Site visit inspection report on compliance with HTA minimum standards

Southmead Hospital

HTA licensing number 12413

Licensed under the Human Tissue Act 2004 for the

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

4-5 September 2014

Summary of inspection findings

This inspection was conducted jointly with assessors from the United Kingdom Accreditation Service (UKAS), who assessed the mortuary against selected licensing standards on behalf of HTA.

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

Although the HTA found that Southmead Hospital (the establishment) had met the majority of the HTA standards, four minor shortfalls were found in relation to the information leaflet for perinatal and paediatric post mortem examinations, traceability of fetal specimens in the mortuary, training of portering staff and mortuary storage contingency plans.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual (DI) are set out in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The mortuary at Southmead Hospital ('the establishment'), North Bristol NHS Trust, stores deceased adults, neonates and fetal specimens admitted from within the Trust. The mortuary does not receive bodies from the community. No post-mortem (PM) examinations are conducted there; adult and perinatal/paediatric cases for PM examination are transferred to other HTA-licensed establishments. Adult cases are not returned to this establishment following PM examination. Paediatric / perinatal cases are returned, prior to release to the funeral director.

The establishment's pathologists perform adult coronial and hospital (consented) PM examinations at the mortuary to which these cases are sent. Tissue samples they retain for histopathological analysis are returned to the establishment for processing into paraffin wax-embedded tissue blocks and microscope slides.

The establishment has adopted the HTA's model consent form for adult hospital PM examinations. For perinatal/paediatric cases, it uses the consent form from the HTA-licensed establishment where the PM examinations are carried out. Consultant obstetricians or experienced registrars seek consent for intrauterine deaths; gynaecologists seek consent for very early pregnancy losses. A minor shortfall was identified in relation to the information leaflet for consented perinatal/paediatric PM examinations (refer to standard C2).

Since the previous site visit inspection in 2010, a new hospital build has been completed at the hub site. Its maintenance is managed by the private company which built the hospital. Mortuary activities transferred there from the old hospital building in May 2014. The new mortuary has 58 fridge and freezer spaces, including dedicated spaces for storage of bariatric and superbariatric patients. One set of fridge trays is set aside exclusively for fetal specimens. An alarm rings in the Estates office should fridge or freezer temperatures fall outside expected limits (refer to advice item 8). The body store at Frenchay Hospital, which is licensed by the HTA as a satellite site of Southmead Hospital, has been decommissioned.

In addition to the storage of bodies prior to PM examination, storage of relevant material for use for scheduled purposes also takes place under the establishment's HTA licences in the following areas:

- The Neuropathology Department, which stores formalin-fixed brains, paraffin-wax embedded brain tissue blocks and microscope slides from forensic, coronial and hospital PM examination cases for use for research. With appropriate consent, such material may be retained for use for scheduled purposes following the end of coronial authority. This collection will be moved from Frenchay Hospital to Southmead Hospital in 2015. The Department also houses a tissue bank of brain tumour and blood samples from living patients, which has National Research Ethics Service (NRES) Research Tissue Bank status. Consent for donation of these samples is sought by consultant neurosurgeons or research nurses. The Brain Tumour Bank Committee reviews applications from researchers requesting access to samples from the bank. Samples are released for use under material transfer agreements.
- The Respiratory Research Laboratory, which stores blood and pleural fluid samples from patients participating in clinical research trials. Donor consent is sought by consultant clinicians or research nurses. The majority of samples are stored for projects with favourable opinion from NHS Research Ethics Committees (RECs) and are thus exempt from the Human Tissue Act 2004's (the HT Act) licensing requirements for storage of relevant material for use for a scheduled purpose under the Human Tissue 2004 (Ethical Approval, Exemptions from Licensing and Supply of Information about Transplants) Regulations 2006. Samples collected for research projects whose ethical approval has now expired are stored under this licence. All samples are stored in –80 ^{o}C freezers.
- The Forensic Toxicology Department, which analyses post-mortem blood, vitreous humour and urine samples. With appropriate consent, samples can be retained following the end of coronial authority for the scheduled purpose of performance assessment. Samples are refrigerated at 4 ^{o}C prior to analysis and at −20 ^{o}C following analysis.

The establishment has been licensed by the HTA since July 2010. One previous site visit inspection took place in November 2010. This report describes the second routine site visit inspection of the establishment, which was conducted jointly with the United Kingdom Accreditation Service (UKAS). UKAS assessors visited the mortuary and assessed compliance with licensing standards GQ1-4, PFE1-5 and D1 on behalf of HTA.

The HTA inspector visited the mortuary and histopathology laboratory, and the areas listed above where relevant material is stored for use for scheduled purposes. They met with staff involved with licensable activities and reviewed documentation. Traceability audits were conducted on three PM examinations where tissue samples were taken for histopathological analysis (two coronial cases and one hospital case). In addition, samples from seven donors and the associated documentation were audited across the Neuropathology and Forensic Toxicology Departments and Respiratory Research Laboratory. No anomalies were found in any of these audits.

As well as tissue for use for research, the Neuropathology Department stores whole brains and samples of brain tissue under police authority. Under s39 of the HT Act, relevant material

held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority, that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process, police holdings were reviewed by 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.

North Bristol NHS Trust holds other HTA licences under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Human Tissue (Quality and Safety of Organs Intended for Transplantation) Regulations 2012 (licensing numbers 11143, 40048 respectively). South West Dementia Brain Bank, situated at Southmead Hospital, is licensed under the HT Act (licensing number 12273). Activities taking place under those licences were not reviewed at this inspection.

Inspection findings

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

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C2 Information about the consent process is provided and in a variety of formats.	The Trust's 'Hospital post mortem examination of a baby' information leaflet states that tissue blocks and slides are usually kept as part of the deceased child's medical record. The HTA considers blocks and slides stored as part of the deceased's medical record are being kept for potential use for a scheduled purpose and therefore valid consent must be obtained for their storage and use. This is not clear from the information provided to parents.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Portering staff admit bodies, neonates and fetal specimens into the mortuary. However, there is no formal programme of training in local procedures and key areas of risk for portering staff from staff working in the mortuary. Without specific training from mortuary staff on local procedures, and ongoing competence assessments for portering staff, the DI cannot be assured that operating procedures are being complied with and that suitable practices are taking place. *(Refer to advice item 4)*	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The Trust Chaplaincy Service oversees processes for the sensitive disposal of fetal specimens by cremation, including maintenance of traceability records and consent forms. Fetal specimens are stored in the mortuary fridges in a dedicated set of trays, and are cremated in batches every month. The process is set out in the 'Sensitive disposal of fetal tissue' flowchart. No records of receipt of fetal specimens into the mortuary are kept. This poses a risk to traceability. Any discrepancy is likely to be discovered only when specimens are being prepared for cremation by the Chaplaincy Service, at which point it may be too late to resolve them. Also, without local records, mortuary staff cannot perform audits of compliance with admission procedures for fetal specimens. *(Refer to advice item 2)*	**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.	Storage contingency arrangements, for example if the mortuary approaches full capacity or becomes temporarily unusable, have been considered, but are not formally documented.	**Minor**

Advice

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

No.	Standard	Advice
1.	C3	The DI is advised to maintain lists of staff who have been assessed as competent to seek donor consent for samples for research. The DI is also advised to assure himself through periodic audits that donor consent is being sought by staff from such lists.
2.	GQ1	Regarding mortuary documentation the DI is advised that: (a) the 'Sensitive disposal of fetal tissue' flowchart should be developed into a formal documented procedure. It should also make it clear to porters that: • the top tray in the dedicated bank of fridges for fetal specimens is not to be used, and; • that adult bodies are not to be placed in this bank of fridges. (b) standard operating procedures (SOPs) for the release of bodies to funeral

		directors, and for conducting viewings, should state clearly which of the deceased's person's identification details, such as their name, date of birth and hospital number, must be verified by staff. Regarding Neuropathology Department documentation the DI is advised that; • table 3.3 of the 'Tissue storage and disposal' SOP should clarify that storage of relevant material for use for scheduled purposes requires valid consent under the HT Act; • the hierarchy of qualifying relationships set out in the HT Act should be listed in the 'Autopsy dataset and reporting' SOP, so staff can verify if an appropriate person has consented for retention of relevant material for scheduled purposes after coronial authority ends; • there should be a documented procedure for undertaking tissue retention and consent audits.
3.	GQ2	Regarding quality management, the DI is advised: • to re-commence audits of the admission and release procedures of deceased persons. These procedures have not been audited since movement into the new mortuary; • to document the findings of tissue audits conducted in the Respiratory Research Laboratory; • to audit the wet tissues retained from PM examinations; • to update the version number of the Brain Tumour Tissue Bank consent form, which has undergone minor revisions.
4.	GQ3	Regarding staff training, the DI is advised: • to make hard copies of key SOPs and procedural flowcharts available in the mortuary for portering staff; • to assess competence of portering staff against documented procedures; • to ensure records are kept demonstrating mortuary staff have read new or amended SOPs. The DI may occasionally be required to admit and release deceased persons. His ongoing competence to perform these tasks should be assessed periodically, and records of such assessments maintained.
5.	GQ4	The DI is advised to set a defined retention period for the checklist used at admission of deceased persons to the mortuary. This checklist is a key traceability document as some information written on it is not recorded elsewhere.
6.	GQ7	The DI is advised to remind mortuary staff of the Pathology Incident Reporting process for reporting minor incidents and non-conformances.
7.	PFE5	Regarding mortuary body fridges and freezers, the DI is advised: • to confirm with the Estates Department the upper temperatures at which the fridge and freezer alarms are activated, and to state these in the relevant SOP; • to develop a regular schedule of testing for alarms, and; • to periodically audit fridge and freezer temperature logs, so any gradual upward or downward drifts, or excursions from appropriate limits, are

		identified.
8.	-	The DI is advised to nominate Persons Designated (PDs) in the Maternity Department and all laboratories where relevant material is stored for scheduled purposes. The DI is further advised to hold periodic governance meetings with all PDs to keep abreast on activities taking place under the HTA licence in those areas.

Concluding comments

Despite the four minor shortfalls, areas of strength were identified. There are robust processes for seeking consent for donation of research samples from living donors. There is a good working relationship with the local Coroner's Office, and tissue traceability systems are generally well maintained.

There are a number of areas of practice that require improvement, including four minor shortfalls. The HTA has given advice to the Designated Individual with respect to strengthening of governance and quality systems and documentation.

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: 20 October 2014

Report returned from DI: 3 November 2014

Final report issued: 3 November 2014

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 20 November 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.

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.