Site visit inspection report on compliance with HTA minimum standards

Trycare Limited

HTA licensing number 22587

Licensed for the

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

12 December 2013

Summary of inspection findings

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

Although the HTA found that Trycare Limited (the establishment) had met the majority of the HTA standards, six shortfalls were found in relation to Governance and Quality Systems and Premises, Facilities and Equipment. The shortfalls relate to the need for systems to be in place to allow for verification that the standards of quality and safety of imported tissues/cells are equivalent to those outlined in Directions 003/2010, and the need for relevant material to be stored in appropriately controlled conditions that maintain tissue/cell integrity. The establishment's documentation dealing with Serious Adverse Event and Reaction (SAEARs) reporting should include the requirement to report such incidents to the HTA within 24 hours and primary packaging containing tissues/cells should be labelled with the information required by Directions 003/2010. The establishment should also hold regular, minuted governance meetings in relation to the activities being carried out under the authority of their HTA licence and implement a more consistent approach to staff appraisal.

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.

'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 Trycare Limited. The establishment is licensed for the storage, distribution and import of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The establishment has been licensed by the HTA since 2009 and has been inspected on two previous occasions.

Trycare Limited was founded in 1996 and supplies a wide range of products to dental surgeries and chiropodists throughout the UK. Under the authority of its HTA licence, the establishment imports, stores and distributes a range of acellular bone products for use in dental surgical procedures. The bone products are sourced from a single supplier in the US which is registered with the FDA to process, package, store, label and distribute Human

Cells, Tissues, and Cellular and Tissue based products (HCT/P's), specifically bone allografts. The supplier is also accredited by the American Association of Tissue Banks. Mandatory serology testing is carried out on all donors by the procurement organisations in the US. Formal agreements are in place between the establishment and the tissue supplier.

Relevant material arrives as a finished, packaged product and is accepted into the establishment by trained staff according to well-defined procedures. Samples are stored in specified areas of the warehouse and provision has been made for the separate storage of any non-conforming consignments. When orders are received, a 'pick list' is generated and the required products are identified. A second member of staff then checks that the correct products have been selected before a third member of staff packages them up for distribution to the end user. Products sent out to end users are accompanied by documentation which includes information on SAEARs reporting and on the requirement to store traceability data. Delivery is tracked by the courier, with all delivery and dispatch notes retained on file at the establishment.

This report describes the establishment's third site visit inspection which took place on 12th December 2013. The inspection included interviews with key members of staff working under the licence, including the Designated Individual and members of staff involved in purchasing and distribution. A review of documentation relevant to the establishment's activities and a visual inspection of the areas of the establishment where licensable activities take place were also conducted as part of the inspection.

An audit of the 13 samples held in storage at the time of the inspection was performed. Storage locations were cross-checked with appropriate records to ensure that they contained all relevant documentation and that the information contained therein, such as unique product identification numbers and expiry dates, was accurate. 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
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	Although staff across the company meet informally on a regular basis, at the time of the inspection, regular, minuted governance meetings were not being carried out by the establishment.	**Minor**
n) The establishment ensures imports from non-EEA states meet the standards of quality and safety set out in Directions 003/2010.	Trycare Limited performs regular accreditation checks on its US tissue supplier and has a formal agreement in place which includes a declaration from the supplier that the imported irradiated bone products meet the requirements of EU Directive 2004/23/EC. However, the establishment do not have systems in place to allow for verification that these standards are being adhered to and no further steps have been taken by the establishment to ensure that the products they are importing meet the standards of quality and safety set out in Directions 003/2010.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
h) There is a system of staff appraisal.	Following the last inspection, the establishment has implemented a more formalised system of staff appraisal. However, this is being inconsistently applied across the company, with the majority of staff who are carrying out activities under the authority of this licence not being included in the process.	**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 establishment has a number of standard operating procedures (SOPs) and staff checklists that make reference to the reporting requirements associated with Serious Adverse Events and Reactions (SAEARs). However, they do not include the requirement to report SAEARs to the HTA within 24 hours as set out in the "Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment" which forms the Annex to Directions 003/2010.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	Although product labels indicated that the bone samples should be stored between 18-25^{o}C, the establishment's temperature monitoring logs indicated that the temperature within the storage facility frequently went outside of this specified temperature range. At the time of the inspection, the establishment were unable to provide evidence to support the fact that the storage conditions were appropriate and ensured the integrity of the bone products. Some bone products are packaged in a vials containing liquid. As the temperature in the warehouse is not regulated, there is the possibility that during the winter months, the liquid surrounding the bone products may freeze, which may, in turn, compromise the integrity of the bone product. Whilst the establishment had previously informed the HTA that the packaging materials used to package bone products were robust and able to withstand large temperature fluctuations, at the time of the inspection they were unable to provide comparable assurances for the products themselves.	**Major**
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination.		
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.	At the time of the inspection, primary product packaging did not include information on the UK distributor, as required by Directions 003/2010.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	A number of the establishment's SOPs, and its agreement with its US supplier, make reference to HTA Directions 001/2006, 002/2007 and 004/2007. These have since been revoked by Directions 003/2010 which consolidate and clarify the standards required under the Human Tissue (Quality and Safety of Tissues and Cells for Human Application) Regulations 2007. The DI is advised to update SOPs and the agreement accordingly to ensure that all interested parties are directed to the most relevant information sources for the work they are involved in.
2.	GQ1k	The DI is advised to update the establishment's pharmaceutical returns policy to include the steps to be taken in the event that a product distributed under the authority of their HTA licence is returned. Although this happens infrequently, and staff are aware of the action to take, the procedure for dealing with such products has not been formally documented.
3.	GQ2b	The DI is advised to review the information captured on audit report forms to ensure that they contain sufficient details which will enable completed audit forms to be used to track findings and corrective and preventative actions. For example, audits reports of products held in storage should, as a minimum, contain information on the number and type of products included in the audit and the records, both electronic and paper, checked as part of the exercise. The DI is also advised to amend the scope of supplier accreditation checks to include a review of any formal agreements that are in place between the establishment and the US supplier. This will help ensure that agreements remain up-to-date and reference the current legislation/guidance that relates to the activities being carried out under the authority of the HTA licence.
4.	GQ4i	Although the establishment has systems in place to inform end users, *i.e*. dental surgeries, of the requirement to ensure traceability is maintained to the recipient, the DI is advised to consider other control measures, such as the use of feedback forms and audit, to ensure that this requirement is being met.
5.	GQ4m	The DI is advised to update the establishment's SOP on document storage (SOP22) to ensure that it accurately reflects the requirements set out the "Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment". In particular, the DI should ensure that those sections of the SOP dealing with the transfer of records in the event of a termination of activities capture the requirement for records to be transferred to another HTA-licensed establishment.

Concluding comments

The HTA saw several examples of good practice during the course of the inspection.

The establishment has put in place a number of robust procedures to ensure that the correct products are sent to end users, including the physical separation of similar products within the warehouse and the carrying out of multiple cross-checks of items selected for dispatch. Sample receipting procedures have been well-thought out and clearly documented and staff

are supported in their roles by clear aides-memoire located in appropriate places within the facility. The establishment also conduct frequent audits of end users to ensure that they are, and remain, appropriately registered with the General Dental Council.

Six areas of practice were identified during the inspection that require improvement, including one major and five minor shortfalls. These relate to the establishment's approach to governance meetings and staff appraisal, the information that accompanies distributed products, and to the need for documentation to capture the required timelines for SAEARs reporting. Systems should also be in place to verify that imported samples meet the standards of quality and safety set out in Directions 003/2010 and are stored in a manner that maintains their critical quality attributes.

The HTA has given advice to the Designated Individual with respect to a number of practices and procedures with a view to helping the establishment further develop their working practices and governance systems. This includes advice relating to the content of a number of the establishment's SOPs, the information captured during internal audits, and the approach used to ensure that traceability data is maintained by end users.

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: 10 January 2014

Report returned from DI: 23 January 2014

Final report issued: 27 January 2014

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: 27 January 2014

Appendix 1: HTA standards

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

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

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
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.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
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.
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.
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.
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.