Site visit inspection report on compliance with HTA minimum standards

Harrogate District Hospital

HTA licensing number 12118

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**

12 March 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 Harrogate District Hospital (the establishment) met the majority of the HTA standards, four minor shortfalls were found. These relate to consent training and documentation; standard operating procedures and risk assessments for licensable activities; and; documented procedures for reporting HTA Reportable Incidents to HTA. Advice is also given to the Designated Individual on nominating additional Persons Designated in all areas where activities take place under this licence, and seeking support from the Corporate Licence Holder contact, as required, to effect changes to meet licensing standards.

Examples of strengths 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 out 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

The mortuary at Harrogate District Hospital (the establishment) admits bodies from the hospital and the community. Approximately 200 adult post mortem (PM) examinations take place each year, mainly under authority of HM Coroner for North Yorkshire, including forensic and high risk cases. A small number of adult hospital (consented) PM examinations take place annually. Perinatal and paediatric cases are transferred to another HTA-licensed establishment. The establishment uses consent documentation produced by the Stillbirth and Neonatal Death charity for perinatal/paediatric PM cases, and the HTA's model consent form for adult hospital cases. Clinicians who have completed the Trust's online consent training may seek consent for hospital PM examinations (refer to shortfall against standards C1, C3).

The mortuary has 55 fridge spaces, including five in deep freeze, split between the mortuary body store and the fridge bank situated in an adjacent area. Perinatal/paediatric cases are stored on dedicated trays within the adult fridges.

Tissues taken at PM examination for histological analysis are processed into formalin-fixed paraffin wax blocks and microscope slides in the histopathology laboratory. Whole organs, and samples for toxicological analysis or other tests, are sent to other HTA-licensed centres. With appropriate consent, PM tissue blocks and slides are stored for use for scheduled purposes.

Sampling of tissues from deceased children in sudden unexpected death in infancy cases is performed in the Emergency Department by consultant paediatricians, under pre-emptive authorisation from HM Coroner.

The establishment has been licensed by the HTA since August 2007. One previous site visit inspection took place in March 2011. This report describes the second, routine, site visit inspection of the establishment, which was conducted jointly with the United Kingdom Accreditation Service (UKAS). UKAS assessors visited the mortuary and histopathology laboratory, and gathered evidence against licensing standards GQ1-6, PFE1-5 and D1 on behalf of HTA. The HTA inspectors met with staff involved with licensable activities and reviewed documentation. Storage locations and identifiers for three bodies, and traceability records for three coronial PM examinations where tissues were taken for histology, were audited. No anomalies were found.

Forensic PM examinations take place at this establishment. Under section 39 of the Human Tissue Act 2004 (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, procedures for forensic PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by 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
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.	Deficiencies in consent training and documentation for hospital PM examinations were identified: • the consent training presentation needs to be version controlled to ensure staff do not inadvertently refer to outdated hard copies (three different hard copy versions of the consent training presentation were seen at the inspection); • the presentation does not explain the actions staff should take if consent for PM examination is withdrawn, and does not clarify the retention or disposal options for PM tissues; • records of completion of consent training are not up to date; and • when PM examination consent forms are printed from the Trust's intranet, no document control information appears on them. This makes it difficult to verify whether a printed copy of the consent form is the current version.	**Minor**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.		

Governance and Quality

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.	Some standard operating procedures (SOPs) contain insufficient detail on mortuary working practices. For example: • the Trust's 'Procedures for the viewing of a body in Harrogate District Hospital mortuary' and 'Conduct of the post mortem examination' SOP (MO-LP-002) do not specify the identifiers to be used to identify a body prior to a viewing or a PM examination, respectively; • the 'Release of bodies' SOP (MO-LP-009) does not state what actions to take if there is a discrepancy between the name of the deceased person, as written on their identity tag, and on the release document brought by a funeral director; and; • upper and lower operational temperature limits for mortuary fridges and freezers, and the process for three-monthly testing of fridge alarms, are not documented. To fully address this shortfall, the establishment should review all mortuary SOPs to ensure the appropriate level of detail is contained. *(Refer to advice items 1-3)*	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The mortuary 'Adverse Incidents' SOP (MO-LP-017) describes the current HTA Reportable Incident (HTARI) categories, the correct reporting timeframe and current method for making notifications. However, the Pathology 'Adverse Incidents' SOP (HP-LP-024) and the Trust 'Identification, reporting and management of incidents including SUIs' document contain incorrect information about incident reporting to HTA. *(Refer to advice item 5)*	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment developed several risk assessments to address a minor shortfall identified at the previous site visit inspection. Further risk assessments have been written since then. However, risk assessments require further development to ensure that all existing risk control measures are fully documented and, if there are additional mitigating measures which can be implemented, these are clearly described and have an assigned owner and completion date. As examples, the 'Undertaking a post mortem examination without appropriate consent' (MO-RA-018) and 'Undertaking a post mortem examination on the wrong body' (MO-RA-12) assessments do not reference the existing same/similar name procedure as a risk control measure, clarify the minimum identifiers used to confirm the identity of the deceased, or consider how potential risks could be reduced further, for example the pathologist and APT signing to confirm they have completed identification checks. In view of the findings of this site visit inspection, the establishment should also consider whether the residual risk rating, which in many risk assessments is calculated to be 'low', is appropriate.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised that using multiple identifiers when bodies are being identified for viewing, release and PM examination reduces the potential risk of misidentification, for example if there are two or more deceased persons with the same, or similar sounding, names. The HTA recommends a minimum of three identifiers, one of which should be unique; these might include, for example, the deceased person's name, hospital number, home address or date of birth. The DI is also advised that relevant SOPs should clarify what actions staff should take if a discrepancy, for example in the spelling of a name, is noticed.
2.	GQ1	Regarding policies and SOPs, the DI is advised: • to omit reference to the obsolete 'Sudden Infant Death Syndrome' document (MO-LP-006) from the 'Management of the Mortuary' SOP (MO-MP-001); • to add to the Trust 'Care of the dying adult bereavement policy' that it is the responsibility of the Coroner's Office to seek families' instructions for tissues retained during coronial PM examinations; • to add to the Trust 'Death certification, cremation forms and PM examination policy' that it is the pathologist's responsibility to confirm the scope of the consent for a hospital PM examination;

		• to include more information about the mortuary quality management system in the Pathology and the Histopathology quality manuals, and; • relevant material for use for the scheduled purpose of research in connection with disorders, or the functioning, of the human body may be stored under the authority of a PM sector licence, if the DI is willing to oversee such storage. The DI is also reminded of the licensing exemptions for storage of relevant material for use for this scheduled purpose: https://www.hta.gov.uk/sites/default/files/Code_of_practice_9_-_Research.pdf The relevant section of the Trust 'Policy for consent to examination and treatment' should be amended to reflect this.
3.	GQ1, D1	Revision of the Trust 'Policy for the disposal of fetal remains', which is beyond its review date, was put on hold until HTA's new guidance on sensitive disposal of pregnancy remains was published. The DI is advised that: • this HTA guidance is being published in March 2015, and; • revision of this policy, in light of the new HTA guidance, should be completed as a matter of priority. https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf
4.	GQ3	In relation to staff training, the DI is advised: • that competence assessment of mortuary staff should be carried out to set criteria, and • to ensure that re-assessment of competence for all mortuary staff is undertaken in line with the Trust's specified timeframe of three years.
5.	GQ7	The DI is advised to nominate additional persons who may make an HTARI notification to HTA. This will ensure prompt reporting if the DI is unavailable to make a notification within the five working day timeframe. Additional reporters will need to create their own individual logins for the portal. Access to the online portal is available at: https://portal.hta.gov.uk/user/login?destination=node/109
6.	PFE1	There are cracks in the mortuary floor between seals, and the wall covering is starting to detach in some places. These could present a potential health and safety risk, as biohazard material could become trapped in these difficult to clean areas. The inspection team was informed that the Trust intends shortly to upgrade the mortuary suite and so has not taken remedial actions. The DI is advised to consider what measures can be taken prior to refurbishment to minimise potential health and safety risks from trapped biohazard materials. The Trust's infection control team may be able to provide advice in that regard.
7.	PFE3	A verbal agreement is in place with another HTA-licensed PM establishment to transfer a bariatric patient there if that patient cannot be accommodated in the mortuary fridges. The DI is advised to request an email, or other written communication, from the DI at that other establishment to confirm this arrangement.
8.	PFE5	Regarding premises, facilities and equipment the DI is advised: • to maintain local copies of records of equipment maintenance visits carried out by the Trust Estates Department or its subcontractors, and; • to monitor periodically air flow and air changes in the PM suite.

9.	-	The DI is advised to nominate additional Persons Designated (PDs) within the Trust to provide greater oversight of activities taking place under the HTA licence, such as in the Emergency Department, the Maternity Ward and the mortuary. The DI is also advised to ensure that she has regular communication with all PDs. In addition, the DI is advised to seek support from the Corporate Licence Holder contact (CLHc), as required, to ensure corrective measures required to meet shortfalls identified at this inspection are implemented.

Concluding comments

Despite the minor shortfalls, strengths were identified. There is effective communication between the establishment and HM Coroner's Office. Staff were knowledgeable about local practice and procedures, and demonstrated care and respect for the deceased and their families.

A number of areas of practice require improvement, including four minor shortfalls. The HTA has given advice to the DI regarding governance and quality, premises and facilities, and disposal standards. Advice is also given on ensuring that the DI has appropriate oversight of all activities taking place under this licence, and seeking support from the CLHc to implement changes required to meet licensing standards.

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.

Report sent to DI for factual accuracy: 30 March 2015

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 18 April 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: 23 June 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.

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.