Site visit inspection report on compliance with HTA minimum standards

Sunderland Royal Hospital

HTA licensing number 22610

Licensed for the

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

24 February 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.

Although the HTA found that Sunderland Royal Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found in relation to governance and quality systems. The establishment has no detailed documented procedure for the reporting of serious adverse events or reactions (SAEARS), risk assessments have not been updated since the last HTA inspection and there has been no audit in an independent manner against HTA standards.

This was the establishment's third HTA inspection, the last inspection having been a themed inspection. Since the last inspection, only a limited number of procurements of chondrocytes have taken place, as the processing company used has withdrawn from the European market.

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 Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

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

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

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

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

Licensable activities carried out by the establishment

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

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

'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
Cartilage	**E**						
Skeletal allograft				**E**			

Background to the establishment and description of inspection activities undertaken

The establishment carries out two distinct activities under the HTA licence: storage of allograft for use in elective and trauma surgery, and procurement of chondrocytes for autologous use.

Allograft material in the form of femoral heads, bone struts and tendons is purchased from another HTA licensed establishment for surgery on specific patients. However, if not used in the operation for which they were intended, the allografts are stored for use in other

procedures, including non-elective trauma surgery, therefore requiring an HTA licence for storage.

Allograft is ordered by a specific member of theatre staff and is delivered to the operating theatre store, where that trained person checks delivery paperwork, packaging integrity and expiry dates of allograft, entering details into the 'Allograft log book'. Hospital porters then transfer the allograft to a monitored, alarmed, freezer within the Department of Haematology. A separate 'Porters log book' is maintained to detail the transfer of allograft to storage, and subsequently from laboratory to theatre for use, and includes details of the intended recipient patient. The porter transporting the material signs against the allograft record in the Porters book on storage and release, as does the laboratory staff member.

When allograft is released for use, details of the recipient are also recorded within the Allograft log book, maintaining traceability. The unique allograft record number is also entered into patient clinical notes, and entered into the electronic operating theatre register, which records details of each operation.

The other licensable activity carried out by the establishment involves a consultant orthopaedic surgeon procuring cartilage from patients for use in Matrix-induced Autologous Chondrocyte Implantation (MACI).

The establishment has a service level agreement with the cartilage cell processor, covering supply of the tissue biopsy kit, transportation of the biopsy and mandatory donor testing. When the cartilage cells have been processed, they form an Advanced Therapy Medicinal Product (ATMP) and fall outside the remit of the HTA. Accordingly, procurement is the only licensable activity carried out by the establishment in relation to MACI.

The MACI process encompasses two stages: retrieval during an arthroscopic knee operation and implant in an open surgical procedure. A blood sample is taken from the patient prior to anaesthesia for the arthroscopy and sent to the processor's testing laboratory for mandatory testing. Results of mandatory testing are then forwarded to the establishment.

Traceability is maintained by the use of unique biopsy kit numbers, which are applied to all documentation relating to the consent, testing, transport and processing of samples, as well as patient name, date of birth and hospital number.

This was a routine, scheduled, inspection. The establishment had previously been inspected in 2011 and in 2013, the latter being a themed inspection.

The inspection comprised a visual inspection of the bone storage refrigerator, and discussions with key staff relating to procedures and processes carried out during a review of documents on paper and on the Trust intranet.

In addition, an audit of traceability was carried out:

- The only allograft being stored in the freezer was located, and the traceability and expiry date details were noted and compared against those held in the two log books and against the relevant delivery note.
- For two patients who had received allograft during hip revision surgery, the electronic operating theatre records were reviewed and details of the four allografts, two for each patient, compared against the records held in the log books.
- For the most recent MACI patient, the clinical file was reviewed for presence of signed consent documentation, and the corresponding MACI procedure record book checked for records of mandatory virology testing results and the certificate confirming release of processed chondrocytes.

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.		
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	The HTA noted that provision for audit in an independent manner is referred to in the uncontrolled document 'Programme of audits for the safe procurement and storage of allogeneic material'. However, no audit in an independent manner had been carried out within the last two years, as required by this standard. Advice has also been provided below regarding this standard	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.	The HTA notes that the requirement to report serious adverse events or reactions (SAEARS) is contained within the agreement entered into with the MACI processing company, but that, with regard to storage of allograft, there is only brief mention of reporting of SAEARS in one SOP. This does not specify the procedure to be followed, the responsibilities of personnel, or procedures to be carried out relating to tissues and cells affected. The HTA also notes that the Trust incident reporting policy, NQ4.II.V4.1 is silent with regard to the need to report SAEARS to the HTA.	**Minor**
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.	Risk assessments relating to the licensable activities were carried out and recorded after the last HTA inspection. However, these have not been reviewed or updated. In addition, risk assessments are recorded in electronic format in a location which is not widely accessible to staff working within the unit.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1b	Procedures relating to the storage and use of allograft are governed by two standard operating procedures (SOPs); Haem-SOP-T094,'Policy for the use of bone products and storage', primarily used by the laboratory staff, and SOP 6, 'Receipt, storage and transfer of allograft material within Sunderland Royal Hospital', used by orthopaedic staff. The presence of two such documents, dealing with the same procedure in differing levels of detail, accessible by different staff working in different departments raises a risk of confusion. The DI is advised to combine both SOPs in one document for use by all staff.
2.	GQ1b	The DI is advised to review the procedural documentation used within the department to ensure that references to storage temperatures for allograft are consistent throughout and reflect current procedure where temperature is between -30ºc and -40ºc. Document Haem-SOP-T094 refers to a storage temperature of -40ºF. The storage temperature is a critical measure, as it materially affects the expiry date of allografts supplied to the establishment. The HTA notes that the storage temperature provided to the allograft supplier is correct.
3.	GQ1d	The DI is advised to amend document Haem-SOP-T094, or any future version thereof, to provide greater detail on which staff may accept allograft into the department. This SOP should also be amended to reflect the working practice by which allograft is transferred to and from the storage freezer, in particular with reference to the involvement of porters and the completion of traceability details within the two log books.
4.	GQ1h	The DI is advised to provide greater detail within procedural documentation on how staff should deal with any allograft where the packaging is noted to be damaged. This could form part of procedural documentation relating to SAEARS reporting.

5.	GQ2a, GQ2b, GQ4b	The HTA noted the presence of a document named 'Programme of audits for the safe procurement and storage of allogeneic material' which is a schedule of internal audits and audit in an independent manner. The DI is advised to amend this document to refer to procurement of autologous material as no procurement of allogeneic tissues takes place. The DI is also advised that this document should be in controlled format, as required by the Trust 'Policy on Policies' CA2.DMD.V5.4.
6.	GQ2c	The HTA notes that the DI had intended that staff working under another HTA licence within the establishment could carry out audit against HTA standards in an independent manner, but those staff are now based at another hospital within the Trust. The HTA advises the DI to consider the involvement of the hospital audit department staff in carrying out the required audit, provided they do so using a methodology which results in the audit being carried out in an independent manner.
7.	GQ4b	The HTA noted the presence of two records of audit, 'Audit for MACI procedures' dated November 2014 and 'Log of Allogeneic material', undated. These appeared to be a review of traceability records and documentation relating to the MACI procedure and storage and use of allograft, but neither detailed the exact date of audit or any findings, and made no reference to the methodology used. The DI is advised to formalise the audit procedure by ensuring documentation meets the requirements of the Trust 'Policy on Policies' and that details of the auditors involved and audit methodology are recorded, with any findings and actions arising also being noted.
8.	GQ4i	The DI is advised to securely mark the existing log books and MACI record files for non destruction for a period of 30 years from implantation date. The HTA notes that records relating to MACI are held locally by the DI but the requirement to hold records for 30 years is mentioned only in a local policy/procedural document Haem-SOP-T094 with specific regard to allograft. The requirement to retain traceability records is detailed in the contract with the MACI processor. However, the Trust record policy is silent with regard to such records and failure to identify them for storage presents a risk of inadvertent destruction with resulting loss of traceability.

Concluding comments

The HTA saw examples of good practice during the inspection. The licensed activity is carried out principally by the DI or other consultant surgeons working with a small number of staff within the department. Communication between staff appears to be open. The DI has refreshed his Good Clinical Practice training as part of research work and has undertaken specific consent training relating to procurement of cartilage cells for MACI work.

Record keeping appears thorough, with staff involved in transporting allograft from receipt to storage and from storage to theatres signing log books to evidence receipt and maintain traceability.

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has given advice to the Designated Individual with respect to some elements of documentation, in particular to ensure that all documents fall within the controlled document procedures used within the Trust.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 16 March 2015

Report returned from DI: No comments on factual accuracy received

Final report issued: 31 March 2015

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: 23 August 2016

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.
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.
o) There is a complaints system in place.
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.
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.
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.
GQ8 Risk assessments of the establishment’s practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
d) Records are kept of transportation and delivery.
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.