Site visit inspection report on compliance with HTA minimum standards

Royal National Orthopaedic Hospital

HTA licensing number 11135

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**

7 January 2016

Summary of inspection findings

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

The Royal National Orthopaedic Hospital was found to have met the majority of the HTA standards; however, a minor shortfall was found in relation to the Governance and Quality standards, namely the requirements around donor testing.

The shortfall relates to an example found where a chondral tissue donor had not been tested for all of the mandatory serological markers was found during an audit of patient clinical notes.

Particular examples of 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.

'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
Chondrocytes	**E**		**E**		**E**		
Bone				**E**			
Tendons				**E**			
Nerve grafts				**E**			

Background to the establishment and description of inspection activities undertaken

The establishment is licensed for the procurement, testing, storage and distribution of tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

The establishment procures chondrocytes which are distributed to another organisation for manufacture into an advanced therapy medicinal product (ATMP). Donor consent is sought by clinicians treating the patient and is recorded in the patient's clinical notes. Mandatory donor serological testing is carried out by the establishment and is identified in the agreement between the establishment and the ATMP manufacturer as the responsibility of the HTA licensed establishment. Once procured, tissue is packaged into a uniquely labelled kit provided by the ATMP manufacturer and sent to the manufacturing facility via the ATMP manufacturer's courier. After being processed into an ATMP, tissue is returned to the establishment for autologous end use.

The establishment also stores various tissues for use in orthopaedic and related surgery. These tissues are stored in a secure -80^{o}C freezer which is still under warranty. The freezer's temperature is monitored and recorded manually by staff during normal working days in addition to having an alarm which would be triggered should the temperature deviate from the set limits. The alarm system contacts the establishment's security team, who contact establishment staff to attend should an alarm be triggered outside of normal working hours. Staff record the use of tissue in the recipient's clinical notes and the establishment's tissue register, which is also backed-up electronically. The establishment has access to a second -80^{o}C freezer in the pathology department, which acts as a contingency facility in the event of a main freezer failure. The use of this second freezer as a contingency store has been risk assessed and formalised in a documented procedure, which describes how tissue is packaged prior to transfer.

During the inspection, a number of audits were performed relating to the tissue stored under the licence. Details were taken from: three tissue products stored in the -80oC freezer; one tendon; one femoral head, and; one unit of ground bone. The tissue type, tissue identifier and expiry dates were cross checked between the tissue and the establishment's tissue register. No anomalies were identified.

An audit of patient clinical notes was also undertaken. Three sets of clinical notes for patients who had received stored femoral head tissue were reviewed. In total, the three sets of records related to the use of five femoral heads that had been in storage. Dates of use, tissue identifiers, tissue expiry dates and patient identifies were cross checked between the clinical notes and the establishment's electronic back up of the tissue register. In one of the five cases, the expiry date for one of the femoral heads has been incorrectly recorded in the electronic back-up of the establishment's tissue register. A review of the archived hard copy tissue register showed that the correct expiry date, as recorded in the clinical notes, had been recorded on the hard copy and the error was due to a transcription error while entering the data into the electronic back-up tissue register. No other anomalies were found during the audit of femoral heads. Advice regarding audits has been given below.

Two sets of clinical notes relating to the use of three tendons were reviewed. Again, dates of use, tissue identifiers, tissue expiry dates and patient identifies were cross checked between the clinical notes and the establishment's electronic tissue register. No anomalies were found.

One set of clinical notes relating to the use of ground bone was reviewed where dates of use, tissue identifiers, tissue expiry dates and patient identifies were cross checked between the clinical notes and the establishment's electronic tissue register. No anomalies were found.

One set of clinical notes relating to the use of two nerve grafts was reviewed where again dates of use, tissue identifiers, tissue expiry dates and patient identifies were cross checked between the clinical notes and the establishment's electronic tissue register. No anomalies were found.

Finally, two sets of patient clinical notes were reviewed where the patients had undergone chondrocyte treatment. In both sets of patient records signed donor consent forms were present in the clinical notes, as were the respective records of the autologous cells which were returned to the patients. The 'cell return form' had the tissue's unique identifier and demonstrated that the cells had been implanted in the patient within their expiry period assigned by the manufacturer. The first patient's clinical notes had all of the results from the mandatory serological marker screening. The second patient's clinical notes contained most of the mandatory serological marker test results. However, the serological test result for syphilis was not present in the second patient's notes. The establishment produced evidence demonstrating that this test had been ordered; however, it had not been conducted by the testing laboratory due to technical reasons *(Minor shortfall, GQ5b).* The establishment also demonstrated that this test has been carried out at the manufacturing organisation; however, this additional testing does not fall under the authority of the establishment's HTA licence. There was no mechanism in place at the establishment to verify that all of the necessary serological tests had been carried out on chondral tissue donors, meaning that the omission of the syphilis serological test in one of the patients undergoing chondrocyte procurement had not been detected by the establishment.

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
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
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.	An example where a chondral tissue donor had not been tested for one of the mandatory serological markers (syphilis) was found during an audit of patient clinical notes. Additionally there was no mechanism to verify that all of the mandatory serological tests had been carried out on chondral tissue donors meaning that the omission of any of the tests would not be detected by the establishment.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(b)	The establishment has a range of procedural documents covering the licensable activity taking place. These standard operating procedure (SOP) documents describe the various procedures undertaken at the establishment. However, in some cases, they would benefit from containing more detail about specific areas of the procedure. For example, staff involved in tissue receipt procedures all described the process that is followed and actions to take if any tissue did not meet the required specification. However, although describing that integrity checks take place, the SOP did not contain details of all of the checks performed, including noting the time that the courier collects the samples and arrives at the establishment in order to ensure that transit time is less than 12 hours. The DI is advised to review the establishment's SOPs to ensure that they fully reflect current practice. SOPs which would benefit from review include but are not limited to :- 'Tissue receipt at the establishment' 'Seeking consent for chondrocyte procurement' 'Incident reporting through internal reporting system'.
2.	GQ1(c)	Matters relating to licensed activities can be raised as part of various meetings taking place, such as theatre team briefings. The DI is advised to hold at least one additional formal governance meeting each year, where all staff who are involved in licensed activities can discuss issues relevant to the establishment and its work under the licence.
3.	GQ2(b)	During the audit on patient's clinical notes undertaken during the inspection, an example of an expiry date being incorrectly transcribed into the electronic back-up of the establishment's tissue register was found. This particular record had been subject to internal audit but the discrepancy in the expiry date had not been detected. Internal audits are usually conducted by one member of staff. The DI is advised to schedule some of the planned internal audits as a two person audit so that there can be greater scrutiny and quality control of both the data being audited and the audit data itself.
4.	PFE3(b)	The establishment's freezer alarm is subject to regular checks to assure the DI that it is functioning appropriately. The alarm is additionally linked to a call out system which contacts the establishment's security team should the alarm be triggered during out of hours periods. The DI is advised to expand the scope of the tests undertaken on the alarm system to include some tests being undertaken during out of hours periods. This way, the establishment will verify both that the alarm triggers as it should and that the security team contact an on-call member of staff.
5.	General	In the past, the establishment has been involved in the surgical resection of cancerous bone, which is packaged and transferred to another hospital to be irradiated. The irradiated bone is then promptly returned to the establishment, where it is surgically implanted in its original anatomical location. This has not taken place for several years and, from discussions with the DI, it was clear that there are no immediate plans to undertake this activity in the future. The HTA considers the irradiation of bone to be processing for which the establishment is not currently licensed.

		The DI is advised that, should the establishment wish to restart procedures where bone is procured, irradiated and returned to the patient, an application must be made to the HTA to have the licensable activity of 'processing' added to the establishment's licensing arrangements prior to the activity taking place. In addition, the DI would need to submit a process preparation dossier (PPD) to the HTA, describing the procedure and providing evidence that it attains the desired results, and does not render the tissue clinically ineffective. Only if the PPD is approved by the HTA, and the licence is amended to include processing, could the procedure take place.

Concluding comments

Several areas of good practice were observed during the inspection, some examples of which include:

- The establishment continues to demonstrate good working relationships between the various staff working under the licence.

- The establishment has developed and implemented competency assessments and quizzes following training which help staff to evaluate their understanding of the training content.

- The establishment has also added separate compartments to the tissue storage freezer meaning each tissue type is stored in its own dedicated drawer within the freezer. This helps staff when locating a specific item of stored tissue. In addition, as only the drawer holding a specific tissue type is opened, the risk of other stored tissues being subjected to temperature variations resulting from opening the freezer door is reduced.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the Designated Individual with respect to procedural documentation, audits, alarm monitoring and governance meetings.

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 / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 4 February 2016

Report returned from DI: No Comments received

Final report issued: 10 March 2016

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: 16 March 2016

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
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.