Site visit inspection report on compliance with HTA minimum standards

Kingston Hospital

HTA licensing number 12023

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**

15 July 2015

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 Kingston Hospital (the establishment) had met the majority of the HTA standards, one minor shortfall was found with regard to the Governance and Quality Systems (GQS) standards. The shortfall was in relation to an absence of governance arrangements for other departments undertaking activities licensed by the HTA. Advice has been given on matters across the range of standards and also in relation to licence management.

Particular examples of 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 (DI), Licence Holder (LH), premises and practices are suitable.

The statutory duties of the DI 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 licenses 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

This report refers to the activities carried out by Kingston Hospital (the establishment), which deals with around 1,300 bodies each year. Approximately 300 PM examinations are carried out annually, the vast majority of these being under HM Coroner, London West. In addition, approximately six adult consented PM examinations and two Home Office PM examinations are undertaken each year.

Coronial and Home Office PM examinations are performed by one of three visiting consultant pathologists and consented PM examinations by one of two consultant pathologists employed by the hospital. Childhood deaths requiring PM examination include cases of sudden or unexpected death in infants and children (SUDIC; approximately eight each year). These are referred to the mortuary at Guy's and St Thomas' NHS Foundation Trust. Stillbirths and neonatal deaths requiring PM examination (approximately 60 cases each year) are referred to the mortuary at St George's University Hospitals NHS Foundation Trust. This arrangement is not subject to a formal Service Level Agreement (SLA; *see Advice item 1*).

Pregnancy remains of all types up to 18 weeks gestation are sent to the Trust's Cellular Pathology Department for disposal, accompanied by the relevant paperwork; foetuses of more than 18 weeks gestation are released to funeral directors via the mortuary.

Licensable activities occur within the mortuary, Cellular Pathology and Emergency Departments.

<u>The mortuary</u>

The mortuary is purpose built and is separate from the main hospital building. The entrance for funeral directors is screened from public view. Entry and exit points are monitored by CCTV but there are no electronic access control or no out-of-hours intruder alarm systems. Although suitably staffed, lone and out of hours unaccompanied working does occur and there are procedures to cover these activities.

The body store contains 81 refrigerated spaces, three of which can be used for bariatric storage. There is a separate refrigerator containing twenty spaces for stillbirths, neonatal deaths and foetuses of more than 18 weeks gestation. There is a separate bank of six spaces for freezer storage. One Nutwell unit is available as additional space at times of high demand.

Refrigerator and freezer temperatures are recorded manually by the mortuary staff. If temperatures exceed the set limits, a local audible alarm is sounded and the Trust's Facilities and Estates Department is informed for action. There is an Anatomical Pathology Technologist (APT) on call if the movement of bodies to other units is required. The DI is investigating the use of a remote wireless system which will contact the hospital switchboard who will then notify the 'on-call' APT.

There is a separate refrigerator for the storage of samples for toxicological analysis (*see Advice item 7)*.

The PM room has six PM tables, each with an accompanying dissection bench, and has adequate working space and good lighting. Cases up to Hazard Group 2 are managed within the facility. Hazard Group 3 cases are transferred to Fulham Public Mortuary but the HTA did not see any evidence that this arrangement is governed by an SLA (*see Advice item 1*).

Clean, transit and dirty areas are clearly delineated, and there are wall notices and diagrams clarifying when and how personal protective equipment (PPE) should be worn.

There are clear policies and procedures for cleaning and decontamination and detailed records of cleaning and decontamination are maintained.

There is a contingency plan for disaster recovery and individual plans for additional body storage demand depending upon the nature of the requirement.

Movement of bodies and samples

Bodies arriving from outside the hospital are brought in by funeral directors. All bodies from within the hospital are transported by porters.

Stillbirths, neonatal and childhood deaths requiring PM examination are transported from the mortuary (and returned to the mortuary) by a specific funeral director (*see Advice item 8*).

If the PM examination is carried out by a Home Office pathologist, any tissue taken for histopathology is transported by a specific courier company to a separate HTA-licensed establishment for analysis. For PM examinations carried out by hospital pathologists, delivery of formalin-fixed (wet) tissue specimens to the Cellular Pathology Department is by direct handover. After processing and histopathological analysis, blocks and slides are stored in the Cellular Pathology Department. Archived blocks and slides are stored offsite at a separate HTA-licensed establishment.

Tissue and organs are occasionally sent offsite for specialist examination; they are taken by a specific courier company to either King's College Hospital NHS Foundation Trust or St George's University Hospitals NHS Foundation Trust.

Samples sent for toxicological and asbestos fibre analysis (where appropriate) are transported by specific courier companies.

Records

Upon arrival of the body, information is entered into the mortuary register and each body received by the establishment is given a unique, sequential number. Where a body undergoes a PM examination, a separate PM number is also allocated and a record is kept in the PM register. Records from both registers are entered into the electronic mortuary database.

The details of tissue samples and organs taken for analysis during PM examination are recorded on the histopathology request card and on the Coroners 'Next of kin statement'. These details are then entered into the tissue retention and disposal register and the mortuary database. They are also recorded on the WinPath software system used by the mortuary and laboratory staff.

All records are subject to a detailed audit as part of the audit schedule.

Emergency Department

In SUDIC cases, tissue is removed by paediatric consultants in a secure area, which ensures the dignity of the deceased. Samples removed (whole blood and urine for biochemical analysis, and skin biopsies for cytogenetic analysis) are sent by courier to St George's University Hospitals NHS Foundation Trust. The DI was not aware that their responsibilities as DI extend to this activity (*see inspection findings against standard GQ1, below*).

Obstetrics and Gynaecology Department

Stillbirths are transferred to the mortuary at the earliest opportunity. Pregnancy remains are stored in a refrigerator in the Department pending transfer to the laboratory for histopathological analysis or mortuary for release (*see Advice item 7)*. Although pregnancy remains are considered to be tissue from the living, the HTA advises that the DI should be aware of procedures governing the management and disposal of such specimens (*see Advice item 9*).

The inspection process

This was the fourth site visit inspection of the establishment since it was issued an HTA licence in June 2007 (the last inspection was in December 2011). It was a routine inspection, to assess whether the establishment is continuing to meet the HTA's standards and also to provide the HTA with assurance about the suitability of the premises and facilities.

The Trust was subject to three inspections by the HTA in 2011. In February 2011, the HTA's inspection highlighted poor governance and communication arrangements between the DI and staff working under the licence, and poor traceability systems for blocks and slides containing samples of tissue taken during PM examination. The inspection resulted in six major shortfalls (including shortfall in relation to the unsuitability of fridges and freezers) and six minor shortfalls. Following up in September 2011, the HTA found that some consent and governance and quality standards remained unmet and that the fridges and freezers used to store bodies remained unsuitable; this shortfall was now considered to be critical. The HTA issued Directions in September 2011 to ensure that planned works to provide suitable storage facilities for bodies were completed. The inspection resulted in one critical shortfall, one major and five minor shortfalls. The third inspection, in December 2011, was a further non-routine inspection to check progress in meeting the requirements of the Directions that had been issued. The establishment was found to have met the requirements of the Directions, which were removed in December 2011 as the facilities were now considered to be suitable.

The timetable for the present site visit inspection was developed after consideration of the establishment's previous inspection reports, compliance update information and discussions with the DI. The site visit inspection included a visual inspection of the mortuary, body store,

viewing area, PM room, and the Cellular Pathology, Accident and Emergency and Obstetrics and Gynaecology Departments.

Meetings were held with staff working under the licence. They were: the DI (Service Line Manager - Department of Cellular Pathology); the Person Designated (PD; Mortuary Manager); two Hospital Consultant Pathologists; an APT; the Bereavement Midwife; and, the Divisional Director - Clinical Support Services (representing the Corporate LH Contact; CLHC).

A documentation review and horizontal and vertical audits were carried out.

A horizontal traceability audit was conducted on two bodies in the refrigerators. Body location and identification details on wrist tags were checked against the whiteboard, mortuary register, mortuary database and WinPath system. A horizontal traceability audit was also conducted for two perinatal cases which had been sent to another establishment for further examination.

A vertical audit was conducted on the removal of tissue during PM examination from four bodies (two Coronial cases and two consented cases). The samples had been processed into blocks and slides. Sample details were checked against the PM register, the tissue retention and disposal register, the mortuary database, the records on the WinPath system and the families' wishes on the completed Coroner's 'Next of kin statement' or Hospital 'Consent form for adult PM examination', as appropriate.

No discrepancies were found in any of the above cases.

Inspection findings

The HTA found the DI and the CLH to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality Systems

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.	There are no governance arrangements covering staff working under the licence in areas remote from the mortuary. *See Advice items 5 and 6.*	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	To ensure consistency in service, the DI is advised to put in place formal SLAs with organisations providing non-Coronial PM examination services.
2.	C1	The DI is advised to liaise with the Coroner and his officers with a view to modifying the 'Next of Kin Statement' by amending the option 'retained as part of the deceased's medical records' so that it concludes with 'for the future use and benefit of the family'.

3.	GQ1	The following documents are due for review: - 'COSHH forms' for: 'limelight' cleaner, 'liquidator', 'virosolve', 'Hospec' thick bleach (all review dates unknown). - 'Consent form for adult PM examinations' (review date 18/12/2014).
4.	GQ1	Although the standard operating procedures (SOPs) are well constructed, the DI is advised that documents should not be 'signed off' by the author of the document.
5.	GQ1	To ensure consistent governance across the Emergency and Obstetrics and Gynaecology Departments, the DI is advised to appoint PDs in these areas to oversee licensable activities taking place, to keep staff up to date on HTA-related matters and to report back to the DI on any issues or concerns.
6.	GQ1	The DI is advised to set up a forum, attended by all PDs and other relevant staff, at which staff can discuss regulatory issues. In other establishments, governance meetings cover items such as adverse incidents, changes to SOPs, audits and their findings, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items). These meetings should be governed by an agenda and minutes recorded and circulated. The minutes should include timelines for identified actions and there should be a standing agenda item for discussing progress against actions identified at previous meetings.
7.	PFE3	The DI is advised to the link the toxicology and Obstetrics and Gynaecology refrigerators to the electronic call-out system.
8.	PFE4	To ensure a consistent service for the transport of bodies, organs and tissues, the DI is advised to enter into formal agreements with funeral directors and couriers for the transport of bodies and samples when not under Coronial authority. The DI is referred to the 'Model agreement between mortuaries and funeral directors for the removal of bodies' on the HTA's website.
9.	D1, D2	The DI is currently developing a policy for disposal of pregnancy remains. In line with the HTA's 'Guidance on the disposal of pregnancy remains following pregnancy loss or termination', the woman should be offered burial, cremation and incineration as disposal options.

Concluding comments

During the site visit inspection of the establishment, areas of good practice were noted:

- The Mortuary Manager is developing a comprehensive training course for all porters.
- Transportation, delivery and receipt of bodies, organs, tissues and other samples by funeral directors and couriers is tightly controlled and is recorded by the use of faxback forms and tracking records.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the DI with respect to the Consent, Governance and

Quality Systems, Premises, Facilities and Equipment, and Disposal standards, as well as to licence management.

The HTA requires that the DI addresses the shortfall 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: 12 August 2015

Report returned from DI: 19 August 2015

Final report issued: 16 September 2015

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 05 April 2016

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below.

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)

  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 and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- 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 outlines 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).

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.

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.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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 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.