Site visit inspection report on compliance with HTA minimum standards

Hospital of St Cross

HTA licensing number 12319

Licensed for the

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

13 August 2013

Summary of inspection findings

The Hospital of St Cross (the establishment) was subject to a themed site visit inspection. The themes selected for inspections in this sector for 2013 / 2014 include quality management, contingency planning and risk management.

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 establishment had met the majority of the HTA standards, seven minor shortfalls were found with regard to the Governance and Quality Systems (GQS) standards. The shortfalls were in relation to standard operating procedures, governance meetings, audit, contingency planning and donor selection and testing. Advice has also been given relating to the GQS and Premises, Facilities and Equipment (PFE) standards.

Particular examples of 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 (DI), 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.

However, a themed inspection may be carried out at establishments which have been found previously to represent a lower risk. Themes target standards against which the HTA identified common shortfalls across the human application sector in 2012. The themes selected for 2013/14 are outlined in the table below.

Themes	**HTA Standards**
Quality management	
Standard operating procedures for licensed activity	GQ1(b)
Document control system	GQ1(d)
Quality Management System – continuous and systematic improvement	GQ2(a)-(c)
Internal audit system for licensable activities	
Contingency Planning	
Plan to ensure records of traceability are maintained for 10 or 30 years as required.	GQ4(m)
Risk Management	
Procedures for the identification, reporting, investigation and recording of adverse events and reactions	GQ7
Risk assessments	GQ8
Traceability	GQ6

In addition to the standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Cartilage / chondral tissue	**E**	**-**	**-**	**-**	**-**	**-**	**-**

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by the Hospital of St Cross (the establishment). This was the third site visit inspection of the establishment since it was issued an HTA licence in January 2008 (the last inspection was in August 2011). It was a routine 'themed' inspection to assess whether the establishment is continuing to meet the HTA's standards.

The establishment procures articular chondral tissue for Matrix-induced Autologous Chondrocyte Implantation (MACI) of damaged knee cartilage. Approximately 12 such procurements occur annually. During this procedure, a blood sample for serological testing is also taken. Tissue processing and serological testing is arranged by a company based in Denmark. This company is licensed under the EU Tissue and Cells Directive by the Danish Medicines Agency. All samples are collected by a courier arranged by the company. Once processed, material is returned to the establishment for reimplantation into the patient as an Advanced Therapy Medicinal Product (ATMP). The manufacture and distribution for end use of the ATMP is generally outside the scope of the establishment's HTA licence. However, the DI is still obliged to monitor sample traceability to reinfusion and to report to the HTA any serious adverse events or adverse reactions (SAEARs) associated with the tissue at any stage.

The establishment also occasionally receives cryopreserved tendon meniscus from an HTA-licensed establishment and fresh-frozen femoral heads from NHS Blood and Transplant (NHSBT). Both tissue types are used immediately upon arrival.

The establishment has entered into service level agreements (SLAs) with NHSBT, with the HTA-licensed supplier and with the company responsible for tissue processing and serological testing (*see Advice item 1*).

Following the previous site visit inspection of the establishment, minor shortfalls were found relating to the lack of inclusion of completed consent and serological testing forms in the patient records. These were assessed as being met following notification by the establishment in 2012.

The present site visit inspection included a visual inspection of the 4°C refrigerator located outside the operating theatre complex and used to store the biopsy kit, and the area where records were kept. Meetings were held with the DI and the Lead Theatre Nurse. Telephone discussions were held before the inspection with the Corporate Licence Holder contact and

the Theatre Manager. A documentation review and audit trail were carried out. Details of the audit are provided below; no anomalies were found.

A vertical audit was carried out on six sets of patient notes from tissue procurement to ATMP reimplantation. All appropriate sample records and forms were present and all details were correctly recorded.

Inspection findings

The HTA found the DI 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.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	Some procedures still need to be created and developed. *See Advice items 3 and 4*.	**Minor**
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	There is no existing regular governance meeting, which covers HTA issues, for staff working under the licence. *See Advice items 5 and 6*.	**Minor**
GQ2 There is a documented system of quality management and audit.		
a) There is a quality management system which ensures continuous and systematic improvement.	Although there are elements in place, the quality management system (QMS) would benefit from further development. *See Advice item 7*.	**Minor**
b) There is an internal audit system for all licensable activities.	There is no documented audit schedule in place. *See Advice item 8*.	**Minor**
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.	The establishment does not yet have a regular independent audit to verify compliance with protocols and HTA standards.	**Minor**

GQ4 There is a systematic and planned approach to the management of records.		
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.	Although a Standard Operating Procedure (SOP) for contingency has now been created, there is as yet no written agreement with another HTA-licensed establishment to transfer traceability records and raw data in the event of termination of licensable activities.	**Minor**
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.	The DI is required to ensure that HTLV-1 antibody testing must be performed for donors living in, or originating from, high prevalence areas, or with sexual partners originating from those areas, or where the donor's parents originate from those areas. Neither the establishment's current donor selection procedures, nor the SLA with the company responsible for serological testing, indicate that such additional testing may be needed or performed.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The DI should ensure that all SLAs are up to date and have been signed.
2.	GQ1	The DI should ensure that locally stored Trust policies (e.g. those for for consent, complaints, incident management and disposal) are the most up to date.
3.	Principally GQ1(b) but also relevant to standards GQ4(a), (h) and (i); PFE2(c) and PFE5(f)	The DI is advised to develop SOPs to cover the following areas: • record creation, access, amendment and destruction. • retention of critical raw data (for 10 years) and traceability records (30 years). • cleaning and decontamination.
4.	Principally GQ1(b)	There is inconsistency in the format of SOPs. The DI is advised to consider the inclusion of the following features to each document to

	but also relevant to standard GQ1(d)	create a more robust system: • Document control information, such as a revision history and version number. • Review date (at least every two years). • Issue date. • Pagination. • The names of both the author and the reviewer who has authorised the content of the document (the reviewer should have knowledge of the relevant procedure but need not be more senior than the author).
5.	GQ1(c)	In other establishments, regular governance meetings have covered items such as: reportable incidents, changes to SOPs, audits, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items).
6.	GQ1(c)	The DI may wish to consider setting up meetings with other DIs working in the Trust, to share information and experience with them and their Persons Designated (PDs). This may help facilitate learning and understanding of staff at the establishment as well as being a forum for the discussion of good practices.
7.	GQ2(a)	The quality management system (QMS) for this sector is described in the document 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment' (paragraph 29): 'The quality management system should include the following documentation: • A quality manual which provides an overview of the quality system. • Standard operating procedures. • Guidelines from relevant professional bodies or advisory committees. • Training and reference manuals. • Reporting form. • Donor records and any records required by the HTA. • Information on the final destination of tissues and cells. • A risk management system. • Non-conformances and incident monitoring and follow-up, including serious adverse event and reaction management. • A mechanism to control changes to ensure these do not adversely affect the quality and safety of the tissues and cells and which allows for the mitigation of risk associated with change'. http://www.hta.gov.uk/_db/_documents/Annex_-

		Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment.pdf The DI may wish to consider appointing a PD to assist in further development of the QMS.
8.	Principally GQ2(b) but also relevant to standard GQ4(b)	The DI is advised to divide the audit schedule into small increments, carried out by different team members. This should include horizontal audits to ensure that SOPs accurately reflect current practices and vertical tissue traceability audits, from records of procurement to reimplantation. The results of all audit findings, and actions taken, should be formally recorded.
9.	GQ3(e)	There is a designated clinical team associated with HTA activities. The DI should ensure that all members of that team are familiar with the range and content of all the relevant SOPs. There should be records of those members of staff who have read specific policies, SOPs and risk assessments, and records of those members of staff who have been trained in such procedures. All other staff should be aware of the names of these team members.
10.	GQ4(e)	The DI is advised to consider whether a single, electronic tissue register, which had restricted access only to nominated staff, would be beneficial.
11.	GQ7(a)	The DI is advised to keep a record of adverse events, including non-conformances, within the Department.
12.	GQ7(b), (c)	The Trust Incident Management Policy and the Departmental SOP on 'Adverse Events' do not state that SAEARs associated with any stage of the procedure should be reported to the HTA within 24 hours of discovery or confirmation, as requested by the HTA. The DI is advised to create a separate, additional SOP relating specifically to 'Serious Adverse Events and Adverse Reactions' which details the reporting obligations to the HTA, the receipt of HTA regulatory alerts and which identifies the personnel who should report SAEARs in the DI's absence. The DI should ensure that the Trust Incident Management Policy is also updated accordingly. The DI is referred to the HTA's website page for further information: http://www.hta.gov.uk/licensingandinspections/reportingtothehta/adverseeventandreactionreporting.cfm
13.	GQ8(b), (c)	Having now established a set of risk assessments, the DI is advised to ensure that these are reviewed regularly and that all staff are made aware of risk assessments during training.
14.	PFE5(b), (e)	The DI is advised to ensure that records of refrigerator service visits and agreements with maintenance companies are held within the Department.
15.	PFE5(k)	The DI is advised to formalise and document the contingency plan for refrigerator failure and ensure that all relevant staff are aware of this plan.

Concluding comments

During the site visit inspection of the Hospital of St Cross areas of strength and good practice were noted:

- All surgeons undertaking licensable activities are trained and have signed certificates of training provided by the company responsible for tissue processing.
- Quality management has developed further since the last HTA site visit inspection.
- There is a small, cohesive body of staff working under the licence. This provides continuity and the establishment derives benefits from this stability and commitment.
- The surgical team has developed a good working relationship with the local representative of the company responsible for tissue processing.

There are a number of areas of practice that require improvement, including seven minor shortfalls. The HTA has given advice to the DI with respect to governance and quality systems and premises facilities and equipment.

The HTA requires that the DI 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 site visit inspection.

Report sent to DI for factual accuracy: 12 September 2013

Report returned from DI: 1 October 2013

Final report issued: 16 October 2013

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 1 September 2015

Appendix 1: HTA standards

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

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

Consent

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

Governance and Quality

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

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

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.

PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
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.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
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.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.

D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.

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.