Site visit inspection report on compliance with HTA minimum standards

Nottingham University Hospitals NHS Trust

HTA licensing number 11035

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**

25-26 February 2015

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.

Nottingham University Hospitals NHS Trust (the establishment) was found to have met all applicable HTA standards.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

Licensable activities carried out by the establishment

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

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

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

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Femoral head	**E**	**-**	**E**	**E**	**E**	**-**	**-**
Rib	**E**	**-**	**E**	**E**	**-**	**-**	**-**

Background to the establishment and description of inspection activities undertaken

Nottingham University Hospitals NHS Trust (the establishment) is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Quality and Safety Regulations 2007) for the procurement, storage and distribution of human tissue for human application, and donor serology testing. The establishment does not carry out the licensable activities of processing, import or export.

The establishment comprises the hub (Queen's Medical Centre) and two satellites (City Hospital, Nottingham and Nottingham Woodthorpe Hospital). The majority of the activities performed under this HTA licence relate to femoral heads procured from living donors during hip revision surgery. Donor selection, consenting and procurement of femoral heads takes place at the satellites (procurement ceased at the hub in 2014).

Identification of potential donors, and their consenting for procurement, is performed by pre-operative assessment nurses. Following procurement, femoral heads are stored for short periods in −80 ^{o}C freezers at the satellites, prior to transfer to the hub by Trust transport. Donor testing for all mandatory serology markers required by the EU Tissues and Cells Directives, and microbiological testing of tissues, is carried out by the Microbiology Laboratory at Queen's Medical Centre. The establishment has a documented agreement with this laboratory.

Once microbiological and serological testing results are confirmed to be negative, femoral heads are moved from quarantine to the release freezer for use. Femoral heads are distributed to the satellites for use in orthopaedic surgical procedures where a bone graft is required, and also to two unlicensed establishments under documented end user agreements. Femoral heads are transported to end users on the day of surgery in validated transport containers.

The establishment also procures ribs for autologous use from younger patients for use in scoliosis correction procedures. Ribs are procured and used at Queen's Medical Centre only. Consent for procurement is normally sought by a consultant surgeon (refer to advice item 5). Donor testing and tissue storage arrangements are as for femoral heads; there is a specific drawer in the bone bank quarantine freezer for storage of ribs (refer to advice item 6).

The establishment receives acellular products, including demineralised bone matrix and decellularised dermis, and occasionally fresh frozen tissues such as cortical struts, from NHS Blood and Transplant (NHSBT). Storage of acellular products for end use is not currently licensable; storage and traceability of such tissues were not reviewed at this inspection.

The establishment has been licensed by the HTA since January 2007. The HTA inspects establishments licensed under the Quality and Safety Regulations 2007 every two years. This establishment has received three previous routine site visit inspections (in March 2009, March 2011 and February 2013).This report describes its fourth routine site visit inspection in February 2015. The inspectors met with staff involved in licensable activities, visited the storage areas at the hub and satellite sites and the Microbiology Laboratory, and reviewed documentation. The following traceability audits were performed:

- storage locations of two femoral heads in the release freezer at the hub were confirmed; the relevant donor records were reviewed;
- donor and recipient records were reviewed for another three cases where femoral heads were used for hip revision surgery;
- donor records were reviewed for three femoral heads stored at City Hospital awaiting end use, and;
- records of procurement, transportation and storage at the hub of two femoral heads procured at Woodthorpe Hospital were reviewed.

No anomalies were found in those audits. However, one minor anomaly was noted in the bone bank ledger, in which the details of the disposal of one femoral head had not been recorded.

Nottingham University Hospitals NHS Trust holds other HTA licences under the Human Tissue Act 2004, the Quality and Safety Regulations 2007 and the Human Tissue (Quality and Safety of Organs Intended for Transplantation) Regulations 2012 (licensing numbers 12258, 11073 and 40017 respectively). Activities taking place under those licences were not reviewed at this inspection.

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.	C1a, GQ1b	The establishment intends to procure humeral heads from living donors undergoing shoulder surgery, as an alternative source of bone for use in surgical procedures where use of a (physically larger) femoral head would lead to unnecessary wastage of surplus tissue. When this activity commences, the DI is advised there should be suitable arrangements and documentation for such aspects as donor selection / exclusion and informed donor consent. The DI is also advised to notify HTA when activity begins.
2.	C1d	The DI is advised to revise the 'Consent for the donation of bone to the Nottingham Bone Bank' form for femoral heads as follows: • ensure the name and signature of the person seeking consent are recorded rather than, as is current practice, the consent seeker signing on behalf of the surgeon; • remove the section for the donor's next of kin or guardian to sign on their behalf, as this does not occur for femoral heads, and; • refer the donor to the patient information leaflet for details of how to withdraw consent for use of tissues for human application. **Prior to completion of the inspection, the establishment made these revisions to the form. The revised form was shown to the inspectors for verification.**
3.	C1d	The DI is advised to revise the consent form for procurement of ribs to record the name and signature of the person seeking the donor's consent. While donor consent is currently being sought by surgeons, non-surgical staff may also in the future seek consent.
4.	C2c	The DI is advised to develop a patient information leaflet for ribs procured for autologous use.
5.	C3a	The DI is advised to consider consent training arrangements for surgeons and other staff who may seek consent for autologous rib procurement. **Prior to completion of the inspection, the establishment outlined proposals for formal consent training for surgical staff procuring ribs for autologous use.**

6.	GQ1b	The DI is advised to review standard operating procedure (SOP) 'Retrieval of autologous rib in spinal theatres' (NBB-SOP053) to ensure it is sufficiently detailed on: • who may consent to procurement, storage and use of a rib for human application if the donor, for whatever reason, is unable to give their informed consent; • within which drawer of which bone bank freezer a rib is to be stored, and; • the use of the stand-alone register for ribs, rather than the bone bank ledger, to record traceability information.
7.	GQ2b	The establishment periodically audits the laboratory providing serological and microbiological testing services. The audit checklist used does not clarify whether auditing of samples, the review of quality documentation, or receipt of verbal information is taking place. Clarity on how this audit is performed will assure the DI of its rigour, and enable other staff to perform such audits in the future.
8.	GQ2c	Stringent auditing against applicable HTA licensing standards is carried out and action plans developed to address shortcomings identified. Such audits have recently been performed by a member of staff associated with the bone bank. This could create a perception they are not truly independent. The DI is advised to seek input from persons working under another human application licence, or a member of the Trust's clinical governance team, when performing such audits for full assurance on their independence.
9.	GQ4a	Inconsistencies in recording of dates and times of procurement of femoral heads were observed in records at one satellite. To address this, the DI is advised to consider if the 'Date/time harvested' field on Form 5.5 should be 'Date and time of harvest', or indeed if it is necessary to record the time of harvest at all. **Prior to completion of the inspection, the establishment amended Form 5.5 to record the date of procurement only.**
10.	GQ4m	The establishment has a documented plan for storage of records of traceability and raw data in the unlikely event of termination of bone banking activities and the revocation of this HTA licence. The DI is reminded that, in line with paragraph 212 (c) of the HTA's 'Guide to quality and safety assurance of human tissues and cells for patient treatment', ownership of such records must remain under the authority of another HTA human application licence. The Trust currently has another HTA human application licence, facilitating such transfer of responsibility.
11.	GQ8a	The DI is advised to ensure that the most up-to-date donor selection risk assessment (Ref BBR1, dated 11 February 2015) is filed with the donor selection SOP (NBB-SOP002). An outdated version of this risk assessment (dated October 2014) was seen to be filed with the donor selection SOP.
12.	PFE1a	The bone bank freezers at City Hospital are soon to be re-located within the theatres complex. The DI is advised to update the premises risk assessment to reflect this and to confirm that security and temperature monitoring arrangements remain suitable to mitigate potential risks to quality and safety.
13.	PFE4b	The DI is advised to develop a documented SOP for packaging and transportation of tendons to end users. This SOP should specify the transport box to be used and that dry ice, not ice packs at -23 ^{o}C, is placed in the box.

14.	D1a	The DI is advised to clarify in the tissue disposal SOP (NBB-SOP018) that reference to tissue from the deceased relates to such tissues as freeze dried bone and cortical struts from NHSBT.
15.	D2a	The traceability register for autologous ribs contained a recent entry where tissue disposal had been authorised, but the reason for disposal had not been provided. The DI is advised to request information on reasons for disposal of ribs as assurance such tissue is no longer required.

Concluding comments

The establishment has met all applicable licensing standards. Several examples of strength were noted. The establishment has a mature and robust quality management system. Documented SOPs and risk assessments are to a good standard. Wide-ranging audits of practices and premises are carried out at all sites, with corrective and preventive action plans developed where deficiencies are identified. The DI is well supported in her role by her PDs. Freezers at all sites are appropriately monitored and maintained, and have laminated instruction sheets affixed to them for staff to refer to as needed. As an example of good practice, the establishment responded proactively and promptly to advice items given at the inspection, which was evidenced by information received verbally and in documentary form at the feedback meeting.

The HTA has given advice to the DI with respect to consent documentation, revision of governance and quality documentation, and on tissue disposal.

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

Report sent to DI for factual accuracy: 17 March 2015

Report returned from DI: 26 March 2015

Final report issued: 27 March 2015

Appendix 1: HTA standards

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

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

Consent

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

Governance and Quality

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

b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
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.
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.
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.
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 afailure 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.