Site visit inspection report on compliance with HTA minimum standards

Wescott Medical Ltd.

HTA licensing number 22586

Licensed for the

- **storage and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

14th and 15th January 2019

Summary of inspection findings

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

Although the HTA found that Wescott Medical (the establishment) had met the majority of the HTA standards, six minor shortfalls were identified. Of these, five related to the governance and quality standards, specifically raw data capture and retention, document control procedures, traceability arrangements and implementation of procedures for capturing the Single European Code (SEC). The sixth shortfall, under the premises, facilities and equipment standards, related to temperature monitoring and review procedures.

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 Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Cartilage; Cartilage				**E**	**TPA**		
Musculoskeletal, Bone; Acellular bone chips				**E**	**TPA**		
Membrane; Fascia Lata, Fascia Temparalis				**E**	**TPA**		
Membrane, Pericardium; Pericardium				**E**	**TPA**		

Background to the establishment and description of inspection activities undertaken

Wescott Medical Ltd. (the establishment) is licensed for the storage of a range of processed tissue (allograft) products, and for distribution of those products to end users. All products are purchased from a single supplier, which is based within the EU and also licensed under the European Tissue and Cells Directives (EUTCD) by the relevant competent authority. Donor selection, consent, serology testing, processing and distribution take place under the licence of the supplying establishment. The supplying establishment provides all the primary product packaging, upon which the product code, donor lot information and SEC label are printed in both eye-readable and barcode form. Each package includes a supplier-issued traceability label to be included in patient notes at the point of end use, thus enabling traceability from

donor to recipient. Product code and lot information is included in the traceability label but the SEC code is not.

Establishment staff receive deliveries in accordance with documented procedures and record activities using a ‘goods inward’ checklist. Each package is checked against what was ordered and the delivery note provided by the supplier with the shipment. Packages are checked for integrity and damage, and the two barcodes present on the packaging are scanned using a handheld reader. One barcode captures the supplier-issued product code and lot information. The other barcode captures the supplier-issued SEC. This information is captured in a temporary spreadsheet alongside the product name and expiry date, which is entered manually by establishment staff. The spreadsheet information is then manually transferred to establishment databases for stock management and dispatch activities. Electronic data is archived using backed-up systems. The establishment also retains paper copies of relevant documents including order forms, delivery notes, receipt forms and authorised procedures. The goods inward checklist used to receipt each delivery also captures release of delivered products for sale by establishment personnel.

Products released for sale are stored on designated shelves within a segregated area in the warehouse. The majority are stored within locked cabinets, with larger volume items being stored on a neighbouring shelf. Quarantined product is stored in a separate location within the warehouse. The warehouse is secured with metal shutters and an alarm system out of working hours and access is restricted to trained establishment staff. The storage area is monitored using a calibrated temperature probe, which transmits temperature readings to software held centrally on establishment computers for review and archive.

Each product has a designated storage location and stock is managed so that items with the shortest expiry dates are dispatched first. When orders are processed establishment staff allocate product to the end user electronically, and the system alerts staff if the current end user agreement is no longer in date. Product is then transferred to a dispatch area, where the integrity of the primary packaging is again checked and the product lot information scanned using a hand held barcode reader. The product is then enclosed in secondary transport packaging along with a Wescott delivery note, and labelled for dispatch in accordance with the regulatory requirements. In addition to the scanned barcode information, the lot number is recorded on a copy of the Wescott delivery note by hand. This is then signed by the member of staff and retained at the establishment. Transport to end users is achieved via a contracted courier company.

The establishment undertakes routine process audits, and a monthly audit of stock held in storage against database records. In addition to this, an audit against all applicable regulatory standards is performed by a member of staff independent from licensable activities. Establishment premises and procedures are subject to risk assessment. These are displayed for staff to see and reviewed on an annual basis.

The establishment has held a licence since November 2009, and this was the fifth site inspection. A visual inspection of the storage and dispatch areas was conducted during which establishment staff demonstrated the processes for product receipt and dispatch. The inspectors compared the processes with the establishment’s documented procedures, and information retained in paperwork and databases against product packages. Selected packs of cartilage, pericardium, fascia lata, fascia temporalis and cancellous bone chips in storage at the establishment were checked against database records. During this audit a discrepancy was detected in the expiry date for a package of 40mm x 50mm fascia lata, which was recorded in the database as July 2023 and on the product package as August 2023. Further investigation identified a total of 6 packages assigned this incorrect expiry date in the database as a result of a copy and paste error. No other discrepancies were detected.

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
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.	Staff training records do not capture all training activities. Those that are captured are not recorded in sufficient detail to enable reconstruction of individual competence in licensable activities at a given point in time. For example, documentation of the reading of reissued SOPs did not capture the SOP identification number(s), version number(s) or title(s).	**Minor**
GQ4 There is a systematic and planned approach to the management 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.	Product-specific data collected during receipt of allograft is captured via a barcode reader on to a temporary spreadsheet, then transferred by establishment staff to a database for long-term storage, stock management and issue. During a review of product receipt procedures it was noted that an incorrect expiry date had been entered for 6 product packages due to a copy-paste error. This aspect of the receipt process is not proceduralised in establishment SOPs, nor is it subject to a second person check or reviewed in routine establishment audits.	**Minor**
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.	Establishment SOPs (e.g. SOP 13 ‘Allograft Data Archive Procedure’) do not capture the requirement to retain relevant raw data for a minimum of 10 years after the use, expiry date or disposal of tissues and / or cells.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
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.	End user agreements require users to retain allograft information in accordance with the requirements of the Directions, but there are no feedback or audit procedures in place to confirm this takes place. In addition, product packages include a sticker containing lot-specific information, which can be included in patient files to simplify traceability procedures. The sticker includes the product lot information but does not include the SEC. There are no additional procedures in place to ensure that traceability via the Single European Code is maintained though to end use.	**Minor**
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	Although the establishment has recently updated their product receipt procedures to include capturing the SEC, this procedure was not in place at the introduction of the Directions in April 2018. The establishment has not retrospectively captured the SEC for all products that were received prior to their procedures being updated, some of which were still in storage at the establishment at the time of the inspection. The risks relating to the traceability of these and other items without the SEC being captured at the establishment have not been formally assessed and documented.	**Minor**

Premises, Facilities and Equipment

Standard	**Inspection findings**	**Level of shortfall**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
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.	It was noted during the inspection that temperature monitoring data for the allograft storage area was lost over the period 22 August to 19 September 2018. This was not detected and assessed in a timely manner and the associated SOP does not stipulate procedures for routine download and review of temperature records which would have hastened the detection of this fault. The system is not programmed to generate an alarm in the	**Minor**

	event of a temperature excursion. Occasions of excursions below the defined storage temperature for cartilage (15-30°C) were not highlighted or assessed. Further, there are several temperature probes used throughout the warehouse, but no procedures in place to identify which probe is monitoring the allograft area over a given time period. Therefore there is a risk that if future review is required it will not be possible to define which data set relates to the allograft storage conditions.	

Advice

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

No.	Standard	Advice
1.	GQ1c	At present, governance meeting minutes do not capture whether allograft-related topics were considered when there were no relevant items to report. The DI is therefore advised to introduce a standing agenda item for governance meetings for the consideration of allograft-related topics, to act as a meeting prompt and evidence the fact that consideration was given to topics relating to licensable activities.
2.	GQ1d	The DI is advised to ensure that electronic versions of establishment SOPs which are accessible to establishment staff are stored as locked, non-editable versions, to avoid accidental uncontrolled loss or alteration of approved procedures.
3.	GQ2a GQ3a, f	The DI is advised to consider updating the establishment Quality Manual, SOPs, and staff job descriptions to better reflect the regulatory basis of activities licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). This would also provide supporting evidence to demonstrate that establishment staff are aware of the regulatory context of their work (a requirement under standard GQ3f). The DI is further advised to update the adverse event reporting form, or create a specific one for allograft material, so that the correct competent authority to contact in the event of an incident is clear.
4.	GQ4e	The DI is advised to define the records held by the establishment that meet the definition of raw data and traceability data within establishment SOPs, to ensure consistent retention, support routine audits and simplify contingency planning.
5.	PFE1 a, c	During the inspection it was noted that plans are underway to move to new premises. The DI is advised to ensure that procedures relating to the relocation of allograft, equipment and records (including electronic) are documented in advance and supported by risk assessment.
6.	PFE2c	It was noted that the routine cleaning scheduled for October 2018 was omitted. The DI is advised to ensure that schedules are regularly reviewed to avoid scheduled activities being missed.
7.	PFE3a	At the point of release establishment staff sign a copy of the dispatch information for retention at the establishment. The DI is advised to consider expanding and formalising this sign-off event, so that for every package leaving the

		establishment a record is retained confirming that integrity checks, packaging and labelling activities were completed in accordance with current establishment procedures.
8.	PFE3c	Establishment temperature monitoring devices take a measurement every 6 hours. The establishment has given consideration to the suitability of this interval period based on the stability of the stored allograft products, but this has not been formally documented. The DI is advised to document this assessment and any supporting evidence, ensuring that the assessment is reviewed, and where necessary updated, should existing or future allograft products stored at the establishment require it. Further to this the DI is advised to consider strengthening existing temperature monitoring procedures by documenting routine checks when staff access the allograft storage area, or consider the use of an alternative device such as a calibrated maximum-minimum temperature probe.
9.	PFE4a	The DI is advised to consider formalising daily (when in use) download of the dispatching barcode reader in establishment SOPs, and include a review of this in routine audits, to ensure the timely transfer of dispatch data from the stand-alone device to the establishment's backed-up computer systems.

Concluding comments

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation. There are a number of areas of practice that require improvement, including six minor shortfalls. Of these, five relate to the governance and quality (GQ) standards, specifically with regard to raw data capture and retention, document control procedure, documentation of training, traceability arrangements and the implementation of procedures for capturing the SEC. The sixth shortfall under the premises, facilities and equipment standards related to temperature monitoring and review procedures.

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: 12 February 2019

Report returned from DI: 19 February 2019

Final report issued: 11 April 2019

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: 21 October 2019

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

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.
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.
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 002/2018.
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.
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.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
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 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.
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.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
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 002/2018.
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.
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.