**Site visit inspection report on compliance with HTA minimum standards**

**Pathlinks**
**(in relation to the Diana, Princess of Wales Hospital, Grimsby)**

**HTA licensing number 12310**

**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**

**26 July 2016**

**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 Pathlinks (the establishment) had met the majority of the HTA standards, a minor shortfall was found in relation to consent documentation.

Advice has also been given to the establishment with respect to some procedural documents, governance meetings, traceability systems and risk assessments.

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

## The HTA's regulatory requirements

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

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

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

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

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

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

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

## Background to the establishment and description of inspection activities undertaken

Pathlinks currently holds two HTA post mortem (PM) sector licences covering four hospital sites from two separate hospital Trusts. The first licence covers the Diana, Princess of Wales Hospital in Grimsby (licensing number 12310) and the second covers the Lincoln County Hospital, Pilgrim Hospital in Boston and the Grantham and District Hospital (licensing number 12314). Activities across the sites are overseen by the same Designated Individual (DI) with the Corporate Licence Holder Contacts being the Medical Directors of the respective Trusts.

Each set of licensed premises were inspected separately; however the inspections reflected the fact that many procedures are aligned and shared. In cases where findings were similar, the same advice and guidance has been offered to the DI in both inspection reports. This inspection report relates to the inspection of the Pathlinks premises at the Diana, Princess of Wales Hospital in Grimsby, which was carried out on Tuesday 26 July 2016.

The establishment has been licensed since August 2007 and this was its third routine site-visit inspection to assess whether it continues to meet the HTAs' standards. The timetable for the site visit was developed taking into accountthe establishment's latest self-assessed compliance information, a review of the previous inspection findings and pre-inspection discussions with the DI and Person Designated (PD). During the site visit, a visual inspection

of the premises, review of documentation and interviews with establishment and Coroner's office staff were undertaken. Audits of bodies and retained tissue were also undertaken.

Both coronial and adult hospital (consented) PM examinations take place at the establishment. Paediatric and infant cases are transferred to another HTA licensed establishment for PM examination. The establishment consists of a body store and two PM suites, a routine PM examination suite and a second high-risk suite where high risk PM examinations take place on bodies with known infections, including Hepatitis, HIV and TB.

The establishment carries out approximately 220 PM examinations per year under the authority of the Coroner from the North Lincolnshire and Grimsby jurisdiction. Although no consented PM examinations have been undertaken there for the last three years, the HTA reviewed the establishment's consent procedure and associated documentation. During the review it came to light that the establishment maintains a supply of out of date Department of Health (DH) PM consent forms. The establishment updated its consent documentation following the last HTA inspection and although the standard operating procedure (SOP) reflects this update, no copies of the updated consent form are available for use. Additionally, the Trust's consent policy refers to the old DH consent form. A shortfall has therefore been identified against the consent standards.

If any tissue is taken during the course of adult PM examinations, it is placed into tissue cassettes in the PM suite and then sent to the other Pathlinks licensed establishment at Lincoln County Hospital for processing into blocks and slides. Following the review of the slides by the pathologist, blocks and slides are stored at Lincoln until the wishes of the deceased's family are received and the Coroner's authority has ended. The establishment then acts upon the wishes of the family and either sensitively disposes of the tissue, returns the samples to the family or stores the samples for future use, with appropriate consent.

The establishment has 36 standard refrigerated body store spaces with three of these reserved for the storage of infants. In addition to these spaces, the establishment has three freezer, three bariatric, four medium bariatric and three high-risk refrigerated storage spaces. All of the establishment's storage spaces have their temperature monitored electronically and should the temperature deviate from the expected range, an alarm sounds in the pharmacy department; staff there alert the mortuary or the on-call Anatomical Pathology Technologist if the alarm sounds out of hours. Hospital portering staff bring bodies to the mortuary outside of normal working hours and record their details in the establishment's mortuary register. Mortuary staff verify the details in the register against the details on the body during the next working day and also record the body on the establishment's electronic database. The mortuary was appropriately secure with controlled access via a swipe card security system. Release of bodies to funeral directors is always undertaken by the mortuary staff.

In cases of sudden unexpected death in an infant or child (SUDIC), where infants or children die in the establishment's emergency department or en-route to the emergency department, some samples are taken for analysis in the department. A suitable area within the paediatric resuscitation area has been allocated and is where samples such as swabs, blood samples, and cerebral spinal fluid are removed by a paediatric clinician. The establishment has a dedicated SUDIC nurse who supports the family and clinicians and who maintains a SUDIC box within the emergency department. This box contains a procedure for staff to follow detailing the samples to be taken and the sample tubes and equipment to collect them in. The Coroner has given approval for samples to be taken in such cases; however, staff at the establishment contact the Coroner in each case. The DI currently has not identified a Person Designated in the emergency department to oversee the licensable activity of removal of

tissue; advice has been offered to the DI below (see advice item 3).

Although paediatric and infant PM examinations are transferred to another HTA-licensed establishment , consent for hospital PM examinations is sought by clinicians working in the maternity department of the Diana, Princess of Wales Hospital. Staff use the consent form and information forms provided by the licensed establishment where the PM examinations are undertaken. In addition, staff have received training on aspects of the PM procedure and use of the consent forms, which include a means to record the family's wishes with regards to any tissue removed during the examination. The DI currently has not identified a Person Designated in the maternity department to oversee the consent process; advice has been offered to the DI below see advice item (see advice item 3).

During the inspection several traceability audits were undertaken. Firstly, an audit of bodies that were stored at the establishment was performed, with details taken from the identification bands on two bodies being cross checked against the details on the storage fridge door and in the mortuary register. The first body was of a person who had died in hospital and their name, date of birth and hospital number were cross checked as part of the audit. The second body was that of a person who died in the community;  details of their name, the place of death and the date of death were cross checked. No anomalies were identified.

An audit of tissue taken at PM examination was also undertaken. Details of tissue taken during four coronial PM examinations were noted. On the following day, during the inspection of the Lincoln Pathlinks establishment (licensing number 12314), the laboratory records were reviewed, blocks and slides sought and family wishes relating to the tissue reviewed. In all four cases the laboratory records matched the details taken on the previous day at the Grimsby Pathlinks establishment and the physical number of blocks and slides also matched these and the laboratory's records. The family's wishes had been received in all cases and the tissue was being retained either with appropriate consent or was still under the authority of the coroner. In summary, no anomalies were identified during the traceability audit.

## Inspection findings

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

## Compliance with HTA standards

### 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. | Despite the establishment's SOP regarding the seeking of consent referencing an up-to-date consent form and information leaflet, these are not readily available for use by establishment staff. Additionally, the Trust's policy on seeking consent for PM examination references an out of date Department of Health consent form, which does not reflect the requirements of the HT Act with regards to consent. | **Minor** |
| C2 Information about the consent process is provided and in a variety of formats. | | |

**Advice**

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

| No. | Standard | Advice |
|---|---|---|
| 1. | GQ1 | The establishment's SOPs referring to receipt, release and PM examinations of bodies all include reference to identity checks that are performed on the bodies prior to critical steps being undertaken. However, they do not always detail which points of identification must be checked, such as name, hospital number, place of death or date of birth, and what they should be checked against.<br><br>The DI is advised to review all of the establishment's SOPs which include identity checks and, where appropriate, amend them so that details of the points of identification that should be checked and what they are checked against are explicitly detailed. |
| 2. | GQ1 | The establishment has a procedure to highlight when two or more bodies with the same or similar names are being stored within the establishment's fridges and freezers. The procedure indicates that bodies with same or similar names have a coloured sticker affixed to the storage fridge or freezer door. Although the same/similar name procedure covers all Pathlinks licensed premises, during the inspection a differing approach to identifying bodies with same or similar names was seen, with not all sites using the coloured stickers to help identify such cases.<br><br>The DI is advised to review compliance with the establishment's same/similar name procedure across all licensed premises to assure himself that the procedure is being followed as he expects and then either amend the procedure to reflect practice or retrain staff working at the establishment in the documented procedure. |
| 3. | GQ1 | The SUDIC nurse plans to review the contents of the SUDIC box and add additional items to the box which would help staff access the required materials more quickly when dealing with SUDIC cases.<br><br>The DI is advised to support the development of the SUDIC sample box within the establishment's Emergency Department. In addition the DI is advised to appoint a PD relating to this area to act as a point of contact and make them aware of any issues that arise and to disseminate any licensing updates or information to staff in these areas. The DI is also advised to invite the PD to governance meetings so that information regarding licensable activity can be shared.<br><br>Additionally, the DI is advised to appoint a PD in the maternity department, where consent for infant PM examination is sought. Although these examinations take place at another HTA licensed establishment and consent is recorded using that establishment's consent procedure, having a point of contact will facilitate the DI being made aware of any changes to the consent procedures so that he may assure himself that they remain appropriate. |
| 4. | GQ1 | During the inspection it was found that Pathlinks-wide governance meetings including staff from the Diana, Princess of Wales Hospital in Grimsby do not take place on a regular basis. This may be due to the geographic location of the Grimsby premises, which is some distance from the other Pathlinks premises at Lincoln.<br><br>The DI is advised to review the frequency and format of governance meetings that include staff from the Grimsby premises. The DI may wish to consider |

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|---|---|---|
| | | other forms of engagement (such as a standing monthly email communication) which could be used to supplement face to face meetings, meaning that the requirement for establishment staff to travel would be reduced. This may help to assure the DI that matters pertaining to licensable activity are being documented and shared with other staff, management and the DI working under Pathlink's licences. |
| 5. | GQ6 | During the inspection it was found that bodies being stored in body bags within the freezer are identified using an identification label affixed to the outside of the body bag.<br>The DI is advised to review and amend this procedure so that all identification of bodies in frozen storage is undertaken using only the identity bracelet attached to the body so that the body identification details which are fixed to the body itself are used. |
| 6. | GQ6 | The DI is advised to ensure that any corrections made to written records should be made by striking through the error with a single line and the correct entry added rather than overwriting the original record or covering it with correction fluid or stickers. |
| 7. | GQ8 | The establishment has a good range of risk assessments which address not only health and safety risks but also risks to the bodies and tissues stored at the establishment. The DI is advised to review these risk assessments to ensure that all of the HTA reportable incident categories have been considered as risks and any procedures to mitigate the risk of them occurring are identified. |
| 8. | PFE5 | Although the body storage facility's temperatures are monitored via an electronic system, the temperature data are not reviewed unless a failure occurs. The DI is advised to check and record temperatures during working days, as carried out at the other sites, which may help to identifiy trends which could indicate a portential equipment malfunction prior to a major failure of the refrigeration equipment. |

**Concluding comments**

Despite the minor shortfall identified, good practice was also observed during the inspection. The establishment has appointed a Corporate Licence Holder Contact (CLHC) from the North Lincolnshire and Goole NHS Foundation Trust which is responsible for the Diana, Princess of Wales Hospital in Grimsby. By appointing the Medical Director as the CLHC, the Trust has representation within the establishment's licence who can input into the governance of the establishment as required.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the DI with respect to some procedural documents, governance meetings, traceability systems and risk assessments.

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 shortfall identified during theinspection.

**Report sent to DI for factual accuracy: 1 September 2016**

**Report returned from DI: 16 September 2016**

**Final report issued: 27 September 2016**

**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 July 2017**

## 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.<br>• 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).<br>• 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.<br>• Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event.<br>• Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). |

- Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained.
- Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.

**C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent**

- There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent.
- Refresher training is available (e.g. annually).
- Attendance at consent training is documented.
- If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

**Governance and quality system standards**

**GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process**

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  *(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)*
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

**GQ2 There is a documented system of quality management and audit**

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).

- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

**GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills**

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.
- There is a documented training programme for new mortuary staff (e.g. competency checklist).

**GQ4 There is a systematic and planned approach to the management of records**

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

**GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.**

**GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail**

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs 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.<br>• 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.<br>• Tissue is disposed of in accordance with the documented wishes of the deceased person's family.<br>• Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.<br>• 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.