Site visit inspection report on compliance with HTA minimum standards

Virgin Health Bank
HTA licensing number 22514

Licensed for the

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

14 February 2012

Summary of inspection findings

A site visit inspection of Virgin Health Bank (VHB) was carried out by the HTA on 14 February 2012.

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

Although the HTA found that the establishment had met the majority of the HTA standards, shortfalls were found, in relation to governance meetings, audits, risk assessments, training records and the content of some documentation in relation to adverse event reporting.. However, good progress had been made in relation to shortfalls found during the establishment's last inspection, in particular with reference to the form and content of consent documentation, Third Party Agreement procedures and validation of transport boxes.

Since the last inspection, the Designated Individual has changed; the new DI has been in post for slightly more than one year. As he has not yet completed the HTA DI e-learning package, which is a standard condition of the licence, this has also been recorded as a shortfall.

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 Paragraph 18 of the Human Tissue Act 2004. They are to secure that:

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

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

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

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

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

Licensable activities carried out by the establishment

'E' = Establishment carries 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
Cord Blood	**E**				**E**	**E**	**E**

Background to the establishment and description of inspection activities undertaken

VHB is licensed for the procurement, distribution and import/export of cord blood in order to provide a source of cord blood stem cells. Procurement of such cells is offered as a service to private individual customers, who are provided with the option to have cells banked purely for future use by the donor child, for family use or for community banking, where 80% of the cells are allocated for public banking, with the remaining 20% being for private use. In the latter case, cells are HLA typed to allow the banked cells to be searched by registries for a recipient match.

Informed consent is taken by trained call centre staff working within an organisation with which VHB has a service level agreement. These staff are trained on the requirements of informed consent and that training is refreshed every six months when staff have to complete a written competency test. The format of the information provided to clients is prescribed by reference to a telephone script, ensuring standardisation. The content and conduct of the telephone communication is subject to periodic audit by call staff supervisors.

In the event clients have any questions, they are referred to VHB's medical officer who can clarify any issues and deal with any questions.

The systems used ensure that a collection kit is not sent to the parents until a signed consent form, contract and medical and behavioural questionnaire have been received by VHB. The collection kit is pre-prepared and sent to the client by another licensed establishment, which subsequently processes and stores procured cells. A unique client number is completed on pre-printed labels and documentation contained within the kit.

Although VHB is responsible for procurement, the activity is carried out by procurement staff acting under the terms of Third Party Agreements (TPAs). The choice of phlebotomist is made by the client, and if they have not selected a particular individual, VHB supply them with a list of phlebotomists or phlebotomy companies to contact. In every case the client is made aware that procurement can only be carried out by a health care practitioner and the systems used by VHB ensure that a TPA is in place for each procurer prior to birth taking place. VHB has also carried out training sessions for various groups of phlebotomists to ensure that those procuring are aware of the particular requirements of the company with regard to minimum collection volume and the particular collection kit used.

At time of delivery, the necessary maternal blood sample is also obtained for serology testing. The procured cells and blood sample are sent by courier in a validated transport box to another HTA licensed establishment where the cells are processed and stored. The serology testing is carried out under the terms of that establishment's licence, with results fed back to VHB. In every case, the serology results are reviewed by the VHB medical officer, who can advise clients on the consequences of any positive result. VHB also ensure that, in each case, repeat maternal blood testing is carried out at 180 days for all donations, and not only those which may be allocated for community, allogeneic, use.

Traceability from consent through procurement to storage is maintained on a dedicated database through use of a combination of unique numbering related to the client, baby and collection kit.

Each client has an individual electronic file which records all communication and all documents issued. Paper copies of signed consent forms, contracts, medical questionnaires and serology test results are kept, with copies scanned into the electronic file.

VHB has considered eventual end use of stored cells and put procedures in place to govern how stored cells may be requested and released, although release and distribution to end use would be carried out under the terms of the licence of the storage establishment.

The inspection was a routine, scheduled inspection and comprised a meeting with key staff where the process was demonstrated to the inspection team. Interviews were carried out with key staff and governance documentation was reviewed.

The establishment was previously inspected in January 2010 and has made good progress in relation to shortfalls found at that time, particularly with reference to the form and content of consent documentation, validation of temperature control of transport boxes and the form of Third Party Agreements entered into with others.

As part of the inspection, an audit of some client records was carried out. Records for three clients were traced on the database and records of communications reviewed. In each case the scanned records were reviewed for the presence of signed consent forms, medical and behavioural questionnaires and serology results.

In all cases there were no discrepancies.

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
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	The DI has regular formal governance meetings with the corporate licence holder contact. He also has regular contact with the medical officer at the establishment, by telephone and in scheduled quarterly face to face meetings. However, the meetings with the medical officer are not subject to a formal agenda, nor are they minuted, therefore there is no formal record of issues discussed and actions taken. Furthermore, the agendas and minutes of the governance meetings held with the corporate licence holder contact are not available for review by other staff. By formalising meetings the DI will be able to record issues raised and actions allocated. This will enable the DI to maintain an oversight of progress against actions and analyse trends in any issues raised within those meetings. By ensuring that agendas and minutes are stored in an accessible form, either in paper or electronically, these will be available to other staff and inform them on governance issues affecting the establishment.	**Minor**

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 audits of various parts of the processes undertaken by the establishment are carried out by staff working at the establishment or contracted to carry out activities on its behalf, there is no audit of all processes in an independent manner. By arranging for such an audit to be carried out, the DI will be informed of compliance with the relevant regulatory requirements and will be able to ensure that any corrective and preventative actions are carried out, which will enable continued improvement of systems and processes.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	The DI has ensured that many of the phlebotomists who carry out procurements on behalf of the establishment under Third Party Agreements (TPAs) have been trained on the establishment's requirements and processes. However, despite the requirement that procurement staff are adequately trained being contained within each TPA, the DI has not been able to demonstrate in all cases that he has reviewed and recorded the training and qualifications of procurement staff. By reviewing and recording the training and qualifications of phlebotomy staff, the DI will be able to assess their competence and target any specific training to ensure that those procuring are fully aware of the requirements of the establishment. By arranging for procurement staff to be trained on the particular processes to be followed and the establishment's requirements the DI will be able to ensure their competence and maintain the quality and safety of procurement processes.	**Minor**

GQ7 There are systems to ensure that all adverse events 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.	The establishment has a documented Standard Operating Procedure (SOP) detailing the procedure to be followed when the establishment is advised of a serious adverse event or reaction. However, this SOP does not detail the requirement that the DI or establishment staff report to the HTA within 24 hours of becoming aware of the event or reaction. By ensuring that the SOP details the relevant reporting requirements, staff will be guided on the need to report serious adverse events or reactions quickly and the DI will ensure compliance with HTA directions. This will also ensure that any necessary actions can be taken promptly helping to minimise risks to patient safety.	**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.	While risks have been assessed in connection with the drafting of policies and processes relevant to the activities carried out by the establishment, they have not been formally documented. As such, they are not capable of being reviewed and cannot be accessed by staff. Documented risk assessments will inform corrective and preventative actions to address any risk identified. They will also help inform the drafting of suitable procedures and policies and, combined with these being accessible to staff will help mitigate risk and aid continuous improvement.	**Minor**
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.		

N/A	The DI has been in post for just over one year but has not yet completed the HTA DI training, either face to face or by e-learning, which, as a standard condition of the licence, is to be completed within 12 months of taking the role. By completing the training, the DI will be provided with background to the Human Tissue Act as well as the standards of compliance he is working to, which will help inform his role as a DI.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(s)	The DI is advised to remind those carrying out procurements of the need to report Serious Adverse Events or Reactions to him within 24 hours after occurrence in order that he can comply with the HTA time requirements for reporting.
2.	GQ2(b) GQ4(b)	The DI is advised to ensure that all audits of processes carried out, including trend analysis of contamination rates, are fully documented and accessible for review, and to extend the audit to include an audit of accuracy of the scanned electronic records against the paper original documents to check accuracy of filing into electronic client records.
3.	GQ4(k)	The DI is advised to liaise with the HTA licensed establishment carrying out storage on VHB's behalf to ensure that, when stored samples are released for transplant, any agreement with end users provides for continued traceability for 30 years.
4.	N/A	The DI is advised to appoint a person designate within the UK office and to consider delegating responsibility for reporting Serious Adverse Events or Reactions in order to minimise any delays caused by the time difference to the DI's location.

Concluding comments

The HTA saw various examples of good practice on inspection. Much thought has gone into the design and execution of the software systems used to accurately record all stages of interactions with clients, with prompts and reminders helping staff to follow flows accurately. Staff taking consent have their performance monitored to ensure they are following processes and their training is refreshed regularly.

There is good and regular communication between all staff members, particularly with the medical officer who is readily available to deal with enquiries from clients at all stages. In addition, all serology results and medical questionnaires are subject to review by the medical officer.

All relevant documentation is kept both in paper form and as scanned records in individual client files, meaning that those with necessary access, the DI and medical officer, can access all relevant records online. Although not required for autologous donations, the establishment carries out repeat testing on all samples and not only those for allogeneic use, to ensure compliance with requirements of regulators outside Europe, and has ensured that the consent obtained covers this, the potential use of non clinical samples for research and for disposal of samples when required.

All staff interviewed demonstrated a willingness to accept advice in an effort to facilitate continued improvement. The DI, while located outside the UK, has ensured regular contact and maintains a good oversight of the activities carried out, by use of on line access and regular communication with key staff.

There are a number of areas of practice that require improvement, including six minor shortfalls. The HTA has given advice to the Designated Individual with respect to; informing staff further on timelines for adverse event or reaction reporting, recording of audits presently carried out, liaising with the establishment storing procured cells in the event of receipt of a request for cell release, and the possibility of nominating a person designate to assume some day to day responsibility when the DI is not available.

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: 20 February 2012

Report returned from DI: No comments on factual accuracy received

Final report issued: 7 March 2012

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: 15 July 2012

Appendix 1: HTA standards

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

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

Consent

Standard
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.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
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.
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.
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.
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.

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.
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.

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.