Site visit inspection report on performance against HTA quality standards
Newcastle Upon Tyne Hospitals NHS Trust

HTA licensing number 12341

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**

27 and 28 July 2011

Executive Summary

A site visit inspection of Newcastle Upon Tyne Hospital NHS Trust (the establishment) was carried out by the HTA on 27 and 28 July 2011. The main site where licensed activity takes place, the Royal Victoria Infirmary, Newcastle, was inspected on the 27 July and the Freeman Hospital, Newcastle, a satellite of the main site was inspected on 28 July.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Some shortfalls were found, particularly in relation to Consent and Premises, Facilities and Equipment. In addition, the HTA found that post mortem samples were being stored on unlicensed premises, contrary to the requirements of the HT Act. This breach of legislative requirements was rectified soon after the inspection.

Any particular examples of strengths or good practice are included in the concluding comments section of the report.

The HTA took the breach of legislative requirements into consideration when assessing the suitability of the Designated Individual (see concluding comments). 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.

All 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 Royal Victoria Infirmary ("the hub") and the Freeman Hospital ("the satellite") carry out coronial and hospital post mortem examinations. The establishment carries out coronial post mortems instructed by 12 coroners and paediatric post mortems referred from nine other NHS Trusts.

In total, the hub and satellite carry out approximately 750 coronial post mortems, including Home Office post mortems, and 350 consented post mortems per annum, the vast majority of those being paediatric, with only around15 adult consented post mortems carried out a year.

The establishment carries out post mortems of known high risk cases at both sites, and the hub has a specific post mortem suite dedicated to such cases.

There are ample body storage facilities, with 105 spaces at the hub and 95 at the satellite. There is provision for storage of bariatric bodies, as well as provision for longer term storage in freezers, and there is allocated storage for babies and products of conception. All storage fridges and freezers are linked to an automated alarm system which notifies of open doors, temperature rises and compressor output falling. The first alarm is dealt with by on call engineering staff and, if they cannot rectify the issue, on call mortuary staff are then called to move bodies to other storage.

When bodies are received from within the hospital out of normal working hours, portering staff transfer the body to the mortuary, place them into storage and log details in the mortuary register. Similarly, bodies received from outside the hospital are delivered by undertakers, accompanied by portering staff, who complete the register and place the body in storage.

Mortuary staff check the register and enter details into the APEX software system on their return to the mortuary.

Traceability of bodies is by name and a unique release number allocated by the bereavement office, together with a specific body number, these being used to ensure correct release in due course. Where a post mortem examination is carried out, there is also a post mortem reference number, with a prefix indicating the origin of the body. This number is barcoded and accompanies any tissues taken during the post mortem examination. Pathologists record details of tissues and organs taken for examination on histopathology sheets, which accompany the organs or tissue through the laboratory. The laboratory database records the number of blocks and slides produced.

Hospital post mortems are carried out at both sites. Consent for these is taken in the main by clinicians and there is an on-line consent training course provided by the DI. Although not all clinicians have completed the course, most of those taking consent for hospital consented post mortems, which amount to approximately 13 a year, have done so. Perinatal autopsies are carried out at both sites. Consent for these post mortems is taken in the maternity ward by trained consultant obstetricians. Tissues taken during post mortem at the satellite are transferred by courier to the hub for processing and storage.

Where perinatal autopsies are carried out on bodies referred from other trusts, consent is taken at those other trusts using the establishment's consent documentation. When received, staff check that any bodies referred for autopsy are accompanied with completed consent forms.

Storage of organs, tissue blocks and slides takes place at the hub. During the course of the inspection, the HTA became aware that blocks and slides were being stored off site in a storage unit owned and managed by the trust. This storage facility is not licensed by the HTA.

The establishment has been inspected previously, in May 2008.

The 2011 inspection comprised a visual inspection at each site, including a visit to the off site storage unit, review of relevant documentation and interviews with key staff.

An audit of traceability was carried out as follows.

At the hub, the details of three bodies in storage were compared against entries in the mortuary register, and details of one were also checked on the database.

In two cases, tissues taken during post mortem were tracked through the laboratory process to storage. In all cases, the appropriate consent forms or coroners authorisations were seen.

Two organs being retained pending disposal instructions were checked against the records kept by the establishment

Minor documentary discrepancies were found in two cases, but overall the results of the audit were satisfactory.

At the off site storage facility, blocks were located for two cases and these were subsequently traced back to slides stored at the hub and to the electronic record. Some minor discrepancies were found in the number of slides recorded on the electronic record, which related to additional slides being prepared but not stained and thus not recorded on the electronic record as a prepared slide. When this was taken into account, the number of slides located matched with the records kept but the method of recording meant there was the potential for confusion.

Although there was no specific record detailing that individual blocks or slides had been transferred to off site storage, the establishment moves material in monthly batches, which means that the principal location is easily noted. A further database spreadsheet provides details of the location of blocks and slides within the unit and storage drawers are labelled with consecutive numbers, ensuring traceability.

Meeting the HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable and the HTA was satisfied that this was the case, subject to the requirement to address the licensing issue arising from off site storage.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

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.	All staff involved in the licensed activity understood the need for tissue to be stored specifically for use for a scheduled purpose and it was clear that tissues were being retained for those purposes. The majority of staff involved in taking consent for hospital post mortems have undertaken an on-line training course. The information in the course relating to adult post mortems makes reference to storage of retained tissues as part of the medical record and is not clear on the need for this to be for a scheduled purpose, though separately refers to consent for storage for use in research and training. This information was drafted several years ago and has not been updated. The information provided in the training course in relation to consent for perinatal post mortems is correct, but the consent form used for these is out of date and refers to storage as part of the medical record, again without reference to use for scheduled purpose. The DI has prepared a newer version of the consent form which corrects this, but at the time of inspection, this was in draft form and had not been issued to those involved in taking consent. The HTA considers there to be a low risk of consent to post mortem being taken inappropriately, as staff involved in that process appeared to be cogniscent of the legislative requirements.	**Minor**
C2 Information about the consent process is provided and in a variety of formats.	While the information provided verbally to those granting consent appears to follow the requirements of the HTA and is in line with the Code of Practice on consent, the leaflet provided to those consenting to adult hospital post mortems is out of date, dating from 2003. As such it does not reference the HTA or Codes of Practice and contains reference to indefinite storage as part of the medical record without specifying the potential uses to which the tissue may be put and ensuing that valid consent is in place.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	Some post mortem blocks and slides are stored in an off-site storage unit, which is not currently licensed by the HTA. This is in breach of the legislative requirement that relevant material which has come from a human body, if stored for a scheduled purpose, must be stored under the authority of a licence from the HTA. An application for a satellite licence relating to the off site storage facility was made shortly after the inspection and has been approved. Accordingly this shortfall has been addressed by the establishment and no further action is required.	**Major**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	C2	The DI is advised to ensure that any training material for consent takers and patient information material given to family members is reviewed to ensure that the information contained therein is up to date and reflects the requirements of the HTA's Code of Practice on Consent. He is also advised to ensure that any other establishments for which post mortems are undertaken are using up to date consent forms training material and information..
2.	C3	The DI is advised to consider how he can satisfy himself that only those clinicians who have completed the on-line training on consent for a hospital post mortem are involved in the taking of that consent, or whether a limited number of individuals within the Trust should be trained, who will attend with clinicians for the purposes of taking informed consent for a hospital post mortem.
3.	GQ2	The DI is advised to schedule vertical audits relating to storage of slides into the existing audit schedule.Should these audits identify a trend where there is discrepancy or confusion between the number of slides retained in physical storage and the details retained on the database, steps to address that issue should be taken.
4.		The DI is advised to enter into discussion with the Coroner in each of the coronial districts with which the establishment has a relationship with a view to rationalising the format of the various different forms used by individual coroners. These should ensure that the options provided to relatives for retention, return, repatriation or disposal of organs or tissues taken during post mortem examination are unambiguous and reflect the need for any retention of tissue by the establishment, with consent of the consentor, to be for use for a scheduled

		purpose, and not simply as part of the medical record.

Concluding comments

Both the hub and satellite sites are modern mortuary facilities, which have ample storage space for the number of cases dealt with per year. In addition, the fact that there are two facilities within reasonably close proximity to each other allows for contingency planning in case of systems failure.

Staff at the establishment were seen to be enthusiastic about their work and there appeared to be a great deal of communication between mortuary staff, laboratory staff and pathologists on both sites. There has evidently been good teamworking in formulating the systems used within the establishment.

The DI maintains good contact with staff at both sites and regularly attends at both. The Licence Holder Contact is also very well informed about the licensed activities carried out.

The off site storage of tissue blocks and slides on unlicensed premises caused the HTA some concern. However, it appeared clear to the HTA that storage involved primarily large numbers of blocks and slides from surgical and diagnostic cases, with the post mortem material forming a very small proportion and that there had been a misunderstanding regarding the extent of the satellite licence. Given the otherwise good oversight and involvement the DI has regarding the licensed activity, and his prompt action to rectify the issue, the HTA find him suitable to perform his role as a DI.

The DI is aware that there is a risk of clinicians who have not yet completed the on-line training on consent being involved in taking consent and has proposed that specific staff within the Trust are trained to accompany clinicians seeking consent for a hospital post mortem.

Various elements of good practice were seen on inspection, including:

- The system whereby at all critical stages there is a double check of identity details;
- The use of specific release numbers for bodies meaning that undertakers cannot request the removal of a body without authorisation from the bereavement office, as well as confirmation from the family or coroner that the body can be released;
- The use of laminated slips applied to body store doors to indicate potential issues such as same or similar name, infection risk, the request for repatriation of tissues/organs and consent for a limited post mortem only;
- The system of monitoring of storage fridges at both sites, which are subject to daily temperature recording as well as a call out alarm with initial back up from an on–site engineer and then from mortuary staff;
- The well developed audit system, which includes audit of records, processes and practices against SOPs within the mortuary on a monthly basis, ensuring that even experienced staff maintain their knowledge of operational procedures;
- Traceability systems, though complicated, appear to be robust and have been developed to ensure almost identical processes at both sites, with the mortuary imposing specific requirements on undertakers for release of bodies
- The changes in practice in relation to visitor access and site security, which resulted

from risk assessment of the facilities;

- The enthusiasm and knowledge demonstrated by staff about their role in dealing with the relatives of the deceased and the great emphasis placed on communication with relatives;

- The patient-focused design of the hub facility, which includes specific viewing facilities for babies, infants and adults, and a special room for ritual washing;

- The good relationship of staff with Coroners and their officers from the various coronial districts with which they have dealings;

All staff appeared keen to take on board any suggestions made for improvement in practices and processes, and this positive approach was noted by the HTA.

Report sent to DI for factual accuracy: 11 August 2011

Report returned from DI: 5 September 2011

Final report issued: 23 September 2011

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.

Date: 30 December 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- 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.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 3: 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.