

Site visit inspection report on compliance with HTA licensing standards

Royal Hampshire County Hospital

HTA licensing number 12014

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

27 April 2017

Summary of inspection findings

The HTA found the Designated Individual (DI), the Licence Holder (LH), the premises and the practices to be suitable in accordance with the requirements of the legislation.

One minor shortfall was found against the governance and quality systems standards. All other standards were met.

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

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

This report refers to the activities carried out at Royal Hampshire County Hospital (RHCH) Winchester (the establishment). The Designated Individual (DI) is a Consultant Histopathologist. The Corporate Licence Holder (CLH) is the Hampshire Hospitals NHS Foundation Trust and the CLH contact is the Chief Executive Officer for the Trust. The mortuary is staffed by a Mortuary Manager, Senior Anatomical Pathology Technologist (APT)

and a Trainee APT. There are four in-house Consultant Histopathologists (including the DI) and four Home Office Pathologists who conduct post-mortem (PM) examinations.

Approximately 480 PM examinations are conducted at the establishment per year, the majority on behalf of the HM Coroners for Central Hampshire and occasionally for the areas of Southampton, the Isle of Wight, Portsmouth, Basingstoke, Dorset, Wiltshire and Bristol. In addition, approximately 70 forensic and a small number of private and adult hospital consented PM examinations are conducted. High risk PM examinations (up to category 3) are conducted. Perinatal/paediatric cases are transferred to another HTA-licensed establishment for PM examination and, on completion of the PM examination, are returned to RHCH before release to the funeral director.

The clinician involved in the patient's care seeks consent for adult hospital PM cases and they are supported by a bereavement officer or an APT. The pathologist checks that consent forms are completed correctly before conducting these PM examinations, ensuring the appropriate person in a qualifying relationship is providing consent. A paediatric consultant seeks consent for paediatric cases. Consent forms are supplied by the establishment conducting the PM examination. Families are provided with information leaflets from the Stillbirth and Neonatal Death charity (SANDS). Staff who seek consent are trained. Currently, only paediatric consultants seek consent; however, the establishment is investigating training bereavement midwives in seeking consent.

The body store has refrigerated spaces for 57 bodies. Nine of these spaces are suitable for bariatric bodies. Four of the bariatric spaces can be converted to freezers, as a unit, if necessary. There is also a temporary storage unit which can be erected to accommodate 12 bodies and there is contingency storage at another hospital within the same Trust. There is a dedicated fridge for paediatric/perinatal cases. Products of conception are sent directly to histology for analysis.

The mortuary also houses a collection of potted specimens that pre-date the Human Tissue Act 2004 (see Advice, item 6)

All fridges and freezers are linked to a 24-hour temperature monitoring system. When the temperature rises above set limits, the system automatically triggers an alarm to switchboard, who contact the on-call member of staff (see Advice, item 5). Fridge and freezer temperatures are regularly monitored to identify trends.

There is CCTV outside and inside the mortuary and swipe card access to the mortuary by a limited number of staff.

Mortuary services are available seven days a week, with on-call cover out of hours. For hospital cases (in and out of hours), porters admit bodies to the mortuary. Porters are trained

by mortuary staff and must be signed off as competent before admitting bodies. Porters have access to one swipe card, which is held in the porters' office. This card must be signed in and out for access to the mortuary. The porters place the body in the fridge, write the name of the deceased on the whiteboard and enter the deceased's details in the mortuary register. It is the APT's responsibility to check the condition of the body, the identification information in the mortuary register and the whiteboard when a body is brought by porters. A unique mortuary number is assigned to each body and this number is recorded on the fridge door and paperwork associated with the deceased. The APT also enters the information into the computer system.

For community deaths during normal working hours, the funeral director informs the APT of an estimated time of arrival. Out of hours, the funeral director contacts the hospital switchboard to arrange for an APT to attend the mortuary. The APT and funeral directors check the identification information on the wrist tag and the paperwork. If there is no ID tag on the body, the funeral director must attach one with at least three identifying details (e.g. first name, surname, age, DOB, location deceased found, police number). Using these details, the APT completes a community death form and writes the unique mortuary number on the top of the form. The form has three pages in carbon copy. The top page is faxed to the Coroner's Office and, after the information is entered into the computer system, this page is put in the release folder. The bottom two copies remain with the body. The mortuary register is filled out and signed by the funeral director and APT.

Bodies are released during designated hours, Monday to Friday, and the APTs arrange a time with funeral directors to collect them. When funeral directors arrive, they call the APT via the intercom outside the mortuary. Upon release, mortuary staff must confirm the identity of the deceased with the funeral director by checking at least three identifiers on the identification tags against the release paperwork, mortuary register and computer records. Bodies are only released if the appropriate release form is provided (i.e. Coroners, hospital, or disposal form). If there are any discrepancies, mortuary staff will not release the body until the correct identification details are confirmed.

Viewings are arranged between the family and bereavement or mortuary staff. Viewings are conducted seven days a week up to 9 pm and an APT always attends. Staff let switchboard know when there is an out-of-hours viewing as there is a personal alarm which alerts switchboard in the event that they feel threatened or in danger.

The PM suite has four tables and a dedicated dissection bench. PM examinations are conducted one at a time to mitigate the risk of organs being returned to the wrong body. High-risk cases are conducted at the end of the day to limit exposure. The air-handling unit for the PM suite is serviced regularly and servicing records were observed to be up to date.

Histology samples taken during PM examination are cassetted in the mortuary and taken to the histology department for analysis. After the analysis is completed, they are kept, reunited with the body or disposed of according to the wishes of the family.

Description of inspection activities undertaken

This was the third site visit inspection of RHCH (the previous inspection took place in 2013). It included a visual inspection of the body store, PM suite, viewing area, histology laboratory and maternity department, which houses a storage fridge and is also licensed for the removal of relevant material as samples for genetic analysis are sometimes required.

Interviews with members of staff, a review of governance and quality documentation and a traceability audit were also undertaken.

The audit trails were conducted on two hospital and one community body stored in the refrigerators. Body location and identification details on body tags were cross-referenced against the information in the register book, paper and computer records. Same/similar name processes were also checked. No discrepancies were found.

An audit trail was also conducted on paperwork and consent forms relating to two hospital consented cases and three Coroner's cases where histology samples had been retained during the PM examination. Relevant paper records, consent forms, and location of samples in histology were checked, as well as the procedures for recording disposal of samples. No discrepancies were found.

Materials held for the police

Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in a separate room within the PM suite were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Inspection findings

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

Compliance with HTA standards

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
<p>b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.</p>	<p>Following the pathologist's review of documentation, evisceration routinely takes place before the pathologist verifies the identity of the deceased and performs an external examination of the body.</p> <p>This is a shortfall against standard GQ1b, and is also contrary to the Royal College of Pathologist's guidelines on the conduct of a PM examination:</p> <p>Royal College of Pathologist's guidelines on the conduct of a PM examination</p> <p>See Advice, item 2</p>	<p>Minor</p>

Advice

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

No	Standard	Advice
1.	GQ1 (a)	<p>A number of the establishment's standard operating procedures (SOPs) make reference to the previous version of the HTA Codes of Practice. Revised Codes and standards were published on 3 April. The DI is advised to update SOPs to make reference to the new Codes and Standards.</p> <p>The DI is also advised to update the HTARI SOP in line with the most recent guidance (February 2016) for reporting HTA reportable incidents in the post mortem sector:</p> <p>Guidance for reporting HTA Reportable Incidents (HTARIs) in the post mortem sector</p> <p>The SOP should include:</p> <ul style="list-style-type: none"> the new classification 'PM cross-sectional imaging of the body of a deceased person included an invasive procedure for which consent had not been given'; and the definition of a near miss.

2.	GQ1 (b)	Changes in practice relating to post mortem examination, which ensure that the identity of the deceased is checked and a thorough external examination of the body is carried out by the pathologist prior to evisceration in all cases, should be reflected in relevant SOPs.
3.	PFE1 (d)	Bodies are brought into the viewing room from the body store and a curtain is pulled across to hide the door. The door is not lockable and, although staff are always present during viewings, there is a risk of visitors gaining access to the body store area. The DI is advised to assess this risk and take any mitigating actions that are identified.
4.	PFE2 (c)	The current fridges in the mortuary measure 22" in width, which is smaller than average and makes it difficult to accommodate many of the bodies that come in to the mortuary. The need for wider fridges has been on the Trust's risk register for some time. The DI should ensure that any new fridges that are installed are of sufficient size to meet service needs.
5.	PFE2 (e)	Fridge alarms only alert the hospital switchboard when the temperature rises above a set limit; alarms should also be set to trigger at a lower range, to mitigate the risk of a body freezing. In addition, mortuary staff are advised to incorporate regular documented tests of all fridges/freezers to ensure that the call out systems are working properly.
6.		<p>The establishment is currently storing a small potted specimen collection in the mortuary. This collection is not currently in use, however, it may be valuable for teaching purposes.</p> <p>Where consent has been given for this use or the specimens are existing holdings, they should be made available for use in the education and training of clinicians. Where this means that they are removed from storage to unlicensed premises, there must be procedures in place that ensure proper care is taken of the specimen and that their removal and return to storage are documented.</p> <p>The DI should also ensure that storage conditions are routinely monitored.</p>

Concluding comments

Staff at the establishment are committed and take pride in their work. They appear to have good communication with the Coroner and police, which helps mitigate any delays in mortuary services.

Mortuary staff undertake annual training of porters, which includes an introduction to mortuary procedures, health and safety, use of mortuary equipment and administrative duties. Porters are required to take and pass a test before being allowed to participate in any work in the mortuary.

There are some areas of practice that require improvement, including a minor shortfall in relation to evisceration procedures. Advice was also given in relation to governance and quality systems, and premises, facilities and equipment.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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: 15 May 2017

Report returned from DI: 25 May 2017

Final report issued: 26 May 2017

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: 16 Jun 2017

Appendix 1: HTA licensing standards

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

Consent
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice
<ul style="list-style-type: none">a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.b) There is a documented standard operating procedure (SOP) detailing the consent process.c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
<ul style="list-style-type: none">a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.b) Records demonstrate up-to-date staff training.c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.d) Competency is assessed and maintained.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

- a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPATH. These include:
- i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;
 - ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;
 - iii. practices relating to evisceration and reconstruction of bodies;
 - iv. systems of traceability of bodies and tissue samples;
 - v. record keeping;
 - vi. receipt and release of bodies, which reflect out of hours arrangements;
 - vii. lone working in the mortuary;
 - viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;
 - ix. transfer of bodies internally, for example, for MRI scanning;
 - x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;
 - xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;
 - xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;
 - xiii. access to the mortuary by non-mortuary staff, contractors and visitors;
 - xiv. contingency storage arrangements.
- b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.
- c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

- d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.
- e) There is a system for recording that staff have read and understood the latest versions of these documents.
- f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.
- g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.
- h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

GQ2 There is a documented system of audit

- a) There is a documented schedule of audits.
- b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.
- c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

- a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.
- b) There are clear reporting lines and accountability.
- c) Staff are assessed as competent for the tasks they perform.
- d) Staff have annual appraisals and personal development plans.
- e) Staff are given opportunities to attend training courses, either internally or externally.
- f) There is a documented induction and training programme for new mortuary staff.
- g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

GQ4 There is a systematic and planned approach to the management of records

- a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- b) There are documented SOPs for record management which include how errors in written records should be corrected.
- c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that all untoward incidents are investigated promptly

- a) Staff know how to identify and report incidents, including those that must be reported to the HTA.
- b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.
- c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- d) Information about incidents is shared with all staff to avoid repeat errors.
- e) The establishment adopts a policy of candour when dealing with serious incidents.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

- a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.
- b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.
- c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

- a) Bodies are tagged/labelled upon arrival at the mortuary.
- b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).
- c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.
- d) There is system for flagging up same or similar names of the deceased.
- e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.
- f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.
- g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:
 - i. material sent for analysis on or off-site, including confirmation of arrival
 - ii. receipt upon return to the laboratory or mortuary
 - iii. the number of blocks and slides made
 - iv. repatriation with the body
 - v. return for burial or cremation
 - vi. disposal or retention for future use.
- h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.

- a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.
- b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

- c) Disposal is in line with the wishes of the deceased's family.
- d) The method and date of disposal are recorded.

Premises, facilities and equipment

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue

- a) The premises are clean and well maintained.
- b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.
- c) There are documented cleaning and decontamination procedures and a schedule of cleaning.
- d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).
- e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

- a) Storage arrangements ensure the dignity of the deceased.
- b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.
- c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.
- d) Fridge and freezer units are in good working condition and well maintained.
- e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.
- f) Temperatures of fridges and freezers are monitored on a regular basis.
- g) Bodies are shrouded or in body bags whilst in storage.
- h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.
- i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

- a) Items of equipment in the mortuary are in a good condition and appropriate for use:
 - i. fridges / freezers
 - ii. hydraulic trolleys
 - iii. post mortem tables
 - iv. hoists
 - v. saws (manual and/or oscillating)
- b) Equipment is appropriate for the management of bariatric bodies.
- c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.
- d) Staff have access to necessary PPE.
- e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.
- f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

Appendix 2: Classification of the level of shortfall

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 risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

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 that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

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, but which indicates a departure

from expected standards.

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 or site visit.

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.