Site visit inspection report on compliance with HTA minimum standards

Queen's Medical Centre

HTA licensing number 12258

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

9-11 August 2016

Summary of inspection findings

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

Queen's Medical Centre (the establishment) was found to have met all HTA standards.

Particular examples of 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

This report refers to the activities carried out at Queen's Medical Centre (the hub) and City Hospital (the satellite) of the Nottingham University Hospitals NHS Trust. As well as post-mortem related activity, the establishment houses The National Repository Centre at its satellite site, where fresh frozen bodies and body parts are stored for use in surgical skills training. It also stores other material for use for scheduled purposes, principally research and education and training.

Pathology services at Nottingham University Hospitals NHS Trust have merged with those of University Hospitals of Leicester NHS Trust to form a partnership known as empath. Under this arrangement, some managerial staff, who are under the management of empath, work between the two Trusts. For the purposes of HTA licensing, the Designated Individual (DI) is a Consultant Neuropathologist employed by the Nottingham University Hospitals NHS Trust. The Corporate Licence Holder (CLH) is the NHS Trust, with the Chief Executive of City Hospital acting as the CLH contact. A Person Designated (PD) has been identified in each area where licensable activity is carried out to oversee activities on behalf of the DI. A Quality Manager oversees governance at both sites.

This was the third routine site visit inspection of the establishment since it was licensed in 2007 (the last inspection having taken place in 2012). The inspection included a visual inspection of the body stores, PM suite, high-risk PM room, storage area for potted specimens that pre-date the HT Act used for training and education, archived PM blocks and slides, and formalin fixed brains for research.

Areas where material is stored and removal of tissue from the deceased may take place, other than the mortuary, were also visited. These included the maternity ward, neo-natal intensive care unit, the early pregnancy unit, paediatric intensive care unit and A&E at the hub site and maternity ward and neonatal unit at the satellite site, where removal of tissue may take place in cases of Sudden Unexpected Death in Infancy (SUDI).

The inspection included interviews with members of staff and a review of governance and quality documentation.

Approximately 2,400 PM examinations are carried out each year at the hub site. These include Coroner's cases for the districts of Central Lincolnshire and Nottinghamshire, hospital consented, paediatric, perinatal, specialist, high-risk, defence, and forensic PM examinations. The establishment also receives referrals from other hospitals.

Consent for adult PM examinations is sought by bereavement staff. Consent for perinatal and paediatric cases is taken by bereavement staff in the presence of the attending clinician. The same consent forms are used for adult, perinatal and paediatric cases. There is a separate patient information leaflet relating to perinatal and peadiatric cases.

Queen's Medical Centre

The mortuary service is staffed by eight Anatomical Pathology Technologists (APTs), two of whom are trainee APTs. An End of Life Support Officer from Bereavement Services helps with mortuary administrative duties such as admission and release of bodies.

The mortuary has 368 fridge spaces, including ten freezer spaces, four bariatric spaces and dedicated spaces for paediatric and forensic cases. These spaces are in three separate storage areas: the main storage area, undercroft storage 1 and undercroft storage 2. The main area, not accessed by porters, has 90 spaces where bodies are stored prior to PM examination and release. Undercroft storage 1 has 189 spaces, and is used by porters to admit bodies in and out of hours. Undercroft storage 2 has 89 spaces and serves as longer-term storage for bodies. There is contingency storage available at other hospitals within the Trust.

All fridge and freezer temperatures are checked and documented daily and there is an electronic alarm system, which alerts staff in case the fridge temperature goes below or above the set limits. Staff participate in an on-call rota and are called to attend the mortuary in an emergency.

When a body is admitted to the mortuary from the wards, porters bring it to undercroft storage 1, place it in the selected fridge space and write the deceased's name on the fridge door. Porters then fill out a notification of death card and put the card in a dedicated box outside the main body storage area. After bodies are admitted, mortuary staff check the identification details on the notification of death card against the identification tags on the body, as well as the condition of the body, and then enter the details into the mortuary database. Porters must be trained and signed off as competent before doing any work in the mortuary.

Body release is only arranged after funeral directors confirm the identification details with mortuary staff and make an appointment to collect the body. Funeral directors must present the relevant paperwork before release. At least three identifiers are checked when releasing a body. These include the full name, address and date of birth for hospital deaths and full name, date of birth, and another identifier available, such as the last known address of the deceased, in cases of community deaths.

Access to the mortuary is by swipe card and there is CCTV, providing additional security.

The PM suite has four downdraft tables. There is a dissection bench that is used for examination of organs by the pathologists. Organs are dissected by the Pathologist one case

at a time. There is a number on the PM table that corresponds with a number on the organ tray to mitigate the risk of returning organs to the wrong body. Paediatric and perinatal PM examinations are carried out in a designated area within the PM room. There is a high-risk room where PM examinations up to category three are carried out. The air handling unit for the PM and high-risk room is serviced regularly and service records were observed to be up to date.

Tissue retained at PM examination is transferred as wet tissue to the Histology department in the hospital, where it is cassetted, fixed, analysed and then stored or disposed of according to the wishes of the family.

Audit trails were conducted on four adult bodies stored in the refrigerators. Three of the bodies shared the same surname as other bodies in the mortuary. Body location and identification details were cross referenced against the information on wrist tags, and the mortuary database. Systems for same/similar names were also checked against standard operating procedures.

An audit trail was also conducted on one coronial and one hospital consented (adult) PM case where histology samples had been retained during the PM examination. Paper records, computer records, consent forms and location of the samples in storage areas were checked. No anomalies were found in any of the audits.

Storage of potted specimens and neuropathological archive

There is a room at the hub site where around 3 to 5,000 potted specimens that pre-date the HT Act are stored. They are in a locked, restricted access, room. All the specimens have been cataloged and entered into the computer database. The DI plans to use the specimens for teaching pathology to medical students from the University of Nottingham. Formalin fixed brains, consented for use for research, are also stored here.

A traceability audit was conducted on two of the potted specimens. The number on the specimen pots were cross-referenced with the records on the database. No discrepancies were found.

An audit trail was also conducted on a formalin fixed brain that was taken and retained in the archive for a research project. Consent forms were cross-referenced with computer records and identification numbers on the container of the brain. No discrepancies were found.

City Hospital

The satellite site at City Hospital is used as a body store for storage of bodies prior to release or transfer to the hub site for PM examination. No post-mortem (PM) examinations are undertaken at this site.

The body store has 75 fridge spaces. This includes three bariatric spaces and dedicated spaces for paediatric and perinatal bodies. In addition, there is a walk-in freezer in which body parts from bodies that have been donated for use in medical education, training and research to the National Repository Centre are stored.

There is key access into the mortuary. The satellite site uses the same alarm system as the hub site. Temperatures of the fridges in the mortuary and freezer for the repository are monitored and recorded daily.

Bodies admitted and released at the satellite site follow the same process as the hub site.

When a body has been transferred to the hub site for PM examination, and authorisation for release has been received, the body is released from the hub site.

When bodies are admitted to the National Repository, blood is taken for serological testing. Bodies are given a unique identifier and are temporarily stored in a fridge while waiting for the results of testing. Once the results are confirmed as negative, the bodies are prepared for storage in a separate preparation room. The body is cut into sections and each section is labelled with the unique number of the body and a letter suffix. Each part is then wrapped, sealed in a separate plastic bag and placed in the freezer for storage. Each unique identifier is entered into the database which is used to track the movement of body parts. When body parts are needed in courses, they are packed in a special container and transported by an approved carrier or by staff working at the repository. A chain of custody sheet and a Material Transfer Agreement (MTA) always accompanies the parts, these being signed off by the DI and the Repository Manager.

Consent for donation is always given by the donor in life, and covers use of their body for medical education, training and research. In the majority of cases, bodies are referred to the Repository from the University of Nottingham Medical School; some donors liaise directly with the Repository Manager before their death. The Repository may also receive referrals from other medical schools that cannot accept the donated body. In cases of referrals, a secondary confirmation is sought from the family to ensure they agree to the donation.

When the body parts are no longer useable, usually within a period of two years, they are prepared for disposal. All parts belonging to the donor are reunited before disposal, placed in a coffin and sent for cremation, unless the family have made their own arrangements. Families are given the option to attend the cremation service.

Audit trails were conducted on three body parts in freezer storage. Identification details on the body parts/bags were checked and compared with consent documentation, receipt and release records, and the computer database records. No anomalies were found.

Tissue Biobank

The satellite site has a Research Tissue Bank (RTB) which has generic NHS Research Ethics Committee approval. All tissue that is accepted into the Biobank is taken from the living. Consent is sought by staff who must be trained in consent procedures and signed off as competent before doing so. Once tissue is taken, it is stored temporarily in a -80 ºC freezer at the hub site for a few days before being transferred to the satellite site for storage in a -80 ºC freezer. Staff at the establishment enter patient information into the database and anonymise the tissue by assigning each sample a unique ID number. Researchers using the sample only have access to this unique ID number and only key staff have access to the linking database.

All freezers containing tissue stored under the HTA licence are in a locked room and access is controlled and monitored. Freezer temperatures are monitored daily and recorded. The freezers are connected to the same electronic alarm system as the fridges in the mortuary and staff participate in an on-call rota and are notified in case of an emergency. There are back-up freezers which are labelled so staff immediately know where to move tissue to in case of a freezer failure.

A traceability audit was conducted on two samples selected from the Biobank's database. Information held within the database was compared with that on consent forms and the samples in storage in the Biobank were located. A reverse traceability audit was also conducted on four samples located in freezer storage in the Biobank and cross-referenced against the database. No discrepancies were found.

Materials held for the police

Under s39 of the Human Tissue Act 2004, 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' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored at the hub site were reviewed by the HTA during the 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 DI and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

The HTA found the establishment to be compliant with all applicable HTA standards.

Advice

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

No	Standard	Advice
1.	C1	The DI is advised that when PM examination consent forms used by the establishment are updated, there are procedures in place to notify referring establishments of the changes.
2.	GQ2	The DI is advised to incorporate peer review of the consent seeking process for adult and perinatal PM examinations into audits.
3.	PFE3	The DI is advised to schedule manual checks of the fridge temperature alarms to ensure that they are operating as expected. This should include checks that the system notifies appropriate staff and that alarm notifications are responded to appropriately. These checks, and any resulting actions, should be documented.
4.	PFE3	There is a computer system that logs fridge temperatures daily and the records produced are periodically reviewed by staff for trends. The DI is advised to document this review.

Concluding comments

Many areas of good practice were observed:

- In addition to audits of mortuary activities, the DI and the Quality Manager carry out a yearly visit to all areas where licensable activities take place to check the activities taking place under the licence and to review procedures. Visits are documented and any follow up actions are acted upon.

- The mortuary database has a traffic light system that staff use to monitor the condition of bodies for viewing which highlights when bodies should be moved into long-term storage.

- Governance processes require PDs to assess activities and facilities at their premises and report this yearly.

- There appears to be good communication between staff in all areas where licensed activities take place, supported by the establishment's Human Tissue Management Group, which oversees governance of these activities.

- Staff who seek consent for tissue to be stored in the Biobank for use for research must shadow a trained member of staff for a minimum of four sessions and be signed off as competent before seeking consent on their own.

- At various areas where licensable activity is carried out, laminated document controlled work instructions or standard operating procedures are affixed to walls to provide guidance to staff.

The HTA has given advice to the DI relating to aspects of consent, governance and quality and premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 6 September 2016

Report returned from DI: 21 September 2016

Final report issued: 22 September 2016

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.