Site visit inspection report on compliance with HTA minimum standards

Musgrave Park Hospital Tissue Bank

HTA licensing number 11032

Licensed for:

the procurement, storage and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007

25 July 2012

Summary of inspection findings

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.

Musgrave Park Hospital Tissue Bank (the establishment) was found to have met all HTA standards.

The establishment acted on advice and guidance provided by the HTA following the previous HTA inspection in 2010 by amending some quality documentation and revising processes and procedures. Some further items of advice were provided to staff during this inspection and are detailed later in this report.

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

The HTA's regulatory requirements

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

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

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;

- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

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

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

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

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

Licensable activities carried out by the establishment

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

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

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

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Musgrave Park Hospital Tissue Bank (the establishment), which has been operating as a tissue bank, under oversight of the same Consultant Orthopaedic Surgeon, for approximately 11 years. The establishment carries out the licensable activities of procurement, storage and distribution of bone in the form of femoral heads. Mandatory serology testing, as well as microbiology testing, is carried out by another HTA licensed establishment acting under the terms of a service level agreement.

Consent to bone donation is obtained by trained staff, having identified potential donors using defined selection criteria. In advance of the meeting to discuss the procedures involved and to document consent, potential donors are sent a leaflet providing some initial information about bone donation. Consent may be taken at an outpatients clinic or when the patient attends the hospital for their hip replacement surgery.

Blood samples required for mandatory testing are obtained by bone bank staff, ward staff or anaesthetists, when the patient attends for surgery.
Bone is procured during hip replacement surgery and the suitability of the procured femoral head is initially assessed by the procuring surgeon, following defined protocols. The procured femoral head is transferred into a quarantine storage freezer by trained theatre staff. The

bone is frozen and stored for allogeneic or, rarely, autologous use.

Two -80°c freezers are in use, quarantine and “cleared for use”, both being subject to regular scheduled cleaning, maintenance and calibration. Temperature monitoring is by means of chart recorders and the freezers are alarmed, sounding locally and by wired link to a switchboard. A documented procedure is in place to govern action to be taken following the triggering of the alarm and there are contingency arrangements in place for equipment failure.

Blood tests for repeat serological testing of donors are obtained after a period of at least 180 days, by bone bank staff, or practice nurses within outpatient clinics. Quarantined bone is not cleared for use and transferred out of the quarantine refrigerator to the “cleared for use” freezer until clear serology test results have been obtained.

Traceability throughout is maintained by use of unique hospital and bar-coded donation numbers, as well as patient names and dates of birth as appropriate. Records for traceability are kept on paper patient files as well as on a dedicated electronic database.

Release of bone for use follows a review of all relevant documentation by bone bank staff, and the release is countersigned by a member of the quality management team. Bone is released from storage in the “cleared for use” freezer for use in hip revision and other orthopaedic procedures within the establishment or supplied to other hospitals with which the establishment has entered into end user agreements.

Where material is supplied to other hospitals, the establishment has procedures to ensure that it receives details of the recipient patient, thus maintaining traceability. End user agreements and product information forms supplied with the donor bone clarify the requirement for end users to advise the establishment of any serious adverse event or reaction, and the need to maintain traceability records. The HTA has provided some advice with regard to the documentation used, which is detailed later in this report.

Disposal of femoral heads which do not meet release criteria, or which are stored beyond expiry dates, is carried out using a defined procedure and the reasons for, and method of, disposal are recorded in both the paper donor file and within an electronic spreadsheet.

This inspection was a routine inspection and comprised a visual inspection of the premises and a review of documentation including the quality manual (site master file), policies and procedures, equipment maintenance and calibration records, temperature records, the results of internal and external audits, staff training records, risk assessments and registers, incident logs and sample patient files.

Key members of staff were interviewed, both during the visual inspection and in formal structured interviews.

An audit of traceability was carried out during the visual inspection: two femoral heads were located in each of the freezers and their location compared with that recorded in the relevant records. The related donor files were reviewed and checked for the presence of donor lifestyle and medical history questionnaires, signed consent forms, serology and microbiology test results, and traceability records. No discrepancies were found.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ1p	The DI is advised to ensure that reference to the testing for Hepatitis B core antibody is detailed within the service level agreement with the serology testing laboratory when that agreement is next renewed, to accurately accord with the mandatory requirements and the current practice.
2.	GQ1s, GQ7g	The DI is advised, when renewing the existing end user agreements, to ensure that they provide information on the timescales within which serious adverse events or reactions should be notified to the establishment to enable the DI to meet HTA reporting timelines. The DI is advised to amend the product information forms supplied with bone sent to end users to incorporate the same information.
3.	GQ2c	The DI is advised to ensure that any external audits cover all aspects of the activities carried out by the establishment and are not restricted to those issues raised following inspection by any regulatory body.
4.	GQ4a	The DI is advised to remind staff of the requirements with regard to the amendment of documents contained within SOP 02:QA:003:05:MPBB ("Record keeping"), to ensure that any alterations made are initialled and dated in order to identify the person who carried out the amendment.
5.	GQ4g	The DI is advised to amend SOPs relating to the release of bone for use (02:QA:015:06:MPBB and 04:QA:025:05:MPBB) to ensure that they accord with current practice whereby any patient identifying information is deleted from packaging prior to dispatch.
6.	GQ4k	The DI is advised to amend end user agreements when next renewed to ensure that they detail the need for end users to maintain traceability records for the required 30 year period. When carrying out this amendment the DI should also ensure that the legislation referred to in end user agreements includes the Quality and Safety Regulations and Guide to the Quality and Safety Assurance of Tissues and Cells for Patient Treatment.
7.	N/A	The DI is advised to amend the information leaflet given to patients receiving donated bone at the establishment to clarify that traceability records within patient files will be retained for 30 years, and not 25 years as currently stated.

Concluding comments

The HTA saw various examples of good practice during the inspection. The NHS Trust of which the establishment forms part has a Licensing Management Committee which governs the various licenses held by departments within the Trust. Meetings of this Committee allow for a free exchange of ideas and dissemination of learning to staff involved in activities carried out under each licence.

A great deal of consideration has gone into the documentation governing licensed activities, with written procedures being extensive, informative and written in a very clear format.

Procedural documentation is subject to review on a regular basis, as well as following any incident or issue arising from the carrying out of the licensed activity and the HTA saw examples of how documented procedures had been changed, following risk assessment, when potential issues had been identified.

Likewise, evidence was seen of the establishment carrying out corrective and preventative action following incidents occurring at the establishment, primarily relating to equipment failure.

Quality management staff at the establishment carry out an extensive range of audits, and agreements are in place to provide for reciprocal external, independent audits of the various licensed establishments within the Trust. The results of audits are documented, with follow up actions being allocated and completion of those actions recorded.

Risks to the quality and safety of femoral heads dispatched for end use have been well considered, with the establishment having carried out extensive validation of transport containers, and routinely using data loggers to ensure that transport temperatures are maintained. In addition, in negotiating the agreement with the courier company used, the establishment has obtained agreement that only three named drivers deal with bone transport, in order to ensure that femoral heads are transported only by those fully aware of the establishment's requirements.

The team involved in the licensed activity is small and close knit, with obvious good communication. In addition, extensive training of other theatre staff has been carried out to ensure that those involved in the procurement, storage and release of femoral heads are competent to carry out the relevant tasks.

The HTA noted that all items of advice provided following the previous inspection had been acted upon. Consent procedures have been updated and the consent form has been revised. The establishment has changed its procedures in relation to transport of femoral heads to end users to address issues identified in the previous inspection. Provision for external audit has been made and an external audit carried out. Contingency plans have been reviewed as suggested. Risk assessments have been carried out in line with the advice provided and appropriate action taken to mitigate risks identified.

The HTA has given advice to the Designated Individual with respect to some elements of the documentation used within the establishment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 1 August 2012

Report returned from DI: 23 August 2012

Final report issued: 23 August 2012

Appendix 1: HTA standards

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

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

Consent

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

Governance and Quality

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

b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo

regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010

are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.

e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.

PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.

f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   Or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.