Site visit inspection report on compliance with HTA minimum standards

Royal Hallamshire Hospital

HTA licensing number 11030

Licensed for the

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

21-22 April 2015

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.

The Royal Hallamshire Hospital (the establishment) was found to have met all HTA standards.

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**	**E**		

Background to the establishment and description of inspection activities undertaken

The bone bank at the Royal Hallamshire Hospital is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 for procurement, testing, storage and distribution of tissues for human application. The establishment's HTA licence also covers the satellite site at Northern General Hospital. Sheffield Teaching Hospitals NHS Foundation Trust is the corporate licence holder and the corporate licence holder contact is the Medical Director of the Trust.

Although the establishment is licensed for distribution, this happens rarely. In 2014, one femoral head was issued by the bone bank and transported by a hospital contracted transport service to another local hospital for end use.

The bone bank is jointly managed by the Department of Laboratory Medicine and the Department of Orthopaedics. Procurement of bone takes place at theatres at the hub site and at the satellite site. Because of their proximity to the theatres, both of these sites have quarantine freezers for the short term storage of procured bone, and 'ready to use' freezers for the storage of bone ready for implantation. The main storage area is located in a secure room near the mortuary at Royal Hallamshire Hospital, where the bone is stored in four dedicated freezers. The hospitals also receive and store bone chips and strut grafts from HTA licensed suppliers within the UK for use in orthopaedic surgical procedures; these are also stored within the bone bank.

Mandatory donor testing and microbiology testing of bone chips and swabs are undertaken at the microbiology and virology laboratories at Northern General Hospital, which has Clinical Pathology Accreditation.

Each year, patients who undergo hip replacement surgery at the hospitals donate around 100 femoral heads for revision surgery. Pre-assessment nurses, who have been trained to seek consent, identify potential donors and provide information on bone donation. They interview potential donors, take their medical and social history and ensure that the initial blood sample is taken for mandatory donor screening. The serology testing panel consists of testing for mandatory markers and includes additional testing for HTLV I/II. Repeat donor testing, including testing for HTLV I/II, is undertaken after 180 days. Potential donors are given the opportunity to withdraw consent and a second confirmatory consent for bone donation is sought if the surgical procedure takes place thirty days after the date of initial consent.

Femoral heads are procured and packaged in laminar flow theatres under the supervision of orthopaedic surgeons. Procured bone is washed using sterile Hartmann's solution. Theatre staff swab the femoral head and remove a bone chip from the cut end of the bone in order to test for microbial contamination. The femoral head is packaged in tamper evident sterile pots, labelled and sealed in a tamper evident bag. Once procured, the bone is not removed from the pots until it is opened in theatres, just before implantation into a recipient.

Each femoral head is assigned a unique identification number. The name of the staff member who handled the bone is recorded in the procurement report, along with the size of the procured femoral head and the batch number of consumables used. Each working day, bone bank staff based at the hub site at the Royal Hallamshire Hospital access the freezers near the theatres at both hospitals to monitor and record the temperature of the freezers, remove procured bone from the quarantine freezers and/or place bone which has been released for surgical use in the 'ready to use' freezers. Bone from Rhesus negative donors is allocated for women of child bearing age, and is stored in a designated area of the freezers. Staff use hospital transport services to transfer procured bone, which is packaged in validated transport boxes, between the satellite site and the hub site.

The DI and medical director of the bone bank review the donor file, which contains the procurement report, mandatory donor test results, including repeat 180 day results and results following microbial analysis of bone chips and swabs, before they authorise the release of bone for surgical use. Femoral heads are disposed of if the mandatory test results are positive or if microbial contamination is detected on the swabs and/or bone chips.

Theatre nurses remove bone for implantation from 'ready to use' freezers and transfer it to the theatres where it is thawed ready for implantation. Femoral heads are swabbed once again in theatres before implantation, and the swabs are tested for the presence of any microbial contamination. Orthopaedic surgeons record the use of bone and relevant recipient data in the theatre implant sheet, which is returned to the bone bank; the relevant records are filed in the recipient's clinical notes. All re-usable equipment is sterilised by the hospital sterile services.

Freezers at the bone bank are monitored using wireless temperature probes, which are linked to alarms connected to the switchboard. The low and high temperature thresholds for the alarms are set at -90^0C and -70^0C respectively. The alarm and the response from the staff based at the switch board are tested each month and the tests are documented. The wireless temperature probes are calibrated each year. Records of temperature monitoring are collected and reviewed each month. On the day of the inspection the temperature of the freezers where bone was being stored was -79^0C.

Records relating to each donation are filed together in individual donor files stored in the bone bank. Summary of data relating to each donation is also stored in a secure electronic file. The bone bank uses a proprietary quality management system which covers document control of standard operating procedures and audits.

This was the fourth routine site visit inspection of Royal Hallamshire Hospital. It included a visual inspection of the hub and satellite premises and interviews with the laboratory manager

at the Department of Laboratory Medicine (the DI), the bone bank manager who is the person designated under the HTA licence, a pre-assessment nurse, a theatre nurse and the orthopaedic microbiology team leader.

A document review was carried out. Standard operating procedures (SOPs) covering donor selection, packaging and labelling, document control and storage and authorisation of bone for implantation were reviewed. Staff training records, competency assessments, temperature monitoring records, including manual records and electronic records, maintenance records and disposal records were reviewed. Audit reports, audit findings and corrective actions were also reviewed.

Audit trails relating to four transplanted femoral heads were traced from the implantation data sheet in the recipient patient files to records in the bone bank. Four donor files stored in the bone bank were reviewed; records of consent, mandatory donor test results, procurement report, swab and bone chip microbial test results authorisation for release of bone (signed by the bone bank medical director and the DI), theatre request for allocation of the bone, lot number of Hartmann's solution used to wash femoral head, swab lot number, sterile pot lot number, tamper evident bag number and the implantation report were reviewed. There were no discrepancies.

Inspection findings

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

Compliance with HTA standards

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.	GQ1b	The DI is advised to • remove all references to cranial flaps when the SOPs are next reviewed, as cranial flaps are no longer procured or stored at the establishment; • remove the reference to the import of tissues in section 7.3 of the Bone Bank Quality Manual, as the Bone Bank is not licensed to import tissues from outside the EU and does not undertake this activity.
2.	GQ3c	The DI is advised to encourage key staff who work under the licence to attend external meetings organised by professional organisations in order to ensure continuous professional development and to develop links with professionals from other bone banks.

3.	PFE1a	At the Royal Hallamshire Hospital, the corridor leading to the bone bank is used by persons who are external to the hospital, such as funeral directors and members of the public. Secure access to the bone bank is provided by a keypad on the door, which also has an automatic door closure mechanism. The HTA inspection team observed that the door closure mechanism was not functioning effectively. The DI is advised to follow up on this finding as there is a potential risk of unauthorised entry to the bone bank as the door is used continuously during the day. *The establishment informed the HTA that action was taken and that the door closure mechanism is working effectively.*
4.	PFE2d	The DI is advised to arrange for a hand sanitizer dispenser to be placed near the corridor used by bone bank staff to access the theatre area at the Royal Hallamshire Hospital. *The establishment informed the HTA that following the inspection, a hand sanitizer was placed outside Theatres 3 and 4.*

Concluding comments

The DI, Bone Bank Medical Director, Bone Bank Manager and staff, including the pre-assessment nurses and theatre nurses, work well together as a team. There is an effective system for training staff to seek consent, which includes on going competency assessments. A range of vertical, horizontal and traceability audits are undertaken by bone bank staff and the Quality Manager who is based at the Northern General Hospital. Non-conformances are identified and corrective actions are implemented.

There are robust systems in place to ensure the quality of bone released for implantation, which includes authorisation by the DI and the bone bank Medical Director. Bone bank records relating to each donation and corresponding implantation are filed together, ensuring traceability from donor to recipient. Chain of custody forms are used to document the transfer of bone from the theatres to the quarantine freezers near the theatres, the bone bank, the 'ready to use' freezers located near the theatres and finally to the theatres where bone is implanted into recipients.

All issued bone is accompanied by detailed instructions for the implanting surgeons. The instructions cover thawing and washing of bone, a statement which informs the surgeon to inform the Bone Bank of any adverse clinical event or reaction that arises as a result of the use of the bone, and the return of completed implantation data sheets to the bone bank.

There are good systems in place to monitor freezer temperatures and there are weekly checks on the response of switchboard staff at the Royal Hallamshire Hospital to freezer alarms.

The HTA has given advice to the Designated Individual on a range of issues, including updating SOPs and ensuring bone bank staff attend external professional meetings

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

Report sent to DI for factual accuracy: 13 May 2015

Report returned from DI: 2 June 2015

Final report issued: 3 June 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
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.
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.
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.
d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
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.
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.
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.