Site visit inspection report on compliance with HTA minimum standards

Scarborough General Hospital

HTA licensing number 12093

Licensed under the Human Tissue Act 2004 for the

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

18 September 2012

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.

Although the HTA found that Scarborough General Hospital (the establishment) had met the majority of the HTA standards, two major and three minor shortfalls were identified. A major shortfall has accumulated against the consent standards, due to several minor shortfalls found in relation to paediatric consent documentation and training. A further major shortfall was identified against standards relating to governance and quality systems, in particular, procedures in place for checking the identity of the deceased.

Currently, only one full-time member of staff works within the mortuary. They are supported by trained porters, who have taken on some additional mortuary duties and help cover the work of a part-time member of mortuary staff who is on long-term sick leave. Staff shortages have led to a weakening of procedures for checking the identity of bodies of the deceased transferred from wards to the mortuary. The establishment needs to address this major shortfall as a matter of priority, as it increases the risk of a PM examination being carried out

on the wrong body or the wrong body being released. The HTA noted that the establishment has put forward a business case for the recruitment of an additional member of mortuary staff, but that this has not yet been approved.

Some improvements in practice since the last inspection were noted. Further positive changes are anticipated as a result of consolidating working practices between Scarborough General Hospital and York Teaching Hospital, of which it is a satellite for the purposes of HTA licensing. The proposed changes also include renovation of the mortuary at Scarborough General Hospital and increased staffing. With the change in licensing arrangements, the DI is new to overseeing activities carried out at Scarborough General Hospital and needs to ensure sufficient time is dedicated to visiting the satellite site, particularly during the early stages, to ensure compliance against HTA standards continues to improve.

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 Paragraph 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

Until recently, Scarborough General Hospital held its own independent HTA licence (12395) and had been scheduled for a routine inspection, following its first site visit inspection in 2009. Changes have been made to the licensing arrangements and Scarborough General Hospital is now licensed as a satellite of York Teaching Hospital. As the latter was inspected in 2011, the HTA decided it would be appropriate to inspect the new satellite site only on this occasion.

Scarborough General Hospital carries out approximately 460 routine coronial post-mortem examinations every year and a small number of Home Office cases. Adult consented hospital PM examinations are not undertaken and paediatric cases are transferred to another licensed post-mortem facility, though staff at Scarborough are responsible for taking consent for these.

The inspection comprised interviews with members of staff, a review of procedural documentation and records and visual inspections of the mortuary, body store and histology laboratory tissue storage area. The inspection team carried out checks on two bodies stored within the body store, selected at random. The name, date of birth, date of death and hospital number of the deceased were checked on the wrist tag, the notice of death form attached to the shroud covering the deceased and the mortuary register. No anomalies were found. In addition, two cases in which tissue had been retained at PM examination were selected. The blocks and slides from these cases were audited against the mortuary records of the wishes of the next of kin for retention, repatriation or disposal of tissue samples. One set of tissue blocks and slides had been disposed of and a record made of this, the other set was being retained with appropriate consent. Records pertaining to wet tissue samples stored in a dedicated fume cabinet were reviewed; these tissues were held under the coroner's authority awaiting sensitive disposal. No anomalies were found.

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
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 no SOP or policy on consent. These documents are available at York but have not yet been shared with staff in Scarborough. Minor shortfall.	**Major (Cumulative)**
C2 Information about the consent process is provided and in a variety of formats.	Several different versions of patient information booklets are available to staff to provide to parents when taking consent for a paediatric PM examination; most of these are out of date and some contained inaccurate information. The current version was provided to the HTA for review, but it was unclear if staff had been made aware of this latest version. Minor shortfall.	
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Staff involved in taking consent for paediatric cases have not received training in the process, although training is due to be offered in the coming weeks to some members of the team. The absence of trained staff increases the risk of insufficient information being provided to parents, who should be fully informed in order for their consent to be valid. Minor shortfall.	

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.	A single member of staff currently works in the mortuary. In their absence, staff from York Hospital or locum staff, who are not familiar with the day to day running of the mortuary, provide cover. There is a generic induction pack; however, there is no local induction pack to guide new staff in the operational procedures and systems used in the mortuary as well as key staff and contact details. There is also a lack of an established way to check that locum staff are competent in all the tasks they need to carry out. The permanent member of staff is always on call for forensic PM examinations and issues arising out of hours. Were they not able to attend for any reason, this would cause difficulties for the establishment and presents an operational and reputational risk.	**Minor** **Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Bodies brought to the mortuary from the ward are wrapped in a clean sheet with the notice of death attached to it; this includes the deceased's name, date of birth and hospital number. Due to staff shortages, on admittance to the mortuary the deceased is not unwrapped to check the wrist band before details are recorded in the mortuary register. An incident has occurred recently, where the wrong hospital label was attached to the notice of death form and went undiscovered until enquiries were made to the mortuary about a deceased person for whom they held no records. Mitigating steps are required to prevent such an error and ensure any discrepancies are picked up at an early stage to avoid potentially serious incidents from occurring.	**Major**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has carried out a number of risk assessments on the premises and processes that relate to health and safety. Risks of non-compliance with regulatory requirements and risks to the safety and security of bodies and tissue samples, such as loss of traceability, have not been considered.	**Minor**

Advice

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

No.	Standard	Advice
1.	NA	The bodies of several deceased patients have been received in the mortuary from hospital wards without last offices having been completed, the eyes and mouth having been left open. This may be distressing for relatives viewing the body if it cannot be corrected by mortuary staff because of the progress of rigor mortis. The DI is advised to ensure that the procedure for last offices is completed in full. Any non-compliance should be monitored and, if necessary, escalated accordingly.
2.	C1, C2 & C3	The Sudden and Neonatal Death Charity (SANDS) will be publishing a model consent form, guidance for consent takers and information for bereaved parents in January 2013. The DI is advised to review the establishment's paediatric consent procedures in light of these, and make adjustments as appropriate.
3.	GQ2	Several traceability audits have been conducted in the mortuary; however some of these are recorded by date only and a tick when completed. The DI is advised to implement a more formal method of documenting records audits so that any errors are recorded and any trends in the data can be identified and acted upon.
4.	GQ2	The establishment has a planned audit schedule, which includes audits of mortuary procedures; however, due to a lack of staff, these have not been completed and are overdue. The DI is advised to utilise staff from other departments where possible to ensure that procedural audits are undertaken, which will help identify any deviations from written procedures or training needs.
5.	GQ4	The histology logbook records data on samples collected at PM examination and goes back many years; the DI is advised to archive the existing book and start a new logbook on a yearly basis in order to lower the risk of losing valuable data if the book were to become damaged or lost.
6.	GQ6	Only bodies which are subject to a PM examination are assigned a unique number. This is not in line with the system at York, where every body is assigned a number on admittance to the mortuary. Assigning each body a unique number provides another point of reference which can be used for identification, particularly of unidentified deceased, or those with a same or similar name. The DI is therefore advised to align the systems of identification at York and Scarborough Hospitals and consider assigning a unique identifier to all the deceased.
7.	GQ6	Notification by the Coroner's officer to the mortuary that a body may be released is usually done verbally. Release of bodies is carried out by several trained porters so communication from the Coroner's officer may need to be passed between different members of staff depending on who is on rota. It is suggested to the DI that notification by e-mail or fax, where possible, would be a more robust system and help minimise the risk of a body being released in error. The Coroner's officer also notifies the mortuary of the wishes of the next of kin regarding any tissue retained at PM examination. When they request that tissue is repatriated with the deceased, the Coroner's officer does not issue the

		notification to release the body until the pathologist informs them that repatriation has been completed. Whilst this system does work, there is no stop check in case of a mis-communication. The DI is advised to consider implementing a system whereby a note is made in the mortuary register of tissue to be repatriated and when this has been completed.
8.	GQ6	The establishment uses stickers to warn staff that there are two or more deceased with the same or similar name The stickers are placed in the mortuary register, on the whiteboard and on the door of the fridge where the deceased is stored. The DI is advised to take this practice a step further and place a sticker on the shroud or wrist tag of the deceased, so that if the body is moved, the prompt is still there.
9.	GQ6	Wet tissue trimmings are stored on a dedicated shelf in the histology fixed tissue store, pending disposal. Occasionally tissue is stored in more than one pot, but there is no record of multiple pots, so there is the risk that when staff come to dispose of the sample, not all are identified. The DI is advised to implement a system (such as writing 'Pot 1 of 3' etc on the label), so it is clear there is more than one pot to be found.
10.	GQ8	The DI is advised to use the HTA serious untoward incident notification list as a basis for risk assessing processes where serious incidents could occur.
11.	PFE1	The entrance door to the mortuary has a small gap underneath it, which allows leaves and debris to blow into the area. It is important that a high standard of cleanliness is achieved in all areas of the mortuary, and the DI is advised to make arrangements for a brush strip draft excluder to be fitted to the bottom of the mortuary door.
12.	PFE1 PFE3	The establishment is in the process of considering plans for renovation and extension of the mortuary, to include greater body store capacity and re-siting of the visitors' entrance, which is currently situated in the same vicinity as the entrance used to bring bodies into the mortuary. The HTA supports the proposed plans, which will provide for increased capacity during summer peaks in the tourist population and winter storage, particularly over the Christmas period. The HTA advises that consideration is given to the inclusion of storage suitable for bariatric bodies.

Concluding comments

A number of strengths and areas of good practice were noted during the inspection and examples are given below.

One member of mortuary staff works significant periods alone; to help ensure their personal safety, a 'man down' alarm system has been installed, and a device is worn by the individual which can be activated if assistance is needed. This system is regularly checked to ensure it is functioning properly.

Due to rearrangements within the Trust, as well as combining HTA licences, communication between York and Scarborough Hospitals mortuary and Histology departments has improved. Staff from both hospitals are working to ensure the same governance system is applied across both sites and where systems differ, the establishments are learning from each other

to ensure elements of best practice are shared and implemented. This new alliance also allows staff to attend training which is being carried out at either site.

The establishment is aware of its limitations with regard to staffing, storage space within the mortuary (23 spaces in total) and the unfortunate siting of the visitors entrance to the mortuary. Individuals work hard to ensure there is sufficient turnaround to prevent the body store becoming full and have planned for contingency space. They try to prevent the deceased being brought to the mortuary at the same time as visitors. The proposals shared with the inspection team to modify the mortuary layout, increase the storage capacity and employ an additional member of staff would provide long-term improvements and reduce the risks associated with each of these issues.

Since the last inspection, when a number of conditions were applied to the licence, the level of compliance has increased. Issues noted at that time have all been addressed with the exception of risk assessments, where further work is still required, and consent, which was previously an issue in adult cases, but now applies just to paediatric cases. The HTA found that there are a number of areas of practice that require improvement, details of the two major and three minor shortfalls being recorded in the table above. The HTA has given advice to the Designated Individual on a range of matters, including audit, risk assessment, records of communication, traceability systems and points to consider for the mortuary renovation.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 18/10/12

Report returned from DI: 25/10/12

Final report issued: 29/10/12

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: 11 April 2013

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 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 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.