Site visit inspection report on compliance with HTA minimum standards

Addenbrookes Hospital

HTA licensing number 11072

Licensed for the

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

15 March 2012

Summary of inspection findings

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

Although the HTA found that Addenbrookes Hospital, Cambridge, (the establishment) had met the majority of the HTA standards, four minor shortfalls were found in relation to governance and quality systems and premises, facilities and equipment.

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 Paragraph 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, and
- 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.

'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
Vessels Tissue grafts				**E**			

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out at Addenbrookes Hospital, Cambridge. Three areas of the hospital have HTA licences; however this inspection deals with activities taking place under licence number 11072, relating to the storage and use of vessels and, occasionally, abdominal grafts in connection with transplant surgery. Although the establishment's principal transplant activity relates to liver transplantation it is also a centre for transplantation of other organs and, more recently, occasional multivisceral transplants where the patient may require the transplant of a cluster of organs such as liver, pancreas, bowel and stomach. Any of these transplant procedures may require the use of donor vessels. Multivisceral transplants may require the utilisation of abdominal wall grafts. The donated vessels and abdominal wall grafts provide additional vascularised tissue which, when required, contributes towards the success of the transplant. These donated tissues are supplied to the establishment by National Health Service Blood and Transplant (NHSBT) having been procured at the time of organ donation. The donor virology testing is undertaken by a separate, HTA licensed, NHSBT establishment. Donor vessels may be used at the time of transplant of an organ into a recipient or may be used during an additional revision procedure within the initial days following transplant. Occasionally, donor vessels surplus to the requirements for the original intended recipient are stored for possible use in a different recipient.

The procurement process is conducted by regional organ procurement teams, which may include the team based at the establishment, working within the NHSBT organ donation framework. Procurement of donated vessels and abdominal grafts is ancillary to the procurement of organs for donation and is therefore outside the licence framework. Donor consent is obtained by trained Donor Transplant Coordinators acting within the NHSBT framework. The inspection was limited to processes and practices relating to the licensable activities, which in this case are storage of tissue received from NHSBT. The tissue may be stored for periods in excess of 48 hours; therefore storage is required to be under the authority of a licence. If not used, tissue is disposed of after 14 days. Records of donor consent are retained by NHSBT. Evidence of consent is available on-line through the NHSBT Electronic Offering System (EOS). Limited donor information is passed to the establishment in accordance with the requirements for donor confidentiality.

This was the third, routine, site visit inspection of the establishment. The inspection comprised a visual inspection of the storage facilities adjacent to the transplant theatres, review of the transplant database, document review and interviews with the Designated Individual, the Corporate Licence Holder Contact, the Operations Manager, Perioperative Care, the Unit Leader, Transplant Services, Perioperative Care and the Patient Safety Manager, Risk and Patient Safety. The timetable for inspection was developed with due consideration of the establishment's licensing history and pre inspection communication with the DI.

The inspection process also included a traceability audit of the storage, use and disposal of selected vessels. The storage refrigerator log book was examined and the entries relating to vessels received and then used, or disposed of, were correlated to the number and identity of the vessels being stored at the time of inspection. There were no discrepancies noted. The inspection provided an opportunity to review the use of the back-up refrigerator following a recent malfunction of the principal refrigerator. This review identified minor shortfalls in record keeping and hence traceability in relation to use of the contingency refrigerator. These shortfalls are reported under standards GQ3 and GQ6 below. A further traceability audit was carried out in relation to stored vessels that had been allocated for use in a patient. A forward audit trail was conducted by tracing the unique NHSBT donated tissue number through to the recipient's unique hospital number. Traceability could also be demonstrated back to the anonymised vessel donor using the patient notes, refrigerator log book, hospital database and the NHS EOS.

The establishment is not licensed for the activity of 'distribution'. However, due to evolving trends in transplant surgery and the establishment's activities, this is a future possibility. Should the need for distribution arise, the establishment is aware that this is an additional activity for which a HTA licence is required.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	The inspection provided an opportunity to audit documents associated with a recent requirement to use the back-up refrigerator at short notice. This involved the transfer of vessels into the back-up refrigerator whilst the principal refrigerator was undergoing repair and the return of vessels to the principal refrigerator following repair. There was no record of the use of the back-up refrigerator within the equipment log books. This highlights a shortfall in the training of members of staff who may be required to transfer tissue between the principal refrigerator and the back-up refrigerator. It is noted that the sequence of events was recorded within the establishment's incident reporting system and that the DI was kept informed throughout.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
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.	The inspection provided an opportunity to audit documents associated with a recent requirement to use the back-up refrigerator at short notice. This involved the transfer of vessels into the back-up refrigerator whilst the principal refrigerator was undergoing repair and the return of vessels to the principal refrigerator following repair. There was no record of the use of the back-up refrigerator within the equipment log books. This highlights a shortfall in the process and procedures for documenting the use of the back-up refrigerator and thus a gap in the traceability record of the stored material. It is noted that the sequence of events was recorded within the establishment's incident reporting system and that the DI was kept informed throughout.	**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.	Whilst the DI and core members of the team are aware of the requirement to report serious adverse events or reactions to the HTA promptly, the relevant Trust Policy and related standard operating procedure (SOP) do not state that the DI has a responsibility to notify the HTA of any serious adverse event or serious adverse reaction within 24 hours of its discovery. It is noted that the Trust's serious incident reporting process includes the HTA as an external body to be notified. However, the specific timeframe for notification is not explicitly stated.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
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.	At the time of inspection the establishment was unable to provide evidence that the back-up refrigerator is subject to regular review in order to provide assurance that it consistently meets the required specifications and is ready for use.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	In light of the inspection findings the DI is advised to further develop the Standard Operating Procedure describing storage of vessels to include stepwise details of the procedures to be followed in the event of the need to transfer vessels to the back-up refrigerator.
2.	GQ6b/D2a	The HTA inspection team endorses the establishment's plans to flag 14 day expiry dates, for stored tissue, through an additional system of labelling on the outer layer of tissue packaging and within the tissue log book. As the expiry dates relate to traceability and timely disposal of tissue, this additional measure will enhance existing systems which ensure that tissue is not used or retained beyond its stipulated expiry date.
3.	GQ2(c)	It is recognised that the audits carried out by members of the local Risk and Patient Safety team are of good quality and are done independently of the theatre team. As a further development of independent audit, the DI is advised to consider the potential for different HTA licensed teams working at Addenbrookes Hospital to audit each other's work.
4.	GQ3(f)	The DI is advised that members of staff at the establishment will benefit from periodic HTA awareness training sessions. The monthly audit meetings would appear to provide a valuable forum to discuss any HTA related matters.
5.	GQ4(c)	The DI is advised to consider refreshing the training of staff in relation to the Trust Document Creation and Amendment policy so that members of staff are reminded of the appropriate way to create and amend documentation in accordance with the Trust policy. Corrections to raw data in documents such as the refrigerator log book should be crossed through so that the original entry is still legible.
6.	GQ8	The inspection provided an opportunity to review existing risk assessments. The establishment's risk assessments are well developed in that they address safeguards that are in place to protect the integrity of stored tissue as well as safeguards to protect members of staff. The DI is advised that, in light of inspection findings, risk assessments could be further developed and expanded to include, but not necessarily be limited to:

		• A detailed risk assessment which specifically addresses the breakdown of the refrigerator used for storage of vessels and abdominal wall grafts. • A detailed risk assessment which specifically addresses the capability and capacity of the refrigerator when/if required to store vessels and abdominal wall graft(s) spanning both negative and positive virology status. • A detailed risk assessment addressing the suitability of the principal and back-up refrigerators to store multiple abdominal wall grafts, as these are larger and of a different shape than the vessels for which the refrigerators were originally intended.

Concluding comments

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

There is evidence of effective communication, close working relationships and good teamwork across the different disciplines that make up the theatre team and between the theatre team and the governance team. There is a strong commitment to continuous improvement across the extended team. The governance arrangements include effective 'HTA Compliance Audits'. Where audits have resulted in recommendations there is evidence that these are followed up and implemented. For example, the introduction of improved cleaning records following an audit of cleaning procedures. The hospital has a number of HTA licences and has in place an effective 'Human Tissue Committee' where the DIs for each of these licences meet on a regular basis to share experiences and practices and to discuss common issues. Communication across team members is facilitated by monthly audit meetings. There is evidence of good communication with colleagues within NHSBT to include the sharing of ideas for the continuous improvement of quality systems and procedures. Advice is offered about providing HTA awareness training as part of the, internal, monthly audit meetings. The establishment has conducted risk assessments from the perspective of safeguarding tissues. Advice is offered regarding extended opportunities for risk assessment to address equipment malfunction and suitability.

There are 4 minor shortfalls associated with this inspection. Two of the shortfalls relate to the process and procedures for use of the back-up refrigerator in the event of breakdown or malfunction of the principal refrigerator.

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 minor shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 21 May 2012

Report returned from DI: 28 May 2012

Final report issued: 28 May 2012

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. Individual standards which are not applicable to this establishment are shown in grey text.

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
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the 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.
b) If third parties act as procurers of tissues and / or cells, the third party agreement 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.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
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.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
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.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of 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.
e) Testing of donor samples is carried out using CE marked diagnostic 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.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
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.

d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
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.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
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.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
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.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
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.