Inspection report on compliance with HTA licensing standards
Inspection date: **01 - 03 February 2022**

King's College Hospital
HTA licensing number 12377

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	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	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **King's College Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Neuropathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*Carried out*	-
Satellite site	Licensed	Licensed	Licensed

Princess Royal University Hospital			
Mortuary (satellite site)	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*Carried out*	-

Summary of inspection findings

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

Although the HTA found that King's College Hospital ('the establishment') had met the majority of the HTA's standards, four critical, four major and five minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to standard operating procedures, traceability of bodies in storage, condition of bodies in storage, the premises and equipment used in the storage and management of bodies, security arrangements, and records management.

During the inspection, critical shortfalls were identified. This resulted in Directions being issued requiring specific action to be taken straightaway.

Whilst the HTA has assessed the establishment as suitable to be licensed for the activities specified, this is subject to compliance with the Directions issued and corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	The written systems at the satellite site to track bodies from admission to release are not effective. During the traceability audit the inspection team identified the following issues: • The establishment are reliant on the use of numerous temporary body storage units and off-site storage arrangements to manage capacity. This means that bodies are frequently moved out of the department at short notice and returned at a later date. The frequency of movements of bodies has led to the mortuary register not being maintained as expected. Two cases were identified where bodies had been released but had not been signed out of the mortuary register. A further review of the mortuary register demonstrated these were not isolated incidents. • Nameplates used on the exterior of the fridge units and the main body location whiteboards have been marked with permanent marker pen. This means that details of bodies which have been released from the mortuary are still visible. • Due to the frequency of body movements within the department, the written system in the mortuary register to record the fridge location is not being maintained effectively.	**Critical (cumulative)**

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	Bodies can arrive at the satellite site from the community with less than three identifiers of the deceased on identification bands. During the traceability audit the inspection team identified one body in freezer storage with only two identifiers present on the identification band. Furthermore, the name of this deceased had been written on the exterior of the body bag which contained a spelling error to the surname. The practice of writing on the exterior of body bags increases risk of release of the wrong body should this information be solely relied upon at the point of release.	
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

a) The premises are clean and well maintained	The inspection team identified the following issues during visual inspection of the premises: **Satellite site** • Whist the premises were generally clean at the time of the inspection, the interior of all body storage units were significantly contaminated with various types of debris, mould and infestation. • A temporary body storage unit is located in the PM room. This unit is mounted on wooden pallets which are contaminated with foul liquid. The unit is soft shell in construction with areas that were not sealed effectively at the time of the inspection. This means that bodies stored in this unit may be exposed to aerosol contamination whilst the PM room is in operation. Furthermore, the unit blocks access to a number of pass-through fridges causing additional internal transfers of bodies requiring PM examination. **Hub site** • Whilst the premises were clean at the time of the inspection, there are areas of damage to walls leaving exposed plaster and some cracking in the floor of body store. The floor of the viewing room appears to have abrasion damage. This means these areas would be difficult to effectively clean and decontaminate The inspection team required the establishment take immediate action to address the findings at the satellite site. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Critical (cumulative)**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	The interior of the body storage units at the satellite site, including the temporary body storage units have not been subject to routine cleaning or decontamination in accordance with the cleaning schedule.	

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Storage arrangements do not ensure the dignity of the deceased is maintained as detailed in shortfalls against premises, facilities and equipment.	**Critical (cumulative)**
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	Whilst there are documented contingency plans in place to manage capacity issues at both the hub and satellite sites, the mortuaries are often at capacity due to insufficient permanent storage space. The contingency plans rely heavily on long- and short-term storage solutions being sought at several off-site locations. Bodies are often moved out of the mortuary to be returned at a later date once capacity in the mortuary has eased. At the satellite site this has led to significant failures in the traceability system. Furthermore, this arrangement does not provide assurance that bodies sent off site are stored in optimal conditions or adequate condition checks are undertaken. The satellite site has five temporary storage units currently in operation.	

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The inspection identified the following significant issues relating to long-term storage and bariatric storage arrangements: **Hub site** • At the time of the inspection there were several adult bodies which had been stored in excess of 30 days in the fridge units. Whilst these bodies were subject to regular condition checking, signs of deterioration were present. Bodies required movement to freezer storage to prevent further deterioration however the long-term storage unit was at capacity. There is an option to convert a bank of fridges to freezer units however, due to the overall lack of fridge spaces, this could not happen. • Perinatal bodies are not routinely subject to condition checking or transferred to freezer storage following fridge storage in excess of 30 days. **Satellite site** • There are no bariatric storage arrangements at this site meaning bariatric bodies have to be transferred elsewhere. • Bodies are not subject to routine condition checking. Furthermore, bodies are not prepared adequately for transfer to freezer storage.	

d) Fridge and freezer units are in good working condition and well maintained	• Many trays used for the storage of bodies have either broken rollers or have surfaces which are heavily damaged with some showing significant rusting. • One fridge door is broken to the extent the door has to be lifted on the hinges in order for the storage unit to be used. Other fridge doors have extensive areas of damage with broken kick plates which expose the internal insulation and wooden structure or broken door catches. • The fridge seals of a number of units are heavily damaged. This does not provide assurance the units are effectively sealed to maintain optimal storage temperatures. • Flooring of fridge units are heavily corroded and have many areas of water ingress into the internal structures.	
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The fridge and freezer unit at the satellite site are not subject to regular alarm testing to ensure they will trigger when temperatures go out of range. This poses a risk to the optimal storage of bodies given the identified issues with the storage units and unit failures.	
h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies	The hub site does not have separate facilities or adequate special measures in place for the storage of babies and infants. Furthermore, the storage arrangements for babies and infants at the satellite site is located in a room only accessible via the PM room. There is no designated area to safely receive and release the bodies babies and infants. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		

a) Items of equipment in the mortuary are in good condition and appropriate for use	The following items of equipment at the satellite site are not appropriate for use: • Trolleys used for the transfer of bodies in the mortuary are not all compatible with the fridge and freezer storage systems in place. • Two external temporary storage units are at a level which requires the use of a ramp. The ramp has to be lifted into place when bodies are moved into and from these units. The ramp is narrow and not compatible with the trolley used. The trolley has no locking mechanism to secure the storage trays when in operation and is heavily rusted and extensively buckled. This means there is a significant risk of accidental damage to the deceased. The inspection team required the establishment take immediate action to address the findings. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Critical (cumulative)**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The main banks of fridge and freezer units at the satellite site have not been adequately maintained. Furthermore, body trolleys used have not been subject to regular servicing or maintenance. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst there are some procedures in place to prevent practices that disregard the dignity of the deceased, the establishment does not have a procedure in place for condition checking and movement to freezer storage for babies and infants at the hub site. There are no procedures in place for condition checking of bodies at the satellite site. Furthermore, bariatric bodies at the satellite site are unrefrigerated for a period of time whilst awaiting transfer due to the lack of bariatric storage space.	**Major**
GQ4 There is a systematic and planned approach to the management of records		
a) 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 is no system for record management across the hub and satellite site. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major (cumulative)**
b) There are documented SOPs for record management which include how errors in written records should be corrected	The establishment does not have an SOP for record management which includes how errors in written records should be corrected. At the satellite site, the inspection team identified many corrections to errors in mortuary written records, making them illegible. This was due to either errors being overwritten, or correction fluid used. This means that mortuary records are not fully auditable. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Not all significant risks are incorporated into the Trust's organisational risk register. This includes: • Significant risks associated with traceability of bodies at the satellite site • The lack of bariatric storage at the satellite site • Risks associated with identified capacity issues at both sites • The inability to deliver PM services at the satellite site on Fridays due to staff actively managing capacity in preparation for the weekend • The lack of freezer storage at both sites Furthermore, the satellite site does not appear to have sufficient staffing for the level and complexity of work being undertaken. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	There are four external temporary body storage units at the satellite site located in an area which is remote and not gated. Whilst the doors to the units are padlocked and there is CCTV to monitor access, the external components of the units are accessible. There is risk of the units being tampered with.	**Major (cumulative)**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The inspection team identified the following issues during visual inspection of the premises: **Hub site** • The main entrance to the viewing room is reliant on a manual lock to maintain security. During the inspection, the further internal doors had been propped open whilst cleaning was in operation. Should the manual lock not be deployed, there is a risk of unauthorised access to the department and into the body store areas. **Satellite site** • Whilst there is a visitors door to the clean office areas of the mortuary, professional visitors with a legitimate right of access to the department currently arrive to the body store entrance and are required to pass through the body store areas to reach the offices. This means professional visitors may not always be accompanied and will have oversight of mortuary activities.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Some SOPs do not include sufficient detail of the procedures undertaken relating to traceability of bodies and tissue. These include but are not limited to: • KMB P08: Identifying Deceased Patients (release): This SOP does not include sufficient detail that information on the body is crosschecked using a minimum of three identifiers of the deceased provided by the person collecting the body at the point of release • KMB P23/24: Arranging & preparing for a visit: Although visitors are requested to provide three points of identification of the deceased at the time of making an appointment and at the time of arrival the SOP does not sufficiently detail how these are identifiers are crosschecked to the information on the body • KMB P25: This SOP does not contain sufficient information of the process in place to confirm arrival of tissue at external locations. To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies, tissues, and organs to ensure they contain sufficient detail of identifiers of the deceased used in procedures.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst the establishment holds regular HTA governance meetings with staff from all licences held by the establishment, these are high level and not PM sector specific. This means that staff working under the PM licence across the hub and satellite site do not have the opportunity to attend HTA meetings relevant to them.	**Minor**
GQ2 There is a documented system of audit		

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Whilst audit findings are uploaded for follow-up to the electronic record management system, the paperbased audit templates used are not routinely fully completed to demonstrate actions taken to address findings.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Visiting pathologists at the satellite site do not receive an induction which includes the establishments policies and procedures.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
e) The establishment adopts a policy of candour when dealing with serious incidents	The inspection team were informed that fridge units at the satellite site frequently breakdown. Major equipment failures which could result in potential harm to bodies or result in bodies being transferred out of the mortuary should be reported to the HTA.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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.

Advice
The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	Ci(b)	The DI is advised to review consent seeking SOPs and policies, so they accurately reflect the withdrawal of consent procedure the establishment has in place. The policies and SOPs in some areas refer to previous HTA codes of practice and should be updated.
2.	C1(c)	The DI is advised to review information booklets provided to those giving consent at the satellite site and remove reference to the term 'Next of Kin' as this is not a term recognised by the HT Act. Furthermore, the DI is advised to consider producing a single booklet for use at both sites.
3.	C1(g)	The DI is advised to review the consent form in use for adult PM examination. The form should be clear on distinguishing the options for tissue to be retained or disposed of.
4.	Gq1(a)	Whilst swipe card access is regularly reviewed, the DI is advised to include detail of how this review is undertaken in the security and lone working SOP KMB P20.
5.	GQ1(e)	The DI is advised to introduce an audit of document acknowledgement. This will ensure all staff working in the mortuary have read and understood relevant policies and procedures.
6.	GQ3(c)	Currently there are two different competency assessment frameworks in use for staff working in the mortuaries. The DI is advised to review the frameworks so there is alignment and consistency across the hub and satellite site.
7.	GQ5(d)	The DI is advised to introduce regular cross site mortuary staff meetings in order for all staff to share learning from incidents.
8.	GQ6(a)	The DI is advised to risk assess tissue traceability in the pathology laboratory to ensure there are no identified risks which could lead to loss of tissue or tissue traceability.

9.	GQ6(b)	Whilst there is a risk assessment in place for risks relating to PM examination, the DI is advised to further review this document and ensure any risks relating to the process of identification and external examination of bodies the day prior to PM have been mitigated.
10.	T2(a)	The DI is advised to introduce a procedure in line with the guidance in Code of Practice B – Post Mortem Examination for the management of tissue in cases where families have indicated they will collect at a later date and then make no arrangement for collection or are uncontactable.
11.	T2(b)	The DI is advised to liaise with the Coroner regarding the family wishes form that is currently in use. The form should include information on what steps will be taken to dispose of tissue should relatives not make their decision known.
12.	T1(g)	Tissue blocks and slides are returned from the laboratory to the mortuary following analysis for storage for scheduled purposes or disposal in line with the families wishes. The DI is advised to ensure laboratory documents reflect the updated processes now in place. As transfer of the material to the mortuary at the satellite site had only recently been undertaken, the DI is further advised to complete the audit of this transfer for full assurance all tissue is traceable.
13.	PFE2(e)	The upper limit at which fridge alarms will trigger is currently set at 12˚C. The DI is advised to review this trigger point to ensure bodies will be stored at optimal temperatures should temperatures deviate. The DI is further advised to introduce testing of the alarm system out-of-hours to ensure that procedures for response work as expected.

Background

King's College Hospital has been licensed by the HTA since February 2007. This was the fifth inspection of the establishment hub site; the most recent previous inspection took place in July 2017 and the fourth inspection of the satellite site; the most recent inspection took place in March 2016.

Since the previous inspection, the Princess Royal University Hospital has revoked the substantive HTA licence held since July 2007 (licence number 12300) and is now a satellite site of King's College Hospital. This change was completed in May 2021. The

establishment now have a single mortuary management structure and policies and procedures at both sites have now mostly been aligned.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and post-mortem room, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the hub and satellite premises which included the mortuary body storage areas, PM rooms and viewing rooms as well as the storage arrangements for relevant material held within the facility. The team also completed a visual inspection of the neuropathology laboratory at the hub site.

Audit of records

<u>Hub site</u>

The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar name, a body in long term storage and a perinatal body. Traceability details were crosschecked between the identification band on the body,

information on the door of the storage unit, the mortuary register, the electronic mortuary database and paperwork. One very minor discrepancy was identified with a fridge location number and corrected at the time of the inspection.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, consent forms, the mortuary electronic database, and tissue blocks, and slides being stored. One case reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. One case demonstrated disposal had occurred in line with the wishes of the family. With remaining cases being stored for a scheduled purpose. Full traceability of tissues was demonstrated for all four cases.

An audit was conducted of traceability of tissue in the neuropathology laboratory for two cases. Information was crosschecked between the laboratory documentation, referral paperwork, the laboratory electronic database, and tissue being stored. No discrepancies were identified.

Satellite site

The inspection undertook audits of traceability for four bodies in storage. This included bodies with same / similar name, a body in long term storage and a perinatal body. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register, the electronic mortuary database, and paperwork. Two bodies were identified as not being present in the mortuary but not signed out of the mortuary register. One body in storage that had not yet been booked into the mortuary as they had recently arrived, however there was a name on the fridge door name plate different to that of the body in storage, which the established explained was due to the erroneous use of permanent marker. The body in the freezer only had two points of identification on the identification band and had a misspelling of the surname written on the exterior of the body bag. The perinatal body was fully traceable with no discrepancies. Due to the nature and complexity of identifiable errors in traceability, the inspection team were not assured that systems to manage traceability were effective.

Due the critical findings identified; a tissue traceability audit was not undertaken at this site. However, following discussion with the mortuary manager regarding the recent relocation of the tissue blocks and slides from the laboratory to the mortuary to align with processes at the hub site, the inspection team were assured that an audit had been completed.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, portering staff, neuropathology staff, pathologists who conduct PM examinations, staff responsible for the removal of relevant material in the Emergency Departments and the DI. The team also met with the site Chief Executive Officer during the visual inspection of the satellite site as critical shortfalls were identified which required immediate attention from a senior Trust board member.

Report sent to DI for factual accuracy: 14 March 2022

Report returned from DI: 01 April 2022

Final report issued: 28 April 2022

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: 16 May 2023

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI 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.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next inspection.

   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. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.