Site visit inspection report on compliance with HTA minimum standards

Sunderland Royal Hospital

HTA licensing number 22610

Licensed for the

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

18 – 19 June 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 Sunderland Royal Hospital (the establishment) had met the majority of the HTA standards, two major and seven minor shortfalls were found in relation to the governance and quality standards and the premises, facilities and equipment standards. The major shortfalls related to the independent audit and the procedure for the management of incidents. The minor shortfalls related to the organisational chart, document control procedures, procedures for dealing with products requiring quarantine, the training programme, procedures for documenting the Single European Code (SEC) and the content and formal review of risk assessments.

In addition to this, the licensing arrangements were discussed with respect to the storage of the allograft within the Pathology department. The HTA will give further consideration to this matter separately to the inspection findings reported below.

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.

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

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone, Bone				**E**			
Musculoskeletal, Tendon & Ligament, Tendons				**E**			
Other, Cartilage (ATMP)	**E***						

Background to the establishment and description of inspection activities undertaken

The establishment is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) for the storage of bone (femoral heads) and tendons. The establishment is also licensed for the procurement of cartilage as a starting material for an Advanced Therapy Medicinal Product (ATMP), although this activity is not currently being undertaken. The establishment has been licensed since December 2010 and this was the fifth routine inspection to assess compliance with the HTA standards.

Allograft material is ordered for use in specific surgeries from another HTA-licensed establishment by a member of theatre staff. When placing an order, the type of allograft

requested, the details of the intended recipient and the order number are recorded in the establishment's 'Tissue Register' book. Allograft is delivered directly to the establishment's theatres where a trained member of staff checks the integrity of the outer packaging. The accompanying paperwork is used to verify that the shipment details match the order and the details recorded in the tissue register.

Once it has been confirmed that the correct order has been received and there is no damage, the outer packaging is opened and the level of the dry ice is checked to ensure that there is sufficient remaining to maintain the integrity of the frozen allograft. The unique tissue identifiers on the container are verified against the paperwork to check that they match. Expiry dates are allocated by the organisation supplying the allograft and are based upon the operating temperature of the establishment's storage freezer, which is set to -30°C. The expiry dates are therefore checked during receipt to verify they are not greater than six months from the date of dispatch. Following verification against the paperwork, tissue identifiers, expiry dates and date of receipt are recorded against the appropriate allograft order details within the tissue register.

Once the checks are completed, a porter is called to take the allograft from theatres to the blood transfusion laboratory where it is stored within a section of an allocated freezer. Transfer of the allograft by the porter is recorded within the 'Allograft Storage' record book which includes the porter's signature, the time the allograft was collected, the time of arrival at the blood laboratory and the signature of the person who took receipt and placed the allograft into the freezer.

The allograft remains in storage until required for use in surgery. If it is not required during the surgery of the intended recipient and has not been removed from the storage freezer, it will continue to be stored for use in other elective or trauma-related orthopaedic surgeries involving different recipients.

When required for use in surgery, a porter is requested to collect a specific allograft from the storage freezer. The collection time, delivery time and porter details are recorded within the 'Allograft Storage' record book. Details of the recipient and date of use are recorded against the appropriate entry in the tissue register. If allograft is requested in theatres but subsequently not used in surgery, it is not returned to the freezer and is disposed of as clinical waste in line with the establishment's Trust disposal policy. Disposal of unused or expired tissue is also recorded in the tissue register.

During the inspection, a traceability audit of allografts was undertaken. The details recorded in the tissue register of the allografts currently in stock were cross-referenced to the allografts located in the freezer. All records matched and there were no discrepancies. Three allograft units that had been removed from the freezer for use in a surgery were selected at random from the tissue register. The details in the accompanying paperwork, the tissue register, the 'Allograft Storage' record book and the electronic theatre record were cross-referenced to confirm all the details matched. There were no discrepancies noted, however one allograft was recorded in the tissue register as having been disposed of, but this was not documented in the electronic records (also referred to as the centrally held record) in accordance with establishment procedures.

Inspection findings

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

Organisational changes to Pathology services mean that allografts are now stored within a department that is no longer part of the South Tyneside and Sunderland NHS Foundation Trust. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as

amended) specify that it is not possible to carry out storage in pursuance of a third party agreement. Although during the inspection the DI provided assurance that he retained responsibility for storage of the allograft, this was not adequately evidenced by documentation that was made available during the site visit. The HTA intends to further review the current arrangements for the storage of allograft in the Pathology department to ensure that it satisfies legislative requirements; this matter will be followed up separately to the inspection findings reported below.

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.		
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.	At the time of the inspection, an organisational chart setting out the lines of accountability and reporting relationships for staff working under the licence was not in place.	**Minor**
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.	There are a number of uncontrolled documents in use at the establishment. These include the instructions attached to the 'Femoral Heads and Allograft delivery notes' folder, the 'Allograft Implant Inventory Guide', the document describing the audit procedure and the establishment's risk assessment. There is a risk that instructions followed by staff may not be subject to the necessary reviews, approvals and controls to ensure consistent practices which are aligned with current approved procedures.	**Minor**
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.	Although staff were able to describe the actions that would be taken in the event a product was received and not accepted for use and/or required quarantine, this information was not documented in a procedure.	**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.	There has been no independent audit carried out to verify compliance with the relevant HTA standards. This was a finding in the previous inspection.	**Major**
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.	Although staff carrying out activities under the licence are trained to undertake these tasks, there is no formal training programme and the training provided is not documented.	**Minor**
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.	Training does not include the scientific and ethical principles relevant to the licensable activities, and the regulatory context.	
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	The Single European Code (SEC) was not recorded in the patient records and there is no documented procedure in place describing how this should be done.	**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.	Serious adverse events and reactions (SAEARs) are referred to in the Trust's Incident Reporting Policy (NQ4.II.V5.1). However, this document does not include a robust procedure for the identification, reporting, investigation and recording of SAEARs at a departmental level, including the documentation of any corrective or preventative actions. In addition, there is no documented procedure for managing incidents identified within the department that are not considered to be SAEARs but that still require documenting and investigation. This includes any incidents that occur in the department in which the freezer is located.	**Major**
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.	The responsibilities of personnel investigating SAEARs have not been defined, including the responsibilities of the department in which the freezer is located.	
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
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.	The establishment's risk assessment does not include document control indicators and it is unclear as to when it was last reviewed. Although this was identified during the previous inspection, there have been no amendments to this document.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
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.	The establishment's risk assessment does not include risks associated with the premises.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(b)	The DI is advised to distribute the standard operating procedure (SOP) dealing with the receipt, transfer, storage, use and disposal of allograft (SOP6) to the department in which the freezer is located, in order that the appropriate staff are aware of the procedure.
2.	GQ1(c)	Matters relating to the licensable activities can be raised if required at the Surgical Directorates general governance meeting, which the DI attends. The DI is advised to consider holding a meeting which includes staff carrying out activities under the licence (e.g. theatre and laboratory staff) in order to review all parts of the quality management system (e.g. procedures, incidents, audit findings, etc.).
3.	GQ1(l)	The DI is advised to update the procedure relating to the transfer of allograft in the event of termination of activities to reflect the recent organisational changes of the currently specified Trust.
4.	GQ3(g)	The DI is advised to include information on the organisational structure and quality systems used within the establishment, which relate to the licensable activities, in the training programme.
5.	GQ3(k)	The DI is advised to consider the addition of a Person(s) Designated (PD) on the licence to support the DI in overseeing licensable activities.
6.	GQ4(b)	The establishment recently carried out a review of the records for implanted allograft from the preceding 12 months. The audit recorded discrepancies but did not document the actions taken to resolve them. The DI is advised to document any corrective and/or preventative actions taken in relation to this type of audit.
7.	GQ4(c)	Information relating to ordered, received and implanted/disposed allografts is documented in the tissue register. Some of the date entries are recorded under the heading of the applicable year. The DI is advised to include the full date for each individual entry. For some entries in the tissue register, labels had been placed over written information in order to correct it. The DI is advised to document a requirement to strike through incorrect information and include the date and initials of the person doing this and re-enter the correct information in a separate entry.
8.	GQ4(e)	During the traceability audit, it was found that information relating to allograft disposal was not always recorded in the theatre record (also referred to as the 'centrally held record'), as stipulated in the relevant procedure, SOP6. Discussions with the establishment staff confirmed that depending on at which point in the theatre pathway the patient is, a theatre record may not be available to record the disposal of allograft in. In these scenarios, traceability is maintained because the disposal of the allograft is also recorded in the tissue register. The DI is advised to align the procedures documented in SOP6 with the process that is undertaken.
9.	GQ4(i)	The DI is advised to periodically scan or photocopy the tissue register so that in the event this record were to be damaged or lost, allograft traceability records would be maintained.

10.	GQ8(a)	Currently the establishment's risk assessment includes risks associated with allografts and autologous chondrocyte implantation (ACI). The DI is advised to separate the two activities and review the allograft procedures to assure himself that all the risks associated with allograft activity are documented.
11.	GQ8(c)	The DI is advised to ensure that staff are aware of and can access risk assessments related to licensable activities, to help ensure awareness of steps in the process presenting a high risk to quality, safety, and/or compliance.
12.	General	From discussions with the DI it was confirmed that chondrocyte procurement was not taking place. The DI is advised that prior to any chondrocyte procurement activity re-starting, he should inform the HTA of the re-commencement and also develop a suite of procedural documents to describe the processes used by the new service provider.
13.	General	During the inspection a meeting took place with a Consultant Ophthalmologist from the Sunderland Eye Infirmary to discuss the requirements for adding a satellite to the licence and the activity of Import. The DI is advised that the applicable amendments to the licence must be made prior to any licensable activities being undertaken at the Sunderland Eye Infirmary.

Concluding comments

There are a number of areas of practice that require improvement, including two major shortfalls and seven minor shortfalls. The HTA has given advice to the Designated Individual with respect to the governance and quality standards.

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: 15 July 2019

Report returned from DI: 16 July 2019

Final report issued: 23 July 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: 12 August 2020

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.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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.

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.