Site visit inspection report on compliance with HTA minimum standards

Guy's and St Thomas' Hospitals, Cellular Pathology
HTA licensing number 12243

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**

30-31 January 2013

Summary of inspection findings

Guy's and St Thomas' Hospitals, Cellular Pathology (the establishment) was found to have met the majority of HTA standards. However, three minor and three major shortfalls were identified: one shortfall in relation to consent and the need to establish a ratified consent operating procedure; three shortfalls in relation to governance and quality, including the need for a unique identification system for community deaths received on-site and a formal operating procedure for SUI reporting; and two shortfalls in relation to premises, facilities and equipment standards, including the need to address the limited capacity for long-term storage and the lack of routine testing of the alarm monitoring system for refrigeration and freezer units.

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

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

Background to the establishment and description of inspection activities undertaken

Guy's and St Thomas' NHS Foundation Trust (GSTT) is a large teaching hospital trust with a wide range of acute and specialised hospital services. The pathology laboratory services entered into a limited liability partnership (LLP) in 2009 and is now trading as GSTS Pathology. The LLP encompasses all pathology testing services (including histology), and tissue blocks and slides of post mortem samples are stored within GSTS Pathology.

The GSTT Department of Cellular Pathology includes the Mortuary & Bereavement Service (MBS) and sits within the Haematology and Oncology Directorate. There are two mortuaries: a body store at Guy's Hospital and the main mortuary at St Thomas' Hospital, where post-mortem (PM) examinations are undertaken. Cellular Pathology Consultant staff remain under GSTT management.

The establishment undertakes approximately 600 PM examinations per annum. The majority are conducted at the request of HM Coroner (Inner South). However, as the establishment is a specialist referral centre, it is instructed on work from a large number of coronial jurisdictions from across the country. High-risk PM examinations are conducted within

dedicated facilities suitable for category 3 cases. Paediatric and perinatal PM examinations are also routinely conducted on-site.

The DI is a Consultant Histopathologist. The LH is Guy's and St Thomas' NHS FT, with the Director of Corporate Affairs acting as the named contact. The mortuary has five full time Anatomical Pathology Technicians (APTs), including the Chief APT, and a mortuary administration assistant.

The establishment was first inspected in November 2009. There were no conditions imposed on the establishment's licence at that time. This inspection was a routine inspection, which provided an opportunity for the HTA to review governance arrangements in respect of licensed activities.

The site visit included a visual inspection of the body store (at both hospital sites), post mortem room and laboratory facilities, and formal interviews with the Desigated Individual, Corporate Licence Holder Contact, Service Manager (Cellular Pathology), Specialist Bereavement Midwife, Senior BMS/Quality Manager, Chief APT/Assistant Service Manager and two APTs.

A number of traceability checks were conducted at the St. Thomas' site. The details on the identification tags of three bodies stored in the mortuary were checked against all associated paper and electronic records. An audit trail of three further cases where histology had been taken was conducted. All paper and electronic records were reviewed and the number of blocks and slides stored in the Cellular Pathology Laboratory was also checked against the relevant paper and electronic records. No anomalies were found. A sample audit of three bodies was also undertaken at the Guy's site, including one in long-term storage. In two of the three cases, the incorrect location was recorded on the electronic database.

A document review of the establishment's policies and operational procedures was also undertaken. This included review of risk assessments, audit reports for 2011/12, incident reports, meeting minutes, maintenance records and the Cellular Pathology Quality Manual.

Inspection findings

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

HTA standards not met:

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice & GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process	There is an up-to-date training programme on taking consent for adult and paediatric post-mortem examination and tissue retention, which addresses the requirements of the HT Act and HTA code of practice on consent. However, the standard operating procedure detailing the process of consent, those able to take consent and mandatory training requirements is currently only in draft form. This SOP has not yet been ratified through the departmental (or Trust) governance system.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process & GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The establishment follows the Trust policy for incident reporting. However, there is no standard operating procedure for the reporting of serious untoward incidents (SUIs) to the HTA stating: • what serious untoward incidents are reportable to the HTA; • who may notify HTA of an SUI, and how to do so; • that a notification should be made within five working days of an SUI occurring.	**Minor**
GQ2 There is a documented system of quality management and audit	The document control system does not extend to all documents related to licensable activities. Some documents such as the consent training package, the PM examination checklist and mortuary procedures training for porters are not version controlled. The lack of version control increases the risk that staff, including hospital porters, may not be following the most update to date procedures. (Please also refer to advice no.3 below.)	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	Only hospital deaths or bodies which are subject to a PM examination are assigned a unique number. Bodies brought to the mortuary from the community display a single ID band with name only (and no unique number). This increases the risk of mis-identification of deceased with the same or similar name. The fridge locations of two of the three cases selected for audit at the Guy's site were incorrectly logged on the database. One of these entries stated that the deceased was still stored at the St. Thomas' site. Errors in recording increase the risk of the occurrence of a serious mortuary incident.	**Major**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records	The freezer unit at St.Thomas' Hospital was over capacity, with multiple paediatric cases stored per shelf. This presents a risk of material being lost within the existing freezer space or misidentified and compromises the dignity of the deceased. Recently, a new freezer has been commissioned and is now available at the satellite site (Guy's Hospital). This is providing some additional capacity but, based on existing numbers of cases in long-term storage, there is insufficient long-term storage space for paediatric cases in particular.	**Major**
PFE 5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored	The ventilation system within the standard and high-risk post-mortem rooms is approximately 20 years old and, according to available maintenance records, regularly breaks down. At the time of the HTA inspection, PM examinations had been cancelled due to a problem with air flow. The environmental monitoring system itself was also faulty at the time of inspection, with panel lights simultaneously indicating that the air flow rate was both adequate ('green') and outside the defined range ('red'). These problems with the equipment have the potential to disrupt service delivery thereby causing distress to families of the deceased. Although there is an alarm monitoring system for refrigeration and freezer units, this is not subject to routine testing. Consequently, mortuary staff are unable to confirm whether the alarm system is working as required.	**Major**

Advice

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

No.	Standard	Advice
1.	C1, C2, C3	The Sudden and Neonatal Death Charity (SANDS) has recently published a model consent form, guidance for consent takers and information for bereaved parents. The DI is advised to review the establishment's paediatric consent procedures in light of these.
2.	C3	Although consent to hospital PM examinations is obtained by trained staff, there is no formal refresher training carried out. As hospital PM examinations are conducted relatively rarely, this introduces the potential risk that staff involved may lose familiarity with the consent process and that consent is not taken in accordance with HTA standards and the Code of Practice on consent. The DI is advised to put in place a programme of refresher training for staff at a frequency deemed appropriate for local needs.
3.	GQ1	Currently, deviations from SOPs are not routinely recorded and monitored; therefore, some practices may be carried out that do not conform to agreed local procedures presenting a potential risk of error, for example, when releasing a body.
4.	GQ6	The HTA is generally assured that the establishment has an effective system of traceability. This was supported by the audit of selected cases which identified no anomalies at the St. Thomas' site. However, the DI is advised to consider additional steps to further mitigate against the potential loss of traceability and to ensure similar robust records entry and management at the Guy's site . For example: • A number of PM examinations are conducted simultaneously on a daily basis. The DI is advised to consider whether an identification system, for example, numbering or colour coding mortuary tables and the bowls used to move organs to / from dissection boards, may mitigate the risk of organs being inadvertently repatriated with the wrong body. • The DI may also wish to consider conducting specific audits across both sites, including physical checks of mortuary slips and wrist/ankle ID tags as part of a verification process for deceased received into either premises. The relevant SOP should also be updated accordingly.
5.	GQ7	Staff working under the licence were not fully aware of HTA SUI requirements. To further raise awareness of SUI reporting requirements, it is recommended that the DI considers maintaining an up-to-date checklist of SUI reporting categories within mortuary premises in a location easily accessible by staff.
6.	GQ8	While the establishment has completed a number of risk assessments, these should be extended to include all HTA SUI categories in order to mitigate risks to the bodies and tissue in the care of the mortuary.
7.	PFE2	The DI is advised to create a record sheet to document the cleaning of the PM room and equipment, which is being carried out after each post mortem examination in accordance with the documented SOP. The DI is also advised to gain access to records kept by the Trust Estates Department, which detail the measurement of air flow within the post mortem rooms.This will help ensure that the maintenance department monitors airflow on a regular basis and takes corrective actions if the rate of airflow is below the recommended ten air changes per hour.

8.	PFE3	The DI is advised to formally document the contingency arrangements in place to deal with occasions where the body store reaches capacity, to reflect those informally agreed with contract funeral directors. This will ensure that any staff unfamiliar with the arrangements have guidance to follow in the event full capacity is reached.
9.	D2	As the form used by the Coroner for Northern Districts does not contain the option for an organ to be repatriated with the body when coroner's authority ends, the DI is advised that instructions relating to disposal, retention or repatriation of relevant material, particularly in cases where whole organs are removed, should be clarified and carefully documented.
10.	-	The HTA emphasises the importance of timely and effective communications with HM Coroners. The DI is advised to clarify and formalise lines of communication with the Coroners' Offices to minimise the likelihood of delayed PM examinations and the resultant impact on families. The HTA has produced a communication flowchart for coroner's PM examinations which the DI may wish to refer to: http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/coroners/coronersfaqs.cfm

Concluding comments

The establishment has an experienced and motivated APT team with a recently appointed Chief APT. All staff working under the licence are fully engaged and committed to delivering a high quality service. The DI communicates effectively with mortuary staff, primarily through the Service Manager (Cellular Pathology), Quality Manager (Research & Governance) and Chief APT.

Examples of strength and good practice were seen. Consent training sessions have been carefully considered and the content of these is comprehensive and up-to-date. Training is offered to various members of staff within the hospital and a register of those trained and approved to take consent for hospital PM examinations is maintained. This enables clinicians who would like to request a PM examination to contact a named individual to meet with the family, provide appropriate information, answer their queries and obtain valid consent.

There are a number of step checks in place for both receipt and release procedures within the mortuary and for movement of relevant material within the histology department at the St. Thomas' site. The mortuary maintains a sophisticated electronic database to manage mortuary records, track tissues to histology and record the option selected by the bereaved for retention, repatriation or disposal of samples; the establishment has a broad schedule of regular audits covering a range of mortuary activities; a strong emphasis on root cause analysis for reported incidents; documented evidence of corrective and preventive actions being tracked through to resolution and closure; and a detailed checklist ('authority to proceed' form) of key steps for PM preparation.

As highlighted above, there are areas of practice that require improvement and the HTA has given advice to the DI with respect to these.

The HTA requires that the DI addresses the six identified 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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 28 February 2013

Report returned from DI: 13 March 2013

Final report issued: 13 March 2013

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: 30 July 2013

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.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

- 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.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as

health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

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.