Site visit inspection report on compliance with HTA minimum standards

Royal Gwent and Nevill Hall Hospitals

HTA licensing number 12036

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**

13-14 May 2015

Summary of inspection findings

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

The Royal Gwent and Nevill Hall Hospitals (the establishment) was/were found to have met the majority of the HTA standards. However, four minor shortfalls were found in relation to standards on Governance and Quality and Premises, Facilities and Equipment.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

Background to the establishment and description of inspection activities undertaken

The establishment comprises Royal Gwent Hospital (RGH, 'the hub') and Nevill Hall Hospital (NHH, 'the satellite'). The hospitals are part of the Aneurin Bevan University Health Board and are based in Newport and Abergavenny, respectively. The establishment carries out approximately 900 post mortem (PM) examinations per annum. The majority of these are on behalf of HM Coroner, with only one or two hospital consented PM examinations per annum.

The mortuary at NHH carries out approximately 100-300 PM examinations on behalf of the Powys and Gwent Coroner. It has a body storage area with 40 spaces and additional temporary storage when required in the form of temporary racking erected within the mortuary. The mortuary at RGH carries out approximately 600 - 700 PM examinations on behalf of the Gwent Coroner. It has a body storage area with 71 spaces and additional temporary storage when required in a separate locked temperature-controlled room. Paediatric, forensic and suspected high-risk cases are transferred to other HTA-licensed establishments for post mortem examination. Consent for paediatric PM examinations is taken by the establishment's staff.

The procedures for admission of bodies of the deceased to the mortuary are the same at NHH and RGH. Bodies from within the hospital are brought to the mortuary by porters, accompanied by ward staff. Bodies from the community are accompanied by funeral services, ambulance staff or police, and are admitted by mortuary staff. A 'Mortuary Notification Sheet' detailing the deceased's name, address and place of death is placed onto the body, with a second copy placed on the shroud. If the deceased does not have a wrist-band (attached on the ward or by the police), a toe tag with their name and unique mortuary number is attached to a lower limb. At NHH this practice was not observed although it was described in the SOP (see shortfall in GQ3).

Release of bodies is controlled; funeral firms must present a Registrars Certificate (the green form) or the relevant certificate of release from HM Coroner. Details from the certificates are checked against the Mortuary Notification Sheet, wristband or toe tag and the mortuary register. The main identifiers checked are the name and address. At RGH, a daily alphabetical list is produced showing names of the deceased and their fridge location. This makes it easier to locate bodies for release and highlights any incidences of same or similar name. Bodies of deceased with similar names are highlighted on the mortuary whiteboard.

Pathologists may retain tissue for histology during PM examinations; these small samples are placed into plastic cassettes and there is no excess material. Tissue samples from both hospitals are processed into wax blocks and sections placed onto slides at RGH. Slides are sent to NHH for analysis as appropriate but are returned to RGH for retention or disposal depending on the consent that has been obtained by the Coroner's Officers. The Lead Anatomical Pathology Technician (APT) and Quality Officer at RGH and the Pathology Quality Manager at NHH carry out a quarterly look back audit on all blocks and slides from PM tissue and check that tissue has been retained or disposed of appropriately depending on the consent provided.

The establishment uses paediatric consent forms provided by University Hospital of Wales. The Maternity and Gynaecology wards are in the process of updating their guidance and procedures for handling deaths and miscarriages within their services. They are encompassing guidance and training provided by University Hospital of Wales and the recent HTA guidance on the sensitive handling of pregnancy remains.

This was the establishment's second routine inspection. The satellite (NHH) was visited on 13 May and the inspection encompassed a visual inspection of the mortuary, including the body storage area and PM suite, a document review and interviews with staff. The maternity ward was also visited. The hub (RGH) was visited on 14 May and the inspection encompassed a visual inspection of the mortuary, including the body storage area, PM suite and the histology laboratory, a document review and interviews with staff. The gynaecology ward was also visited.

Traceability audits were completed during the inspection. The first consisted of a simple body storage audit at each mortuary; two / three names were chosen from the whiteboard and the information sheet and wrist or foot identification and register entries were checked in each case. The second audit was conducted in the histology laboratory; an audit of the tissues retained and / or disposed of after histological examination was carried out. Paperwork, including consent forms, was checked and the procedure for tracing samples between NHH and RGH was discussed. No anomalies were found.

In relation to the premises, maintenance records for the air handling systems and the fridges were checked and found to be up to date.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	There are several examples of Standard Operating Procedures (SOPs) that do not reflect accurately the procedures carried out in the mortuary or contain sufficient detail: • SOP MO0002 does not describe the use of the patient information sheet placed on the patient and shroud at NHH and RGH. • SOP MO002 does not describe the procedure for highlighting patients with the same or similar names. • SOP MO0040 does not describe the movement of specimens between NHH and the RGH histopathology laboratory. • SOP MO0044 does not accurately describe the circumstances or procedure for transfer of patients between the mortuaries at NHH and RGH. • SOP MO0029 does not contain sufficient details regarding the creation of extra body space, e.g. there is no information about extra security measures or temperature monitoring of the temporary storage. • SOP MO0060 identifies the previous Designated Individual.	**Minor**

	• SOP MO0035 states that the temperature of the fridges should be recorded daily during working hours. Temperatures are not currently recorded for the fridges at NHH (see standard PFE3 below). Reviews of SOPs are not comprehensive and do not include all relevant or appropriate parties. For example, staff at NHH are not consulted when SOPs are reviewed. Q-Pulse was cited as the method for recording that staff had read and understood documents. The distribution list on Q-Pulse for critical mortuary SOPs did not include all APTs or the DI.	
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	There were several examples of staff at NHH not following procedures set out in SOPs: • SOPs MO0002, MO0071 and MO0020 state that an identification tag bearing the deceased's name and mortuary register number should be attached to the patient's lower limb. This labelling was not observed at NHH. • SOP MO0076 states that the cleaning schedule for the body store floor should be carried out fortnightly. This is currently carried out monthly at NHH. In addition, at the NHH, there is frequently only one APT for prolonged periods, with no evidence of additional training in aspects of the job that would normally be undertaken by the more experienced Deputy Lead APT, who is currently on long-term sickness absence. See advice item 4	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	In-patients at NHH and RGH are issued with wristbands. If patients die during their hospital stay, the wristbands are often removed by ward staff before they are transferred to the mortuary. This causes an unnecessary risk to traceability at NHH and RGH. The DI should liaise with staff responsible for end of life care at RGH and NHH in order to promote procedures that will ensure patients are clearly identifiable once transferred to the mortuary.	**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.	At the NHH, fridge temperatures are not recorded so there is no system for monitoring fridge temperatures. The fridge alarms are checked as part of a maintenance contract held with external engineers; however, the trigger points for alarms on fridges and freezers are not documented or known by the mortuary staff. The alarm trigger points must be set at limits that would ensure timely intervention in the event of a temperature deviation.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to appoint a Person Designated (PD) to cover the Maternity / Gynaecology wards. This will ensure that licensed activities taking place in these areas are brought within the governance arrangements relating to HTA licensed activities, for example by their attendance at meetings where HTA issues are discussed. Perinatal PM examinations are undertaken at another HTA licensed establishment. The PD should be encouraged to attend consent training provided by that establishment in order to keep up to date with any changes to consent procedures and to further develop links with staff responsible for PM examinations undertaken at that establishment.
2.	GQ1	The DI is advised to hold regular governance meetings with staff working under the licence. Minutes should be recorded.
3.	GQ2	The establishment carries out a range of audits that cover HTA standards; however, the audits do not cover compliance with documented procedures. The DI is advised to ensure that audits are more rigorous and include the content of and compliance with SOPs.
4.	GQ3	The HTA found evidence of staff at NHH not following SOPs (see GQ3 shortfall). The DI is advised to ensure that APTs are fully trained in all tasks necessary to their role. The DI should assess the different competencies required for the role of Deputy Lead APT and APT. Prolonged absence of the Deputy Lead APT may require further training of the existing APT and / or the appointment of locum staff.
5.		The procedure governing PM examination at RGH allows evisceration to take place before the pathologist has made a full examination of the body. There is no documented evidence of the competency of the APTs and there is no clear

		policy setting out the circumstances in which evisceration should not proceed prior to the arrival of the pathologist and their examination of the body, and who is accountable in the event that an error is made. This is contrary to guidance from the Royal College of Pathologists, which the DI is advised to consider implementing.
6.	GQ6	Although there was an excellent system for highlighting patients with similar names at RGH, this was not in evidence at NHH. There were at least two examples of patients with the same or similar names in the register at NHH. There was no indication that these were flagged up in the mortuary register or on the fridge door. The HTA is satisfied that the risk of an error in identification leading to PM examination on or release of the wrong body is mitigated by the use of the deceased's address for identification purposes. However, The DI is advised to ensure that the procedure followed at the RGH is adopted by staff at the NHH.
7.	GQ6	Slides containing tissue are prepared at RGH and sometimes sent to the pathologist at NHH. Once the pathologist has examined the slides, they are returned to RGH for storage or disposal. There is no overview of the slides during their time at NHH and return to RGH. The DI is advised to maintain full traceability of the movement of any tissue samples that are taken during PM examination.
8.	GQ8	Risk assessments do not fully cover potential risks to staff and to the deceased in their care for all activities. The DI is advised to ensure risk assessments cover areas such as the use of temporary body storage facilities and risks due to decreased staffing levels.
9.	PFE	The temporary body storage at RGH is currently located off a corridor that is accessible through four doors. One of these doors was found to be open during the inspection, although no bodies were in storage there at that time. The temporary body storage area itself is kept locked and large containers are moved in front of the door to obscure any view through the door. Security would be enhanced by ensuring this door remains locked.

Concluding comments

This report outlines the second HTA site visit inspection of Nevill Hall Hospital and Royal Gwent Hospital. Despite the shortfalls identified, areas of good practice were observed. Mortuary staff and attending funeral directors discuss the release of each body. Paperwork brought by the funeral director is carefully checked by the mortuary staff. An excellent system for identifying patients with similar names and quickly locating a patient's location in the bank of fridges is in place at RGH. A daily list of patients is compiled in alphabetical order and placed on the wall next to the whiteboard. This list allows bodies to be found quickly but is not relied upon for release. Staff at RGH place a high importance on providing a suitable and sensitive service for bereaved families when viewing takes place. A full audit of all tissue removed during PM examination is carried out at regular intervals and, in addition, pathologists employ tissue sampling techniques that ensure minimal tissue is removed from the body.

There are a number of areas of practice that require improvement, including four minor shortfalls. In addition, the HTA has given advice to the DI on a range of issues, including governance and quality systems and storage facilities.

The HTA requires that the DI 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: 12 June 2015

Report returned from DI: 16 June 2015

Final report issued: 03 July 2015

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: 15 June 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.