**Site visit inspection report on compliance with HTA minimum standards**

**Royal Devon and Exeter NHS Foundation Trust**

**HTA licensing number 11012**

**Licensed for the**

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

- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

**26 July 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 Royal Devon and Exeter NHS Foundation Trust (the establishment) had met the majority of the HTA standards, a shortfall was found in relation to governance and quality systems. The establishment has complied with a previous condition requiring independent audits and followed advice to conduct records audits, but procedural audits have been overlooked. The establishment has been proactive in implementing all the advice provided by the HTA at previous inspections and it is hoped that this continues.

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

The establishment is licensed for activities which are not currently being carried out and advice has been given on how to rectify this.

## 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
- 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 carrying out this activity under their licence.

| Tissue type | Procurement | Processing | Testing | Storage | Distribution | Import | Export |
|---|---|---|---|---|---|---|---|
| **Bone** | **E** | | **E** | **E** | **E** | | |
| **Tendon** | | | | **E** | | | |

## Background to the establishment and description of inspection activities undertaken

The establishment carries out the retrieval of femoral heads from living donors undergoing primary hip surgery for use as an allograft in future patients. Approximately 200 femoral heads are procured each year and stored within the hospital Bone Bank, which consists of three minus-80°C freezers. One of the freezers is used for quarantine of all the bone samples until the results of serology and microbiology tests confirm the tissue is safe to use; another of the freezers is used for allografts released from quarantine; the third freezer is used specifically for autologous donations by patients where there is potential for a second hip replacement operation. The mandatory serology tests are undertaken within the CAP accredited hospital microbiology laboratory, along with microbiology testing carried out on a

bone fragment placed in enrichment medium and a swab of the bone at the point of procurement, followed by a second swab taken at the point the bone is used. Recipient patients are treated with broad spectrum antibiotics as a matter of course as a precaution against infection.

On occasion the establishment has distributed donated bone to another hospital, with which it holds an agreement, for end use. The establishment also purchases and stores for end use human tissue products such as tendons from other HTA licensed establishments with which they have signed service level agreements.

This was the third routine inspection of the establishment; the previous ones having been conducted in 2010 and 2008. The inspection comprised a visual inspection of the Bone Bank situated within the theatres and the microbiology laboratory, interviews with members of staff and review of relevant documentation.

A traceability audit on the frozen bone samples was carried out by randomly selecting three storage positions in the freezers. The positions and sample identification numbers as indicated on a white board in the freezer area were checked. They were also checked against records of what had been collected during surgery then logged into the relevant freezer storage book. The donor consent forms and serology and microbiology test results for these donations were reviewed.

Audit trails were also conducted through review of patients' files. This included review of consent forms, virology and microbiology test results, bone bank donation forms and recipient forms, as well as review of entries into the clinical notes.

Records of disposal due to a positive test result, or if new relevant medical history had come to light regarding the donor, were also verified. Minor anomalies were found in relation to the date recorded for receipt of test results and, in one case, on the consent form (see advice against standard GQ5d below).

## 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 |
|---|---|---|
| GQ2 There is a documented system of quality management and audit. | | |
| b) There is an internal audit system for all licensable activities. | The establishment audits records for accuracy and completeness on a regular basis; however an audit of compliance with procedures has not been undertaken. Staff competency in receipt of tissue samples, tissue procurement, and the packaging of tissue samples for distribution has been assessed, but this is not repeated and | **Minor** |

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| | therefore there is no review to ensure staff are still carrying out procedures correctly or that the SOPs accurately reflect procedures. | |

**Advice**

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

| No. | Standard | Advice |
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| 1. | C1d | The DI is advised to ensure that when the consent form is completed, any field that is not relevant to the donor is marked as 'not applicable' to confirm all fields have been considered and no questions have been overlooked. |
| 2. | C1d | The consent form includes a section for confirming the consent given for situations when the donor signs the consent form days prior to the operation. However, theatre nurses tend to ask patients whether they are still happy to go ahead with the operation and donation of bone even if they have been consented the same day. Consideration should be given to whether the confirmation of consent section of the form could be used in these situations too to record the patient's response. |
| 3. | GQ1d<br>PFE3b | A number of signs are displayed on the freezers to provide information to staff on procedures they should complete. The DI is advised to ensure these signs are also included in the quality management system, to ensure they are reviewed regularly and with any changes in procedures these are also updated.<br><br>Although in general, staff are aware of the procedures to follow or the persons to contact in the event of a freezer alarm, the DI is further recommended to include in the signs on the freezers the action that should be taken and relevant contact details, so that any member of staff hearing the local freezer alarm is aware of the action to take. |
| 4. | GQ2a<br>GQ7h | The establishment occasionally distributes the femoral head bones it procures to another establishment for end use. Any SAEARs are reported back to the establishment, but the DI is advised to seek feedback on a biannual basis to ensure any minor issues are also fed back so trends may be identified and action taken to prevent reoccurrence of these. |
| 5. | GQ5b,e<br>PFE4a | The HTA endorses the establishment's plans to revise laboratory SOPs on testing sterile tissues and fluids to include subsections with specific reference to bone bank specimens. |
| 6. | GQ5d | The establishment staff use a bone donation form to record details of the donor and the results of both the preliminary and secondary virology tests and the microbiology results. Whilst test results are being accurately recorded, there is some variation regarding the date documented, which in some cases is the date the sample was obtained and in others its the date the test result was reported. The DI is advised to standardise the date recorded to make traceability of these test results more robust and also consider reviewing the format of the form to prevent any confusion on how it should be completed. |
| 7. | GQ7c | The procedure for reporting incidents is documented, but not all staff are aware of the need to notify the HTA of reportable SAEARs within 24 hours of |

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| | | discovery. The DI is advised to ensure all staff are aware of the HTA licence and the reporting requirements. |
| 8. | GQ8a | The risk assessments reviewed during the inspection include the risks to the health and safety of staff and the risk to recipient patients due to the quality and safety of the tissues they receive; however not all procedures which could affect the quality and safety of the tissues, such as transportation to another establishment, have been risk assessed. The DI is advised to assess the risk of all relevant procedures to ensure risks such as loss of traceability, inconstant storage temperature and loss of integrity of packaging are mitigated appropriately. |
| 9. | Licence | The inspection team has made the DI aware that the current licence includes the activities of processing, import and export of tissues and cells as well as storage of relevant material for a scheduled purpose, which the establishment does not currently undertake. The DI is recommended to remove these additional activities from the licence unless they plan to be undertaking these at some point in the future. |

## Concluding comments

During the inspection of Royal Devon and Exeter NHS Foundation Trust, one shortfall was identified against HTA standards. Advice has been provided to the DI in the areas of the consent and governance and quality standards. The advice mainly relates to forms being completed clearly, extending the areas of risk assessment and ensuring that staff are aware of the HTA SAEARs reporting requirements. The DI has also been advised to rationalise the activities for which the establishment is licensed.

A number of strengths and areas of good practice were also noted and examples are given below.

The establishment has a comprehensive process for obtaining consent from donors and ensuring that the repeat virology tests are carried out 180 days after donation. The establishment carries out a courtesy call to the donor to inform them of the (negative) test results, where they also confirm that the donor is still fit and well, and happy to donate the sample. This forms the last check point before samples are released from quarantine and on rare occasions has led to samples being excluded as a matter of precaution due to medical conditions that have arisen post-donation.

The results of microbiology tests carried out on the bone samples are collated into a graph and reviewed at the Audit meeting on a regular basis. This ensures that microbiology results are routinely monitored for trends and any spike in positive results would be quickly recognised and acted upon.

The establishment has very robust record keeping of the donor to recipient information. Staff record the donation or use of the bone in the patient's records, but also have separate records of the donation or use which encompasses storage details and a further electronic back up of the information. This ensures the information cannot be lost if one of the records is deleted or goes missing. The process of documenting this information in several places also involves careful cross-checks of the information being recorded to ensure it is accurate, complete and any positive test results are dealt with appropriately.

Since the last inspection, the condition applied to the licence regarding an independent audit

has been met and the most recent independent audit report was reviewed and found to be a thorough review of procedures against HTA standards. The advice given to regularly audit records and document the date, method and reason for disposal have also been fully implemented.

The HTA requires that the Designated Individual addresses the shortfall identified above 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 shortfall identified during the inspection

**Report sent to DI for factual accuracy:** 22/08/12

**Report returned from DI:** 05/09/12

**Final report issued:** 10/09/12

**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: 27 November 2012**

## 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** |
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| 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** |
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| 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. |

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| 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. |
| 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. |
| o) There is a complaints system in place. |
| 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. |

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| 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. |

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| 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. |

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| 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** |
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| 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. |
| 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. |

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| 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. |

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| j) For each critical process, the materials, equipment and personnel are identified and documented. |
| k) There are contingency plans for equipment failure. |

**Disposal**

| **Standard** |
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| 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.