

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

**University Hospital of North Staffordshire**

**HTA licensing number 12417**

**Licensed for the**

- **Procurement and storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007**
- **storage of relevant material which has come from a human body for use for a scheduled purpose**

**24 September 2013**

### **Summary of inspection findings**

University Hospital of North Staffordshire (the establishment) was selected to receive a themed inspection. The themes selected for 2013/2014 business year include quality management, contingency planning and risk management.

The establishment was found to have met all HTA standards relating to each theme.

The HTA previously found the Designated Individual and the Licence Holder, to be suitable in accordance with the requirements of the legislation. Their suitability was not re-assessed during this inspection.

Previously the establishment undertook procurement of tissue for use in patient treatment however this no longer takes place. Advice has been given below to remove this licensable activity from the licence as it is no longer required.

In addition, the HTA reviewed the establishment's compliance with the HTA's Premises, Facilities and Equipment (PFE) standards, specifically, PFE3 (a) – (d) and PFE5 (c) & (k) which relate to appropriate storage conditions for tissue. The establishment was found to have met these HTA Standards.

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.

However, a themed inspection may be carried out on establishments which have been found previously to represent a lower risk. Themes target Standards which the HTA has identified as common shortfalls across the human application sector in 2011. The themes selected for 2012/13 are outlined in the table below.

| Themes  | HTA Standards |
|---|---------------|
| <b>Quality management</b>   |               |
| Standard operating procedures for licensed activity   | GQ1(b)        |
| Document control system   | GQ1(d)        |
| Quality Management System – continuous and systematic improvement   | GQ2(a)-(c)    |
| Internal audit system for licensable activities   |               |
| <b>Contingency Planning</b>   |               |
| Plan to ensure records of traceability are maintained for 10 or 30 years as required.                     | GQ4(m)        |
| <b>Risk Management</b>  |               |
| Procedures for the identification, reporting, investigation and recording of adverse events and reactions | GQ7           |
| Risk assessments  | GQ8           |
| Traceability  | GQ6           |

In addition to the Standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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

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

### **Licensable activities carried out by the establishment**

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

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

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

| <b>Tissue type</b> | <b>Procurement</b> | <b>Processing</b> | <b>Testing</b> | <b>Storage</b> | <b>Distribution</b> | <b>Import</b> | <b>Export</b> |
|--------------------|--------------------|-------------------|----------------|----------------|---------------------|---------------|---------------|
| <b>Bone</b>        |                    |                   |                | <b>E</b>       |                     |               |               |
| <b>Tendon</b>      |                    |                   |                | <b>E</b>       |                     |               |               |

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

The establishment stores bone and tendons for use in orthopaedic surgery. Tissue is purchased from another HTA licensed establishment. A stock of the most frequently used tissues, fresh frozen femoral heads, strut grafts and tendons is maintained by the establishment.

At the time of the last inspection, the establishment undertook the procurement of chondrocytes for autologous use in treatments as part of a clinical trial. This activity no longer takes place and the establishment does not procure any tissue under its Human Application licence. Advice has been given with regards to removing the licensable activity of procurement from the establishment's licence.

The establishment has been licensed by the HTA since 2009 and this routine inspection was the third site visit conducted by the HTA. The establishment had been selected to have a themed inspection based upon the level and risk of the activity being undertaken and the number of previous inspections that the establishment has received. The timetable for the site visit was developed following consideration of the original desk-based assessment of the establishment's licence application, the establishment's recent compliance self-assessment, the establishment's annual activity data, previous inspection report and pre-inspection discussions with establishment staff and DI. During the inspection, a visual inspection of the premises, review of the establishment's documentation and interviews with establishment staff were carried out.

An audit was undertaken during the inspection. The tissue identification numbers and expiry dates of a frozen femoral head and a strut graft were cross-checked between the tissues in storage and those in the establishment's paper and electronic tissue register. No anomalies were found.

Additionally, an audit of patient clinical records was also undertaken. Two sets of paper clinical notes were audited. During the audit of clinical notes, details of femoral heads that had been used in surgery were sought. In addition to tissue identifiers, the recipient's hospital number, tissue expiry date, tissue usage date were reviewed. All details were cross checked between the clinical notes, the paper tissue records and the establishment's electronic database. Again, no anomalies were found.

### 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

All applicable HTA standards have been assessed as fully met.

### Advice

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

| No. | Standard         | Advice  |
|-----|------------------|---|
| 1.  | GQ2(c)           | <p>The establishment undertakes both internal and independent audits of its activity. The independent audits are performed by the Trust's clinical audit team annually and include a review of compliance with the establishment's SOPs and quality manual in addition to audits of tissue usage records.</p> <p>Additionally the establishment's theatres governance group undertakes a review of the establishment's compliance with the HTA standards. This group is made up of independent staff not directly involved in the licensable activity in addition to the DI and theatre coordinator. The results of this compliance review are subsequently scrutinised by one of the establishment's governance committees who are again, independent to the licensable activity.</p> <p>Although the review of the establishment's compliance with the HTA's standards is performed by the theatres governance group which includes independent staff, the involvement of the DI and theatre coordinator means that the reviews are not totally independent. The outcomes of these audits however are reviewed by an independent governance committee who are independent to the licensable activity.</p> <p>The DI is advised to ensure that audits are undertaken in an independent manner and do not involve staff undertaking licensable activity. This could be achieved by the DI and theatre coordinator ceasing involvement in the current audits or introducing an additional audit programme in which again, they are not involved.</p> |
| 2.  | GQ4(h)<br>GQ4(i) | <p>The DI is advised to confirm with the Trust's estates services provider that the freezer temperature traces are being stored for the required 10 year period. These freezer temperature records represent raw data that is critical to the quality and safety of the tissue being stored.</p>  |

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|    |   | Additionally the DI is advised to amend the records management section of the establishment's quality manual to include a reference to the relevant storage periods for both traceability and raw data.  |
| 3. | PFE3(a)<br>PFE3(b)<br>PFE3(c)<br>PFE5(c)<br>PFE5(k) | <p>The establishment stores tissue that requires frozen storage at below -40°C. The establishment's -80°C freezer is not connected to an alarm that would alert the establishment to an equipment failure out of hours. The freezer however does have an audible alarm and is located within the theatre department which is staffed 24 hours a day, seven days a week.</p> <p>Currently, the establishment's storage freezer will alarm if the temperature rises above -43°C. The DI is advised to review the suitability of the freezer's temperature alarm settings to assure himself that the alarm will sound if the temperature rises following an equipment failure. This alarm should provide enough time to move the tissue that is in storage to the back up freezer without the tissue being exposed to storage temperatures greater than -40°C.</p> <p>The DI is also advised to amend the notice on the freezer which advises staff on the process to follow should the freezer breakdown. The DI is advised to include a reference to the freezer temperature which if risen to, should result in a transfer of tissue to the back up storage freezer.</p> <p>Finally the DI is advised to include contact details of a member of the establishment's staff on the notice located on the storage freezer so that they can be contacted and alerted to a freezer failure by the theatre staff outside of normal working hours.</p> <p>During the inspection, the establishment indicated that it plans to purchase a new freezer monitoring system which will both maintain temperature records locally within the establishment and will have an external notification system to alert staff to a freezer failure out of normal working hours. The DI is advised to continue with these plans as they will provide added assurance that tissues are stored at the correct temperatures and additional assurance that the establishment would be alerted to a freezer failure outside of working hours.</p> |
| 4. |   | <p>In the past, the establishment undertook the procurement of chondrocytes for autologous use in treatments as part of a clinical trial. This activity no longer takes place and the establishment does not procure any tissue under its Human Application licence.</p> <p>The DI is advised to request an update the licencing record so that the licensable activity of procurement is removed from the licence.</p>  |

### Concluding comments

All applicable HTA standards have been assessed as fully met and no shortfalls found. The HTA has given advice to the Designated Individual with respect to quality management, contingency planning and premises, facilities and equipment standards.

Areas of good practice were found during the inspection.

The establishment places an emphasis on consent for patients who may require the use of allogeneic tissue during their surgery. The details of the use of allogeneic tissue are discussed with the potential recipient during their consultation with the surgeon and information leaflets are given to them at the same time. The potential recipient's consent is recorded in their clinical records. The establishment has developed an SOP covering the seeking of consent for use of allogeneic tissue during treatment and the establishment audits the compliance of surgeons with this SOP during internal and independent audits.

The Trust also uses acellular material during surgical treatments, both in orthopaedic and ophthalmic work. Although the Trust is an end user of the acellular tissue, and therefore, the DI has included the acellular tissue use into the governance systems used at the establishment. The use of acellular tissue is therefore governed, controlled and traced to the same standards as other tissues.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

**Report sent to DI for factual accuracy: 22 October 2013**

**Report returned from DI: No comments received**

**Final report issued: 23 November 2013**

## 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  |
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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.   |
| 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.   |

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| 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.  |
| <b>GQ2 There is a documented system of quality management and audit.</b>  |
| 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.             |
| <b>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.</b>   |
| 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.   |
| <b>GQ4 There is a systematic and planned approach to the management of records.</b>   |
| 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.   |

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| 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.  |
| <b>GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.</b>  |
| 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.   |
| <b>GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.</b>  |
| 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,  |

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| processed, stored, distributed and exported are traceable from donor to recipient and vice versa.   |
| <b>GQ7</b> 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.  |
| <b>GQ8</b> 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**

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| <b>Standard</b>  |
| <b>PFE1</b> 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.     |

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| 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. |
| <b>PFE2 Environmental controls are in place to avoid potential contamination.</b>   |
| 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.    |
| <b>PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.</b>  |
| 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.  |
| <b>PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.</b>                                     |
| 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.   |

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| 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.  |
| <b>PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.</b>   |
| 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**

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| <b>Standard</b>   |
| <b>D1 There is a clear and sensitive policy for disposing of tissues and / or cells.</b>                                    |
| 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.                          |
| <b>D2 The reasons for disposal and the methods used are carefully documented.</b>   |
| 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.