not consistently being subjected to the same control measures. For example, documents lack unique identifiers and version numbers are not completed. Document author fields are inconsistently completed, as are relevant dates such as 'effective from' and 'review by' dates. There is also an inconsistent approach to document authorisation, with this being absent in some instances.	**Minor**

GQ2 There is a documented system of quality management and audit.		
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	Although evidence of internal audits was noted during the inspection, at present the schedule of audits does not include provision for an independent audit to be conducted every two years aimed at assessing the establishment's compliance with its own protocols and with the HTA's standards.	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.	At the time of the inspection, an effective system for distributing regulatory information was not in place, so communications from regulatory bodies, such as the HTA, are not consistently shared with staff working under the licence.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
a) There are documented risk assessments for all practices and processes. b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.	Although the establishment has a robust approach to risk management at Trust level, at the time of the inspection documented risk assessments were not in place for the licensable activities being undertaken. As a result, the risks associated with the carrying out of these activities are not being reviewed on a regular basis.	**Major**

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ1b	A number of the establishment's SOPs make reference to the Human Tissue Act and certain HTA Codes of Practice where reference to the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment would be more appropriate. The DI is advised to update SOPs accordingly to ensure that users are directed to the most relevant information sources for the work they are involved in.
2.	GQ2a	The DI is advised to implement a clear quality manual relating to licensable activities. Such a document would supplement and clarify the establishment's

		existing quality management systems and act as a useful reference document for those working under the licence.
3.	GQ4c	The DI is advised that all staff should adhere to a consistent, accepted procedure for correcting errors in written records. Such an approach, which could include striking through errors with a single line and initialling and dating corrections, would facilitate audit. The use of correction fluid within written records should be avoided. SOPs relating to the management of records should be updated accordingly.
4.	GQ7a	Although the establishment has an effective and robust approach to incident recording and management, the DI should ensure that all instances of sample disposal resulting from freezer malfunction are reported and investigated in accordance with the systems that are in place. Consideration should be given to whether SOPs or related documentation need to be updated to help ensure that this is the case, and whether the recording of incident reference numbers in the bone register would facilitate this process. The DI is also advised to clarify within documentation relating to incident management the circumstances under which the disposal of samples due to freezer malfunction would be reportable to the HTA as a SAEAR. In line with this, the DI should consider whether incorporating a list of relevant SAEARs within related documentation would be beneficial.
5.	GQ7b	The DI is advised to ensure that at least one other member of staff is able to report serious adverse events or reactions via the HTA's web portal to avoid unnecessary delays in reporting in his absence. This arrangement should be reflected in related SOPs and documentation.
6.	PFE3c	The DI is advised to ensure that the correct graph paper is used in the freezer's chart recorder. SOPs relating to freezer use should state clearly what paper should be used and should include information on the appropriate temperature scale for the chart recorder being used. Compliance should be checked on a regular basis to ensure that records relating to sample storage conditions are accurate.
7.	PFE5c	The DI is advised to review the information captured in the freezer temperature log book on a regular basis so that the potential need for preventative maintenance can be identified prior to freezer malfunction. The DI should also consider whether the inclusion of clear alert/action levels in SOPs relating to freezer operation and monitoring would be beneficial in this regard.
8.	D2a	The DI is advised to ensure that the reason for disposal of tissue is captured in the bone register. Although at present this can be inferred from ancillary records, a more consistent approach to the recoding of this information would facilitate audit and root cause analysis.

Concluding comments

The HTA saw several examples of good practice throughout the course of the inspection.

Staff involved in the inspection were very committed to the successful treatment of patients and there was a clear commitment to further continuous improvement. This was evidenced, in

part, by the recent introduction of an effective, competency-based training program and the introduction of additional local governance meetings. Both of these initiatives should serve to further support staff in their roles and to help ensure that tissue samples are stored in such a way that helps safeguard their quality and safety.

As noted above, the establishment also has a very robust approach to the management of incidents and non-conformances. The system employed by the establishment enables effective root cause analysis to be conducted and helps ensure that any corrective actions are appropriately tracked/implemented. The system in use should also help the establishment identify further opportunities to drive up standards and refine working practices.

Six areas of practice were identified during the inspection that require improvement, resulting in one major and five minor shortfalls. These relate to risk assessments, the distribution of regulatory alerts and the reporting of SAEARs, and to the requirement for an independent audit to be conducted every two years. SOPs relating to licensable activities should contain sufficient information to help ensure the quality and safety of any samples held under the authority of the licence, and all relevant documentation should be subject to appropriate document control. An organisational chart should also be put in place defining the lines of accountability for those working under the licence.

The HTA has given advice to the Designated Individual in relation to a number of practices and procedures with a view to helping the establishment further develop their working practices and governance systems. This includes advice relating to incident reporting and management, the approach to the correction of written records, and the implementation of a quality manual relating to licensable activities.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 12 June 2013

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 16 July 2013

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 13 May 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.

b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.

b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.

l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
GQ8 Risk assessments of the establishment’s practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.

h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   Or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall.

   A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

   or

   A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

   or

   A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

   or

   A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

   or

   A combination of several 'minor' shortfalls, none of which is major on its own, but which,

viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.