Site visit inspection report on compliance with HTA minimum standards

James Cook University Hospital

HTA licensing number 12089

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**

22 and 23 January 2014

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.

The HTA found that the James Cook University Hospital (JCUH) had met the majority of the HTA standards, with two shortfalls in relation to premises, facilities and equipment and governance and quality. A fridge in the maternity unit at JCUH is used for the temporary storage of babies and products of conception for a short period of time before transfer to the mortuary. However the temperature of the fridge is not monitored and there are no governing processes in place to ensure correct maintainence of equipment and traceability systems in place for the transfer of babies and products of conception from the maternity ward to the mortuary.

The Designated Individual (DI) has been in the role since 2007 and has developed good communication links between members of staff across both JCUH and its satellite, the Friarage Hospital (FH), where licensed activities also take place.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

Background to the establishment and description of inspection activities undertaken

Licensed activities are carried out within the mortuary and pathology laboratory and also the maternity unit. On occasion, samples may be taken in the accident and emergency (A&E) department in relation to sudden infant deaths (SIDs). The pathology laboratory stores blocks and slides containing post mortem tissue**.**

Approximately 900 post-mortem (PM) examinations are carried out at JCUH each year on behalf of the Coroner for Teesside and the Coroners for North Yorkshire. In the year preceding this inspection, the establishment carried out five hospital adult PM examinations, 36 hospital perinatal PM examinations and 50 forensic PM examinations. Bodies of the deceased from FH who require PM examination are transferred to JCUH using the pathology department's own transport . The majority are then transferred back to FH following PM examination a for release for burial or cremation.

Consent for hospital adult PM examinations is overseen by the trained end of life care team, who support clinicians involved in the process. Neonatal consent is overseen by the trained midwifery team, who are currently adapting the stillbirth and neonatal death (SANDS) consent form and associated information for future use.

The JCUH mortuary is staffed by four qualified Anatomical Pathology Technologists (APTs) and one healthcare support worker, and provides an on call service outside normal working hours. Members of the portering staff, who are employed by an external contractor, undertake some activities outside normal working hours, including the transfer of bodies form the wards to the mortuary and the receipt of bodies from the community. They are fully trained to undertake these activities by the mortuary department, and clear guidance on the procedures to follow is displayed within the body store of the mortuary.

Bodies of the deceased are assigned a unique mortuary log reference number when received, and a separate identification number is used if they are subject to a PM examination. This PM examination number is to ensure traceability of tissue samples retained. All post-mortem tissue blocks and slides since the centralisation of post mortem serives at the JCUH site in 2009 are processed and stored at JCUH. Blocks and slides from post mortems performed at FHN prior to this are stored on FH site within the histology department.

The wishes of families with regards to disposal are faxed or emailed by the Coroners' Officers to the mortuary. This information is recorded on a retained tissue disposal database, which uses a colour coded system to aid the management of disposal in line with families' wishes.

JCUH mortuary has storage capacity for 78 adult bodies including eight bariatric spaces with a designated fridge for paediatric and neonatal cases. There is a facility for fridge space to be used as freezer storage if required, however this is rarely done.

The PM suite comprises two areas used for PM examinations. The larger area has two tables and is used primarily for routine adult PM examinations and forensic PM examinations. The smaller adjacent area, which has one table, is used for high-risk cases and hospital paediatric PM examinations.

The premises at FH, which is a satellite of JCUH, for the purposes of HTA licensing, comprise a body storage facility for hospital ward and community deaths that fall under the authority of the North Yorkshire Coroners. It is also used for long term frozen storage of the deceased, if required, and acts as part of the contingency plan for JCUH. PM examinations are not carried out at FH, but it requires to be licensed because of the storage that takes place there.

The FH mortuary facility is staffed part time by a member of JCUH mortuary staff. The establishment has stipulated times for funeral directors to attend to collect bodies. Admissions when an APT is not present, either during the day or out of hours, are undertaken by members of the hospital security or portering staff, who have been fully trained on relevant procedures. There is an out of hours service in relation to viewings and an APT is always in attendance.

Release of bodies at both sites is only undertaken by the establishment's mortuary staff.

Practices at both JCUH and FH are governed by the same operating procedures in relation to HTA licensed activities. All documentation is available on the cellular pathology quality management intranet system and hard copies of relevant documents are available on both

sites. Standard operating procedures (SOPs) relating to activities that may be carried out by non moturary staff, for example porters and funeral directors, are displayed on the walls of the body store, allowing easy access when required.

This was the third rountine inspection of the establishment. Included in the two days was a visual inspection of each facility, a document review and interviews with members of staff. During the visual inspection of the JCUH body store, the HTA was able to observe the procedures followed when releasing two bodies to funeral directors.

Extensive traceability audits were completed as part of the inspection, as detailed below:

- Three bodies were located within the body store and their location and identity compared with wrist and ankle identification tags, the mortuarty register and the database;
- A case where consent had been given for a limited hospital adult PM examination with the retention of tissue for use for a scheduled purpose was checked against corresponding electronic and paper records, including the signed consent form;
- Details of three cases where PM tissue had been removed for post mortem analysis were traced from the histology form completed at the time of PM examination, through to the histopathology laboratory database system. In all cases blocks and slides were checked. In two cases, blocks and slides had been disposed of in line with the families' wishes; in the third case, blocks and slides were still in use by the pathologist.
- For one case, a reverse traceability audit of blocks stored in the pathology laboratory was conducted, checking back to the corresponding entries in the database using the unqiue PM number and to the related hard copy documentation of relatives' wishes.

No anomalies were found.

Inspection findings

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

Compliance with HTA standards

Governance & Quality Systems

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	There is no documented procedure for the transfer of babies and POC from the ward to the mortuary or for recording that the transfer has taken place.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The fridge in the maternity unit at JCUH is used for temporary storage of babies and products of conception (POC) prior to transfer from the ward to the mortuary. There is no system for monitoring fridge temperatures or procedure for managing fridge failure, which poses a risk to the bodies and tissues stored.	**Minor**

Advice

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

No.	Standard	Advice
1	C2	The DI is advised to revise the wording in current PM consent documentation to make it clear that retention of tissue samples as part of medical records may only be with consent for use scheduled purposes. The information guide to PM examinations of babies given to families and the Trust policy on sensitive disposal both use wording which does not make this clear, and could lead to confusion around families' wishes for those seeking and giving consent. This issue has been addressed as an item of advice and guidance, as the consent forms used by the establishment make clear that consent for storage for use for scheduled purposes is required.
2	C3, GQ2	The Trust has been using the consent module of the HTA's DI e-learing as part of its consent training programme provided to bereavement and maternity staff. However, this has now been withdrawn and the DI is advised to review the training for members of staff seeking consent and consider extending the existing powerpoint presentation used as part of consent refresher training of bereavement staff to include details relevant to infant and neonatal deaths. The DI is also advised to consider carrying out periodic vertical audits on the consent process to assess the competency of those members of staff seeking consent, and to include these in their training records.
3	GQ1	Along with action taken to address the shortfalls identified above, the maternity unit would benefit from periodic audit of fridge contents, which will help mitigate the risk of an HTA reportable incident.
4	GQ2	The mortuary has a designated person from the quality management team who carries out audits within the department. The mortuary audit

		programme comprises vertical, horizontal and witnessed/task audits carried out as part of a yearly schedule. The HTA suggests that the vertical audits try to cover too much ground and the DI is advised to consider smaller, sectional audits that may be more easily managed and to extend the programme to cover licensable activites under the HTA which may included: • Identification of the deceased • Traceability of retained tissue samples • Storage of blocks and slides • PM examination procedures Disposal in line with families' wishes
5	GQ2	There appears to be good communication across both sites amongst staff undertaking licensed activities, although this is not fomalised. The DI is advised to appoint Persons Designated (PDs) in areas outside the mortuary and to hold a formal bi-annual "HTA licence management" meeting, in addition to the individual departmental meetings already in place, as a forum for staff to discuss HTA-related matters and to build on the good relationships and communication that are already in place.
6	GQ6	PM tissue samples are transported to the laboratory in a sealed pot with a unique PM number printed on the label and an accompanying histology form. However the number and types of sample are not recorded. Although the risk to traceability is low as mortuary staff take the samples to the laboratory, the DI is advised to risk assess this process and to consider documenting the number of cassettes of individual tissue types taken at PM examination on the accompanying histology form.
7	GQ6	There are good risk assessments in place for the mortuary including the risks associated with failure to meet HTA standards. The DI is advised to extend the suite of risk assessments to cover HTA reportable incident types.
8	GQ8	Overall, there is good traceability of PM tissue, including blocks and slides, between the mortuary, laboratory and to the pathologist for examination. However, the DI is advised to consider the risks associated with the movement of blocks and slides from the pathologist back to the laboratory for storage as this is not currently captured on the pathology database system.
9	PFE1	The DI is also advised to replace the porous measuring stick in the body store room of the mortuary at the Friarage Hospital to enhance infection control procedures.

Concluding comments

During the inspection, examples of good practices were observed. The mortuary at JCUH has a facility for ritual washing, acknowledging the religious and cultural needs of its patient population. The area is also used for washing trauma victims to minimise the distress to families wishing to view their loved ones. This shows a high level of respect and commitment by staff to ensure the dignity of the deceased.

Bariatric bodies or those with unusual body morphology, are occasionally stored at JUCH for short periods of time whilst awating transfer to FH where there are bariatric stoarage facilties. To help preservation during this time, the mortuary uses a chest freezer for storing ice packs used to chill bodies which aagain shows a high level of commitment from the members of staff to ensure the dignity and respect for the deceased and families.

Photographs of the deceased are sometimes taken of the as part of the PM examination to record physical damage or for training purposes. The establishment demonstrates good practice in providing families with comprehensive information to help them make an informed decision regarding consent.

Due to the organisation of the service provided by the two sites, bodies are transferred between sites regualry. To mitigate risks associated with these activities, there are strong practices in place for the traceability and dignity of the deceased. There are also good traceability systems for tissue samples taken at PM examination and for the disposal of tissue in line with the families' wishes. There are risk assessments associated with these activities to determine the risk of failure to meet the standards set by the HTA. For example: RAS 0015 Risk Assessment for failure to meet HTA standards for post mortem services.

There is one area of practice that requires improvement, with two minor shortfalls, related to procedures governing fridge temperature monitoring within the maternity unit at JCUH and the traceability systems for transferring babies and POCs from the maternity ward to the mortuary. The HTA has given advice to the Designated Individual with respect to consent training, some elements of documentation,risk assessment and audits.

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

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 6 February 2014

Report returned from DI:

Final report issued: 10 February 2014

Inspection CAPA Plan Closure Statement: 10 February 2014

Completion of corrective and preventative actions (CAPA) plan

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

Date: 30 May 2014

Appendix 1: HTA standards

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

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 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.