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**

26-27 February 2013

Summary of inspection findings

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

Although the HTA found that the Nottingham University Hospitals NHS Trust (the establishment) had met the majority of the HTA standards, two shortfalls were found in relation to Governance and Quality Systems. The shortfalls relate to the establishment's current approach to risk assessment and the scope of activities assessed during independent audits.

Items of advice and guidance provided by the HTA at the last inspection had been considered by the establishment and, where appropriate, acted upon.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

Licensable activities carried out by the establishment

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

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

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone	**E**		**E**	**E**	**E**		
Brain tumour	**E**		**E**	**E**	**E**		

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by the bone bank based at the Queen's Medical Centre (QMC), Nottingham. The establishment, which is part of the Nottingham University Hospitals NHS Trust, is licensed for the procurement, testing, storage and distribution of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The establishment has been licensed by the HTA since January 2007 and has been inspected on two previous occasions.

The bone bank was established in 1991 and currently procures, tests and stores approximately 100-200 femoral heads each year from living donors for use in patients requiring revision surgery, particularly revision hip, knee and shoulder replacements and also

for scoliosis correction in children. Procurement of samples currently takes place at two satellite sites, namely the Nottingham City Hospital and the Nottingham Woodthorpe Hospital. Following procurement, samples are transported to the QMC for storage. Paperwork associated with the procurement process, such as consent documentation and donor medical history forms are also stored long term at the QMC.

Femoral heads received by the bone bank are stored in -80^{o}C freezers, with storage locations reflecting the release status of the samples (i.e. quarantine, pre-release and cleared bone). Bone chips and swabs taken for microbiological testing are sent to the clinical microbiology laboratory within the QMC for analysis and only those samples meeting well-defined acceptance criteria are held for long term storage. Donor testing is also carried out by the hospital's laboratories. In all cases, donors are tested at the time of donation, and again after 180 days, for the mandatory serological markers set out in Directions 003/2010. Once cleared for end use, femoral heads are distributed to five hospitals in the Nottingham Trent region, namely the QMC itself, the Nottingham City Hospital, the King's Mill Hospital, the BMI Park Hospital and the Nottingham Woodthorpe Hospital.

The establishment also stores demineralised bone products purchased from another HTA licensed establishment. As storage of acellular products for end use is not currently regulated, the systems used for the storage of these samples were not assessed as part of this inspection.

This report describes the establishment's third routine site visit inspection which took place on 26-27th February 2013. The inspection included a visit to the QMC (the hub) and both of the satellite sites detailed above. At each site, interviews were conducted with key members of staff working under the licence, including the Quality Director, who is also the Designated Individual, a Research Technician, and several Nurse Practitioners involved in the consent and procurement process. A review of documentation relevant to the establishment's activities and a visual inspection of the areas of the establishment where licensable activities take place were also conducted as part of the inspection.

An audit of three samples held in storage was performed. Storage locations were cross-checked with appropriate records and the donor files were reviewed to ensure that they contained all relevant documentation, including consent forms, serology and microbiology test results, and tissue release checklists. Although the microbiology results associated with one sample suggested a non-conformance associated with the time taken to transport samples to the microbiology laboratory (see below), no further discrepancies 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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.		
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	Although the establishment has set out and implemented a clearly defined schedule of audits in relation to their licensable activities, at present independent audits are limited to an assessment of compliance against the HTA's Governance and Quality standards. These audits do not include provision for assessing compliance with other standards, such as those relating to Consent, Premises, Facilities and Equipment, or Disposal.	**Minor**
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.	Although the establishment has risk assessments in place relating to the licensable activities, acceptable risk levels were not clearly defined in standard operating procedures (SOPs), guidance documents or on the risk assessment forms themselves. Risk levels that would necessitate implementation of additional control measures were also poorly defined.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1a	The DI is advised to update the establishment's consent documentation, in particular Form 1.2 and the patient information leaflet, to ensure that donors have the information they need to withdraw consent should they decide to do so. At the time of the inspection this information was provided verbally to donors at various stages pre- and post-donation, but it was not captured in related documentation. **Prior to completion of the inspection, the DI provided evidence that Form 1.2 and the patient information leaflet had been updated accordingly.**

2.	GQ1p	The DI is advised to consider the wording of the agreement between the bone bank and the microbiology laboratory to ensure it provides sufficient clarity with respect to the duration of enrichment broth culture of bone samples and the circumstances under which test results will be reported to the bone bank after two or five days.
3.	GQ4a	The DI is advised to update the wording on Form 1.1 to reflect the current colour coding used for this document to help ensure that the various carbon copies are filed appropriately.
4.	GQ4b	The DI is advised to review the establishment's approach to the follow-up of non-conformances identified during internal audits to ensure that systems are in place for ensuring that findings are reviewed and resolved in an appropriate manner and timeframe. A consistent approach to this would help ensure that audit findings, such as the noted inconsistent approach to the return of Form 2.4, are considered and acted upon appropriately.
5.	GQ6	The DI is advised to review, and if appropriate standardise, the approach used for dealing with spare barcodes within the microbiology laboratory to ensure that the procedures employed during routine sample processing adequately mitigate the risk of sample mislabelling.
6.	GQ7d	The DI is advised to review the systems used to identify those tissues or cells affected by a deviation from the establishment's standard procedures to ensure they are robust enough to highlight any such incidents prior to release of tissues or cells for clinical use. This should include provision for the review of any critical handling times, such as the time taken to transport samples to the microbiology laboratory. **Prior to completion of the inspection, the DI provided evidence that the tissue release checklist (Form 7.4) had been updated to include an additional review step that would identify non-conformances associated with the time taken to transport samples to the microbiology laboratory.**
7.	GQ8a	The DI is advised to formally risk assess the 'out of specification' alert systems associated with the storage freezers at the Nottingham Woodthorpe and Nottingham City hospitals to ensure that existing control measures adequately address the risk of sample loss through freezer malfunction at these sites. The risk assessment should consider whether the use of auto-diallers, as employed elsewhere under this licence, is necessary.
8.	PFE4e	The DI is advised to revise the wording of SOPs 012 and 045 to ensure there is clarity in the number of ice packs that should be used during the distribution of samples to local hospitals. References to the use of -23^{o}C ice packs should also be amended to ensure that it is clear that this refers to the brand of ice packs to be used during transportation of samples, rather than the temperature at which the ice packs should be stored/used.
9.	PFE4g	Although currently an interim measure, the DI is advised to update SOPs relating to transportation of samples to the King's Mill Hospital and the BMI Park Hospital should the current practice of transporting samples on dry ice become standard practice.
10.	PFE4j	The DI is advised to update SOP012 to include specific details of the information that should be attached to transport containers. This could include, for example, a representative shipping label that could be used for reference purposes.

Concluding comments

The HTA saw several examples of good practice throughout the course of the inspection.

Staff at each of the sites were clearly very committed to the successful treatment of patients and are supported in their roles by effective training programs and performance review procedures. Consent procedures were robust and well documented.

It was also apparent that considerable effort has been put in by the Designated Individual and other staff working under the licence to review and revise working practices in light of the findings of previous HTA inspections. For example, information on Serious Adverse Event and Adverse Reaction (SAEARs) reporting has been added to storage freezers at each site, providing clear guidance on what events need reporting to the HTA and the procedures in place for doing so. As a result of this initiative, and the clear information contained in related documentation, staff awareness of SAEARs reporting was very good.

The establishment also displayed a clear commitment to further continuous improvement. This was evidenced, in part, by the steps taken by the establishment to address inspection findings prior to the inspection team leaving. As noted in the Advice section above, several SOPs and forms were updated during the course of the inspection following discussions between the inspection team and establishment staff.

Two areas of practice were identified during the inspection that require improvement, each resulting in minor shortfalls. These relate to the establishment's approach to risk assessment, which at the time of the inspection lacked clarity in relation to the classification of risk levels and the circumstances under which additional control measures should be implemented, and the scope of independent audits which should be extended to encompass all HTA standards applicable under this licence.

The HTA has also given advice to the Designated Individual regarding a number of the establishment's SOPs and agreements which would benefit from being updated to accurately reflect current working practices. Advice and guidance has also been given with respect to the approach used to follow up audit findings to ensure their appropriate and timely resolution, and the systems used to identify non-conformances relating to tissue procurement, testing, distribution or storage.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 27 March 2013

Report returned from DI: 9 April 2013

Final report issued: 11 April 2013

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: 29 April 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
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 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.