Site visit inspection report on compliance with HTA minimum standards

Colchester General Hospital

HTA licensing number 11104

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**

18 February 2014

Summary of inspection findings

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

Although the HTA found that Colchester General Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found, particularly in relation to the governance and quality standards.

Two minor shortfalls were identified during the inspection relating to tissue traceability and reporting serious adverse events to the HTA. Additionally it was determined that the off-site tissue processing laboratory, where post mortem tissue is processed into blocks and slides for review by pathologists, requires licensing as it is storing tissue for use for a scheduled purpose.

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 consists of a body store and post mortem suite at the Colchester General Hospital site. Tissue taken during post mortem examinations is processed into blocks and slides, which are then reviewed by pathologists. The processing of tissue and review by pathologists takes place at an off-site facility called Chestnut Villa, which is currently unlicensed; however, as it is storing tissue for use for a scheduled purpose, a licence is required. Although tissue is stored at the Chestnut Villa site, storage is not permanent and, following review by a pathologist, blocks and slides are returned to the mortuary at the main hospital site for archiving or disposal in accordance with the family's wishes. The Chestnut Villa site was visited during the inspection and a review of the histopathology laboratory's procedures relating to tissue taken during post mortem examination was undertaken. During the inspection the DI was informed that the Chestnut Villa site requires a licence.

The establishment undertakes adult post mortem examinations, either on behalf of the Coroner or with the consent of the deceased's family where there is clinical interest in a case. Paediatric cases are sent to another HTA-licensed establishment for post mortem examination. Around 830 adult post mortem examinations are performed by the establishment annually (including 20 Home Office cases).

Prior to the inspection, the DI confirmed that there are areas within the hospital outside of the mortuary where storage or the licensable activity of removing tissue from the body of the

deceased takes place. As a result, during the inspection the Accident and Emergency and the Maternity departments were visited. Staff working in these two areas were interviewed to ascertain the nature of the activity taking place.

In the Maternity department, the remains of stillborn infants or miscarriages may be stored prior to being moved to the mortuary so that, where appropriate, families have the opportunity to view the infants while on the ward. Remains are stored in a fridge that is kept in a small room, away from the main ward. Occasionally, maternity department staff assist in the seeking of consent for paediatric post mortem examinations. Staff have attended training at the licensed establishment undertaking the examinations. Currently the storage fridge is not temperature monitored nor has there been a Person Designated nominated within the department to act as a point of contact for the DI responsible for overseeing licensable activities.

In the Accident and Emergency (A&E) department, samples may be taken from infants that have died en-route to the hospital or within it. These samples are taken with oversight of registered medical practitioners in a suitable area within children's A&E. Staff in children's A&E have packs to guide them, including a list of samples to be taken. Written information is available and can be shared with the parents as necessary. The guidelines in the department make it clear that only certain samples can be taken and that the Coroner should be notified; printed checklists help to ensure that this occurs. Again, there has there been no Person Designated nominated within the department to act as point of contact for the DI.

This was the third site-visit inspection of the establishment and was a routine inspection to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit inspection was developed in consideration of the establishment's last self assessed compliance information, as well as pre-inspection discussions with the DI and review of the previous inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

An audit of bodies stored in the establishment's fridges was undertaken during the inspection. Three bodies were chosen at random and identification details recorded on body tags were checked against details in the mortuary register and on the mortuary fridge doors. No anomalies were found during this audit.

Tissue traceability audits were also undertaken during the inspection. Details were taken of three coronial post mortem cases where tissue was taken during the examination. Details of the tissues retained at post mortem examination were cross checked between the mortuary's electronic records and the histopathology records. Additionally, the physical blocks and slides were located and again the numbers checked against the mortuary's electronic records and the histopathology records. Details of tissue taken are not entered into the histopathology's electronic laboratory system and are tracked using the histopathology request cards that accompany the tissue from the mortuary to the laboratory. These histopathology request cards were the records that were checked within the histopathology laboratory.

In all three cases, signed family wishes coronial forms were reviewed. Two of the three cases had additional notes indicating that tissue should be retained for legal purposes. These additional notes were hand written onto additional papers and there was no formal system to log the receipt of such requests. In the third case, the family had requested retention of the tissue. Generally one slide is cut for each block made; however, in some cases the pathologist may request special stains to be performed on additional slides. In reviewing the system for acting on the wishes of the family, the HTA established that if special stains are requested, this is recorded on histopathology request cards, which are held in the histopathology laboratory, prior to tissue being moved to the mortuary where the family's wishes are followed. As the mortuary has no oversight of the histopathology request cards, there is a lack of a formal system whereby the mortuary can be assured that all slides from a

particular case have been identified prior to acting on the family's wishes. The lack of a formal system to alert the mortuary to the number of slides cut in a particular case may increase the risk that not all of the slides are disposed of, returned to the family, released with the body or retained, in line with the wishes of the family. Therefore, when conducting the tissue traceability audit, the HTA reviewed traceability of sides in addition to tissue blocks.

In the three cases selected, all three cases had the expected number of blocks archived in the mortuary. In one case, the slides had not yet been transferred to the mortuary and remained at Chestnut Villa. However, it was confirmed that the expected number of slides were stored there. In the other two cases no anomalies were identified; however the correct number of slides to be expected was only ascertained during the inspection team's visit to Chestnut Villa as there is no system of tracking slides at the mortuary.

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 and Quality

Standard	Inspection findings	Level of shortfall
GQ4 There is a systematic and planned approach to the management of records. GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	As the mortuary has no oversight of the system for completing histopathology request cards, there is a lack of a formal system whereby the mortuary can be assured that all tissue from a particular case has been identified prior to acting on the family's wishes. Any formal system introduced should also include a mechanism to record instances where families have changed their wishes with regards to Post Mortem Tissue. For example, if the family initially wanted sensitive disposal of tissue but then later changed their mind to retention of tissue so that tissue was available for possible legal cases in the future such as asbestosis cases. In an instance such as this the DI is advised to consider recording details of when the information with the new wishes was received and from whom.	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The establishment has no documented procedure covering the reporting of serious adverse events that meet the reportable incident classification to the HTA. *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address the shortfall.*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(c)	Governance meetings occur on an ad hoc basis. The DI is advised to hold regular governance meetings covering items such as: reportable incidents, changes to Standard Operating Proceduress, audits, risk assessments and updates from the HTA (e.g. e-newsletter items).
2.	GQ2	The DI is advised to undertake vertical audits relating to tissues taken at post mortem examination on a more frequent basis and to add these audits into the establishment's audit schedule. Also, in addition to the Quality Manager's audit of compliance against the HTA's licensing standards, the DI is advised to undertake some process audits to assure herself that procedures are being followed correctly and documentation is being maintained appropriately.
3.	GQ8	The establishment has risk assessments in place covering some aspects of licensable activity; however, these relate mainly to health and safety issues. The DI is advised to expand the scope of the establishment's risk assessments so that they review more completely the risks associated with licensable activity. The DI may wish to consider using the HTA reportable incident (HTARI) categories as a basis on which to develop risk assessments.
4.	PFE2	During the inspection, staff were unclear about whether the ventilation in the post mortem suite was subject to checks to ensure that it is working effectively. The DI is advised to determine whether tests on air change rates have been undertaken and to review the results of these tests to ensure that the number of air changes remains appropriate. If these tests have not been undertaken, the DI is advised to arrange for checks to take place.
5.	PFE3	In the Maternity department the remains of still born infants or miscarriages are occasionally stored in a fridge that is kept in a small room, away from the main ward. The storage fridge's temperature is not routinely monitored and there are no temperature alarms in place should the fridge develop a fault and deviate from the expected temperature. The DI is advised to implement a system by which the fridge temperature is regularly monitored to help mitigate the risk of an equipment failure going unnoticed for an extended period. The DI may wish to consider the suggestion of the ward staff whereby a manual review of the fridge temperature is undertaken and recorded twice daily.
6.	PFE3	The main body storage fridges and freezers within the mortuary are linked to an alarm system which would alert staff to an equipment failure or temperature deviation both during the working day and out of hours. The DI is advised to periodically perform a manual challenge of the alarm system to assure herself that the system is functioning as expected and that the switchboard staff who initially receive the alarm notification follow the expected procedure.

7.	PFE4	Paediatric post mortem examinations are not undertaken at the establishment and are transferred to another licensed establishment by the establishment's Trust transportation service. When transferring these cases, the establishment documents the collection of the remains by asking the driver to sign an acknowledgment of collection. However, when leaving the remains at the other licensed establishment, there is no record of receipt. The DI is advised to request a signature from the member of staff at the other licensed establishment to acknowledge receipt of the remains so that this record can be returned to Colchester General Hospital by the Trusts driver and serve as a record of transportation.
8.	D2	The establishment's disposal procedure refers to the next of kin when discussing the wishes of the families of the deceased. The DI is advised to amend the wording within the document to reflect qualifying relationships and their hierarchy as set out in the Human Tissue Act 2004 and associated codes of practice.
9.	General	During the visits to the Maternity and Accident and Emergency departments it was noted that no Persons Designated (PD) have been appointed by the DI in those areas. The DI is advised to appoint a PD in each of these areas to act as a contact point in relation to the licensed activity taking place. In this way, the DI will be made aware of any issues that arise and will, in turn, be better able to disseminate any licensing updates or information to staff in these areas. The DI is also advised to invite the PDs to governance meetings so that information regarding licensable activity can be shared.

Concluding comments

The establishment exhibits a willingness to adapt its processes in order to become more compliant with the legislation. Recently blocks and slides that have been reviewed by the pathologists have been transferred to the mortuary in an attempt to strengthen the tissue handling procedures at the establishment. Although a shortfall has been identified with regards to tissue traceability, it should be noted that the establishment has only recently adopted this new procedure and is still developing its processes.

The establishment adopts a rigorous approach to training covering the seeking of consent for adult post mortem examination. Mortuary staff speak with the clinician prior to consent being sought and discuss key aspects of the post mortem examination. New members of staff being trained in the seeking of consent undertake the Association of Anatomical Pathology Technicians training and observe several consent processes in order to familiarise themselves with the process and requirements.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the Designated Individual with respect to governance and quality system standards, and premises, facilities and equipment standards. Additionally, general advice to update the licensing structure at the establishment so that all areas and premises are appropriately licensed has been given.

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: 18 March 2014

Report returned from DI: 1 April 2014

Final report issued: 22 April 2014

Inspection CAPA Plan Closure Statement:

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: 9 September 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.

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

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

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

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.