Site visit inspection report on compliance with HTA minimum standards

Queen Elizabeth Hospital

HTA licensing number 12368

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**

9 June 2015

Summary of inspection findings

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

Although the HTA found that Queen Elizabeth Hospital (the establishment) had met the majority of the HTA standards, three minor shortfalls were found in relation to staff training for seeking consent for perinatal/paediatric post mortem examinations, audits of tissue samples in the Pathology department and the governance arrangements for removal of relevant material from the body of a deceased person in the Accident and Emergency department.

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 (DI) are set down in Section 18 of the Human Tissue Act 2004 (HT Act). 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

Queen Elizabeth Hospital (the establishment) is part of the Gateshead Health NHS Foundation Trust. It has been licensed by the HTA since May 2007 for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of the deceased and relevant material for use for scheduled purposes.

The establishment conducts approximately 400 post mortem (PM) examinations each year, including high risk (up to Category 3) and Home Office cases. Perinatal/paediatric cases are transferred to another HTA-licensed establishment for PM examination.

Most adult PM examinations undertaken at the establishment are performed under coronial authority. Only one adult hospital PM examination was conducted in 2014. Consent for these is sought by clinical staff involved in the treatment of the deceased in life, accompanied by a member of staff trained in the requirements of the HT Act. The establishment uses a consent form adapted from the HTA's model consent form for adult hospital PM examinations and an information leaflet.

Consent for perinatal/paediatric PM examinations is governed by a consent policy and procedure and consent documentation provided by the HTA-licensed establishment to which these cases are referred for PM examination (refer to advice item 2). Consent is sought by clinical staff, who have received training in seeking consent for clinical procedures. However, there is no formal training in the requirements of the HT Act for staff seeking consent for perinatal/paediatric PM examinations (refer to shortfall for C3).

The mortuary is located in a dedicated wing of the hospital. It is secured by locked doors with key and key code access, and there is an intercom system for staff to allow entry to visitors. There is closed-circuit television (CCTV) monitoring of the mortuary entrances and areas within the body store.

The mortuary receives bodies from the hospital and the community. Bodies from the hospital have a printed identification wrist tag and label placed on the shroud, which include the patient's identification details, including their unique hospital number. Bodies admitted from the community have a handwritten wrist tag attached by the police, which includes the deceased's identification details and a unique identification number. All bodies are assigned a unique mortuary number, which is also used to provide traceability of samples retained at PM examination. The establishment uses the mortuary register to record the details of body admission, PM examination and release to a funeral director. The details of PM examination are also recorded on a series of forms. Perinatal cases are labelled with the mother's hospital identification label, including her name, date of birth and unique hospital number. Perinatal cases are recorded using separate forms to record the details of admission, transfer to another HTA-licensed establishment for PM examination and release to a funeral director.

The mortuary has 83 fridge spaces, including three spaces for larger bodies and five dedicated trays for the storage of perinatal/paediatric cases. The establishment has allocated specific fridge spaces for bodies admitted from the hospital and those from the community. It also has a dedicated bank of freezers, with five trays for bodies that require longer-term storage. This bank of freezers can also operate in fridge mode, should the establishment require additional refrigerated storage capacity. Storage temperatures are continually monitored and there is an automated alarm call-out procedure in the event of temperature deviation. Staff also check and record storage temperatures daily on working days and analyse these records for trends in temperatures that may indicate future possible fridge failure.

The PM suite has three downdraft PM tables and a dedicated bench for the preparation of wet tissue samples. Wet tissue samples taken for histopathological analysis are transferred to

the establishment's Pathology department. Fluids for toxicological analysis are sent to another HTA-licensed establishment. PM tissues are tracked by the unique mortuary number.

With appropriate consent, PM tissue blocks and slides are stored for use for scheduled purposes in two dedicated areas in the Pathology department. A core team of staff manage the storage of these. Archival samples are sent to another HTA-licensed establishment for storage. The establishment maintains records of PM samples, including disposal, on an electronic database (refer to advice item 11). Since the last HTA inspection, the establishment has implemented a system to review storage of PM samples periodically to ensure that samples are disposed of in a timely manner following expiry of coronial authority where consent has not been given for the storage of samples for use for scheduled purposes.

Sampling of tissues from deceased children in cases of sudden unexpected death in infancy (SUDI) is performed in the Accident and Emergency (A&E) department by a core team of staff, under pre-emptive coronial authorisation (refer to shortfall for standard GQ1).

The last HTA site visit inspection of Queen Elizabeth Hospital was in January 2011. This report describes the second, routine site visit inspection of the establishment. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted a visual inspection of the mortuary and storage of PM tissue blocks and slides in the Pathology department.

Audits of traceability were conducted for tissue blocks and slides from two PM cases, including audits of the consent documentation for the retention of these samples. There were no discrepancies in the traceability of these samples or the documentation of the consent for their storage. An audit was conducted of disposal of PM tissue blocks and slides from one PM case, including the records of traceability and disposal. There were no discrepancies in the traceability documentation for these samples and the samples were not found in storage. A traceability audit was conducted for one perinatal case and two adult bodies. No discrepancies were identified. Consent forms for two adult hospital PM examinations were audited. On one consent form the timeframe for consent to be withdrawn had not been recorded (refer to advice item 1).

Home Office PM examinations take place at this establishment. Under section 39 of the HT Act, 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' (ACPO) audit of tissue held under police authority, that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process, the management of tissues and organs taken for criminal justice purposes were reviewed by the HTA at this site visit 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 Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	There is no formal consent training for staff seeking consent for perinatal/paediatric PM examination in the requirements of the HT Act. *(Refer to advice item 3)*	**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.	Removal of relevant material from the deceased is undertaken in the A&E department. This activity is not fully included in the establishment's governance arrangements for activities taking place under the authority of an HTA licence. Staff undertaking these activities do not attend meetings covering matters related to the HTA licence. There is no Person Designated (PD) in the A&E department to support the DI in overseeing this activity. *(Refer to advice item 4)*	**Minor**
GQ2 There is a documented system of quality management and audit.	The establishment does not undertake regular audits of traceability of PM tissue samples stored in the Pathology department. *(Refer to advice item 6)*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to ensure that all staff seeking consent for hospital PM examinations know the timeframes for consent to be withdrawn and are aware that they should record the timeframe for withdrawal of consent on the consent form.

2.	C1	The DI is advised to ensure that he is informed of changes to the policy and procedure for seeking consent for perinatal/paediatric PM examination at the HTA-licensed establishment to which these cases are referred to for PM examination.
3.	C3	The DI should ensure that all staff seeking consent for perinatal/paediatric PM examinations receive training in consent and the requirements of the HT Act. Staff should be assessed as competent prior to seeking consent for PM examination and should receive periodic refresher training. Staff training and competency assessments should be documented.
4.	GQ1	HTA matters are discussed at a number of meetings. The DI is advised to also hold formal meetings dedicated to the governance of HTA-licensed activities, and to ensure that all staff involved in these activities, including staff seeking consent in the A&E department, attend them. Minutes of these meetings should be recorded and distributed to all staff working under the HTA licence.
5.	GQ1	Examples of some documents due for review in the months prior to this site visit were seen during the inspection. The DI is advised to ensure that all documents are reviewed in line with the establishment's document review policy.
6.	GQ2	The establishment should review its audit schedule to include audits of PM tissue samples in the Pathology department. The DI is advised to include audits of tissue samples from storage to traceability records and from traceability records to samples in storage. Audits and audit findings should be documented, including the person responsible for actions arising and the deadline for actions to be completed, where applicable.
7.	GQ6	The DI is advised to consider strengthening the existing systems for highlighting deceased persons with same or similar sounding names, by, for example, using colour-coded identification tags for these bodies to provide an additional visual prompt for staff. Any changes to procedures should be reflected in the establishment's standard operating procedures (SOPs).
8.	GQ7	The DI is advised to have more of the establishment's PDs registered to access the HTA Portal in order to report HTA Reportable Incidents (HTARIs). This will help to ensure that any HTARIs are reported to the HTA within the required timeframe of five working days within the incident being discovered.
9.	GQ8	The establishment has recently introduced a new template to document risks associated with undertaking licensed activities. The DI is advised to archive the previous version. The DI is also advised to ensure that new risk assessments include the name of the person assigned the actions and a date for completion of actions, where applicable.
10.	PFE3	The establishment is advised to amend the label on the door of the bariatric fridge to reflect the number and layout of the trays and their corresponding tray numbers. This will help to ensure that fridge location number is correctly recorded in the mortuary register.
11.	D2	The establishment is advised to amend the electronic database template used for the traceability of PM tissues to include a box to record the reason for disposal. This information is detailed elsewhere in the traceability records on this database but recording it in one location may facilitate audits of this information.

Concluding comments

This report outlines the second HTA site visit inspection of Queen Elizabeth Hospital. Despite the shortfalls identified, areas of strength were observed. There is a good training programme for staff seeking consent for adult hospital PM examinations. The process for seeking consent for adult hospital PM examinations is well-considered, including the use of sample tissue blocks and slides to illustrate the size of samples taken. Staff seeking consent for adult and perinatal/paediatric PM examinations are dedicated to ensuring that the consent process is handled sensitively.

The mortuary staff have worked at the establishment for a number of years and are motivated and experienced in their roles. They have worked towards developing robust mortuary procedures. The team is dedicated to ensuring that the dignity of the deceased is maintained and that relatives visiting the mortuary are treated sensitively. The mortuary staff have developed good working relationships with staff in other hospital departments, visiting pathologists, porters working in the mortuary and local funeral directors.

The DI has a good understanding of the HT Act and works to ensure improvements are implemented as required. He works closely with staff seeking consent for adult PM examinations and those in the mortuary and Pathology department. The DI is well supported by the staff and Quality Manager. Staff working under the HTA licence at the establishment demonstrated a commitment to continual quality improvement.

A number of areas of practice require improvement, including three minor shortfalls. In addition, the HTA has given advice to the DI on a range of issues, including consent, governance arrangements, traceability systems and risk assessments.

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

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

Report sent to DI for factual accuracy: 6 July 2015

Report returned from DI: No comments received

Final report issued: 28 July 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: 24 October 2015

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.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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 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.
- 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.

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.