Site visit inspection report on compliance with HTA minimum standards

Frimley Park Hospital

HTA licensing number 30014

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**

4 December 2013

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 Frimley Park Hospital (the establishment) had met the majority of the HTA standards, three minor shortfalls were found in relation to consent and governance and quality standards. Members of staff seeking consent for adult hospital post mortem examinations within the Trust are not fully trained to ensure compliance with the Human Tissue Authority (HTA) code of practice on consent. The procedure for seeking consent is not documented in a standard operating procedure. In relation to governance and quality systems, members of the Trust portering staff have a large remit of responsibility in the mortuary out of hours, but there is no formal training or process in place to assess their competency. There is a need to ensure that members of the portering staff understand their roles and responsibilities in relation to licensed activities, and carry out their duties in line with mortuary operating procedures.

The Designated Individual (DI) is new to the role and is keen to develop good communication across departments where licensed activities take place; progress has already been made to ensure standards are met.

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

The establishment's licensed premises comprise the mortuary and post mortem suite and the Neonatal Intensive Care Unit (NICU) and delivery suite, where tissue samples may be removed from the deceased for use for scheduled purposes, including determining the cause of death. No samples are taken in the accident & emergency (A&E) Department.

Approximately 500 post-mortem (PM) examinations are carried out each year on behalf of the Coroner for Surrey and the Coroner for Hampshire. No hospital adult PM examinations have been carried out this year to date. Perinatal and pediatric cases are transferred to another HTA licensed establishment, with consent for PM examination first being sought by bereavement midwives (for neonatal deaths) and by an obstetrician (for still births). The establishment uses the stillbirth and neonatal death (SANDS) charity consent form and associated information. Selected high-risk PM examinations are conducted with additional infection control processes in place. No forensic PM examinations are conducted at the establishment.

The mortuary is staffed by two members of staff, one trained to diploma level in anatomical

pathology, and one trainee. Due to the staffing level, lone working can take place during peak times, increasing risks associated with licencable activities when procedures require two people. The level of staff also limits the capacity to train new staff and assess the competency skills required to complete formal training.

Bodies of the deceased are assigned a mortuary log reference number and a separate identification number if they are subject to a PM examination. The PM number is to ensure traceability of samples taken at examination. As the establishment forms part of Surrey Pathology Services (SPS), arrangements are in place to transfer samples to St Peter's Hospital Pathology Laboratory for processing.Once processed, blocks are stored at Royal Surrey Hosptial and slides at St Peter's Hospital. Samples are not returned to Frimley park Hospital unless repatriation with the body is requested by the family.

The mortuary has storage capacity for 60 adult bodies, and has a designated location for neonatal and pediatric cases, and a bariatric fridge with five spaces. The freezer is currently being used as a fridge but can be converted if the need arises. A contingency plan is in place with a local funeral director who can provide additional capacity during peak periods.

This was the second routine inspection of the establishment, the first having been undertaken in 2010. The areas covered by the visual inspection included the body storage area, post mortem suite, histopathology laboratory and delivery suite. The inspection also included document reviews and interviews with staff.

Several traceability audits were completed as part of the inspection. These included checking:

- The identification and storage location of three bodies in the mortuary, by tracing the details from the register to the database, the body store area and the identification wrist tags. This was performed for both ward and community deaths.
- Details of two cases where tissue had been removed for post mortem analysis, by tracing information from the histology record sheet completed at the time of the PM examination and signed by the pathologist taking the samples, through to the Patient Information Chart and mortuary database.
- A case where a whole organ had been taken for analysis and transferred to another HTA licensed establishment, again by tracing the information from the histology record sheet, Patient Information Chart and database, along with the record of receipt from the receiving establishment and disposal wishes of the family.
- Records of retention of tissue samples embedded in wax blocks, including the PM room Tissue Register, Patient Information Chart, mortuary database and receipt of these samples at St Peter's Hospital via the pathology database system. Tissue samples are disposed of either at St Peter's Hospital or Royal Surrey Hospital when consent is not given for their retention.
- Traceability from the maternity suite to the mortuary for babies transferred to St George's Hospital for Post Mortem examination.

No anomalies were found. Staff stated that no material is stored in areas outside the mortuary and the laboratory. Another HTA establishment is used for the storage of archived histopathology samples in the form of wax blocks and associated microscope slides and the establishment confirmed that no material retained since the commencement of the HT Act is held there without consent.

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.	There is no Standard Operating Procedure (SOP) for seeking consent for an adult hospital PM examination, which outlines the process for members of staff undertaking the task and ensures that the requirements of the HT Act and codes of practice are met.	**Minor**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Members of staff seeking consent for adult hospital post mortem examinations within the Trust are not formally trained to ensure that fully informed consent is obtained from the most appropriate person in the hierarchy of qualifying relationships, as set out in the HT Act. Advice and guidance is given below to help the Designated Individual address this shortfall.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Members of the portering staff are responsible for out of hours access to the mortuary to admit bodies of the deceased from the community and the hospital wards. They also oversee any emergencies such as fridge failure/alarm call outs during these periods. There is no formal training in place or systems to assess the competency of porters or their compliance with mortuary operating procedures, and there is no oversight by mortuary staff of mortuary activity out of hours. Portering staff should be fully trained to undertake their responsibilities with regard to the mortuary, which should include where to place bodies, what paperwork to complete and how to report an untoward incident. Advice and guidance is given below to help address this shortfall.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1, C3	The DI is advised to update the current policy governing consent for adult hospital PM examinations to include: • who can give consent and the hierarchy of qualifying relationships • training requirements for staff taking consentcontact details for families wishing to withdraw consent. There should be a comprehensive training programme for staff involved in taking consent to ensure their understanding of the policy and the legal framework on which it is based. The training programme should include records of training and assessment of competency.
2.	C3	Bereavement staff are often asked to witness consent being taken by a member of the clinical team, to ensure that appropriate consent under the HT Act is given. However, these members of staff have not undergone formal consent training. The DI is advised to consider training the bereavement staff in the consent process. The DI may also wish to

		consider whether mortuary staff might support the consent process. The Association of Anatomical Pathology Technology (AAPT) holds an annual Consent Training Day, which may be of interest to mortuary and bereavement staff (http://www.aaptuk.org/go/events).
3.	GQ1	The HTA reviewed standard operating procedures and made the following observations, which the DI is advised to address: • some controlled documents are written and authorised by the same member of staff, and are therefore not subject to independent review prior to distribution; review of drafts by a person other than the author helps ensure that the document reflects working practice and that any errors or inaccuracies are rectified before the document is published • some controlled documents have the standard template footer, which does not reflect the content of the document or include the date or version number. • SOP 27 makes reference to the Hospital Post Mortem Examination form being used for neonatal and paediatric cases, rather than the SANDs form that is now used across departments. Mortuary SOPs should be subject to a system of review and version control to ensure the accuracy of their contents and staff should only have access to the current approved version.
4.	GQ1, GQ4	Methods of amending errors in the mortuary register are inconsistent and so it is unclear who has made amendments and when they did so. The DI is advised to ensure that corrections to data are made in a manner that allows sight of the original entries and that corrections are accompanied by a reason for the change and are initialled and dated. The DI is advised to ensure the new procedure is documented.
5.	GQ2	The DI is advised to update the quality manual to reflect the current management structure within departments where HTA-licensed activities take place, to include the reporting lines and relationships between the DI and those involved in licensed activities.
6.	GQ2, GQ7	The DI is advised to introduce a standard agenda for meetings with staff involved in licensable activities, to include HTA updates via the HTA newsletter and HTARI reporting information. This meeting should be added to the governance group meetings listed in the quality manual as part of the governance arrangements to increase awareness of the HTA standards and licensable activities.
7.	GQ2	The mortuary carries out regular comprehensive horizontal audits against HTA standards. The DI is advised to consider a receipt process for tissue transferred throughout Surrey Pathology Services (SPS). The DI is advised to further consider extending the horizontal tissue traceability audits across Royal Surrey Hospital as evidence of traceability to comply with HTA standards.

8.	GQ3	The DI is advised to consider whether members of staff from the wider network of Surrey Pathology Services (SPS) could be used to provide cover during periods of high demand and staff leave. Staff at the establishment may also benefit from protected time for learning and development, particularly the member of mortuary staff who is currently in training.
9.	GQ6	The mortuary register reference number and post mortem number are not unique to the deceased and work on a rolling year number. The DI is advised to add the year to the existing formats, making the numbers unique and thereby reducing the risk of misidentification.
10.	GQ6	Bodies awaiting the repatriation of tissue or organs are not highlighted in the mortuary register, on the mortuary database or on the body. The DI is advised to reduce the risk of releasing the body prior to repatriation by implementing a system that identifies these, for example by using a colour system similar to that in place for bodies with same name or similar
11.	PFE2	A deep clean of the fridges in the body store room of the mortuary is conducted twice yearly. The DI is advised to document the decontamination schedule, ensuring there is a record of completion for the procedure.
12.	PFE3	A contingency plan is in place to use the facilities of a local funeral director in the event that capacity is reached; however there is no formal agreement outlining the service to be provided. A service level agreement will define the roles and responsibilities of each party and the level of service required in the event of an emergency.
13.	PFE5	There was no documentary evidence that checks of air changes in the PM room had been undertaken since 2005. The DI is advised to ensure that regular checks are undertaken and recorded.
14.	-	The DI is advised to consider identifying a Person Designated (PD) in the Maternity Department to help ensure compliance with HTA requirements in that area.

Concluding comments

Examples of good practice were observed during the inspection. There are strong practices in place to maintain traceability of bodies and tissue in and out of the mortuary; for example, the use of a patient information chart, which documents the deceased's details from admission to release, also recording any investigations and sampes taken.There is also a comprehensive audit schedule which incorporates a monthly audit of retained tissue within the mortuary.

The senior Anatomical Pathology Technologist had been awarded a Certificate of Achievement following a letter from a local Spiritual Leader, who praised her respect for the deceased and her commitment to ensuring their dignity; this included acknowledging their religious beliefs and facilitating ritual washing where requested by families.

Maternity bereavement services offer an extremely sensitive and responsive service for bereaved parents, for example by providinge keepsakes. The maternity suite also has a cold room as part of the department so babies do not need to be transferred to the mortuary away from parents.

There were a number of areas of practice that required improvement, including three minor shortfalls. The HTA has given advice to the Designated Individual with respect to developing communication with the departments under the licence as well as with other DIs within SPS.

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: 3 January 2014

Final report issued: 21 January 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: 26 June 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 program 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 is 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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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 program 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.