Inspection report on compliance with HTA licensing standards
Inspection date: **9 & 10 May 2024**

Royal Bournemouth Hospital

HTA licensing number 12723

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 **Royal Bournemouth Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	-	*Carried out*
Satellite site **Poole Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	-	*Carried out*
Maternity	-	-	*Carried out*
Paediatric ward	-	*Carried out*	-
Neonatal unit	-	*Carried out*	-
Satellite site	Not licensed	Licensed	Licensed

Christchurch Hospital			
Mortuary (satellite site)	-	-	*Carried out*

Summary of inspection findings

The HTA inspection of Royal Bournemouth Hospital ('the establishment') identified three cumulative critical, twelve major and eight minor shortfalls against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

12 of the shortfalls (including three cumulative critical, seven major and two minor) relate to findings from the last inspection in 2022. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

In light of the level and scope of shortfalls identified, the HTA is not assured that the current Designated Individual (DI) is suitable to comply with the duties set out under Section 18 of the Human Tissue Act 2004.

Following the inspection, the establishment confirmed the refurbishment of Royal Bournemouth Hospital mortuary is starting in June 2024.

Compliance with HTA standards

Critical 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.	The Standard Operating Procedure (SOP) governing mortuary procedures does not reflect practice, contains contradictory information and is difficult to follow. The SOP is for all staff who work in the mortuaries at each site but it is not always clear which site the information in the SOP is relevant to. Examples include but are not limited to: • The 'start of day procedure' for mortuary staff refers to adding new names to the mortuary register but section 11.2.1 refers to the porters completing the mortuary register when they transfer bodies to the mortuary. • The documented release procedures do not reflect current practice at Royal Bournemouth Hospital or Poole Hospital. Release forms are not issued to funeral directors from the patient affairs office prior to release. If release forms were used the procedure provides contradictory information about what identifiers can be used to release a body. • The SOP includes providing details of the infection status of the deceased, which goes beyond what is required and is lawful. Funeral directors are routinely notified of the type of infection, whilst the information that should be provided should be limited to whether the deceased could be infectious and the potential route of transmission to enable the Funeral Directors to manage the deceased safely. • The SOP states different operating temperatures of the fridges and is not clear this is for all sites. The SOP also states the upper alarm trigger for the bodystore fridges is 16°C (which would not maintain the optimal condition of bodies). This contradicts the information given to the inspection team on site. • The SOP does not state procedures for staff to follow when they work alone. • Paediatric PM SOP U-MOR-P-2 refers to checking identifiers on the body but not what these could be. There is no detail of what information is brought by funeral directors to transfer a baby for PM examination or what identification checks are completed on release.	**Cumulative critical**

	This is not an exhaustive list. Mortuary procedures require a full review to ensure practices meet the required standard, are consistent, appropriately reflected in SOPs and followed by staff. *This shortfall was identified at the previous inspection in 2022.* *See advice item 3.*	
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Review of the quality management system on site demonstrated that the author and authoriser for some documents is the same person. *This shortfall was identified at the previous inspection in 2022.*	
e) There is a system for recording that staff have read and understood the latest versions of these documents	Not all mortuary staff have read and acknowledged SOPs that govern their work. Where staff have read and acknowledged SOPs, this has not always happened in a timely manner. There does not appear to be a system in place to follow-up when documents have not been read and acknowledged. The inspection team identified a document attached to a record in the quality management system that was incorrect. The house keeping staff at Christchurch Hospital do not formally acknowledge they have read and understood mortuary SOPs.	
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	There is no Persons Designated (PDs) in the maternity unit, neonatal unit or paediatric ward at Poole Hospital but consent for post mortem (PM) examination is sought in these areas. The removal of tissue from the deceased also occurs in the paediatric ward and neonatal unit. There is no PD at Christchurch Hospital to help ensure suitable procedures and practices are being adhered to. The DI cannot be fully assured that suitable practices and procedures are being undertaken in all areas covered by the licence.	

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There is no documented mortuary staff meetings or governance meetings with staff involved in HTA-licensed activities.	
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 mortuary at Royal Bournemouth Hospital receives and stores products of conception (POCs) prior to disposal. The admission and subsequent release of POCs is not formally recorded in the mortuary register or spreadsheet. There is no assurance of traceability for these specimens.	**Cumulative critical**
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	The procedure for viewings across all three sites does not include steps to check a minimum of three identifiers of the deceased provided by relatives against the identification on the body. *This shortfall was identified at the previous inspection in 2022.* In addition, the procedure does not include the part of the process chaplains are involved in, or how viewings are managed out of hours. The inspection team witnessed the release of a body during the inspection. No identification checks of the body were carried out at the point of release. The release process was stopped until appropriate identification checks were completed against documentation brought by the funeral director. The inspection team are concerned this is routine practice for the release of bodies from the establishment.	
e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises	The establishment transfer bodies between sites and to other licensed establishments for long-term storage and PM examination. The inspection team are not assured that appropriate identity checks are carried out at the point of transfer, or that relevant documentation is taken by funeral directors transferring bodies to confirm identification at the receiving site.	
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)	<u>Royal Bournemouth Hospital</u> Although most internal doors to the mortuary were upgraded to swipe card access in 2022, the external door that is used by funeral directors is secured using a key/thumb lock only. In addition, there is no intruder alarm fitted in the mortuary. There is a risk of unauthorised access should the external door not be locked by staff. The decommissioned PM room is used by the estates department for storage purposes. The room is accessed by estates staff via an external door with a key lock. The number and control of the key(s) is unknown. The PM room has two doors which lead to the mortuary office and corridor adjacent to the body store. The mortuary office door has a thumb lock and keypad lock which can be operated from the PM room side. The code to the keypad lock is not known by mortuary staff. The door adjacent to the mortuary body store has a thumb lock only, again operated from the PM room side. There is a risk of unauthorised access to the mortuary office and body store. The inspection team were informed that this room can also be used to house a temporary body storage unit, if required. However, oversight and security of the unit could not be assured. <u>Christchurch Hospital</u> The sliding viewing room door is secured by a chain and padlock when viewings are undertaken. This is not sufficient to prevent unauthorised access to the body store. <u>Royal Bournemouth & Poole Hospitals</u> The internal mortuary CCTV feed for the body stores is fed to the security teams at both sites. There is no assurance in place that footage from the trust CCTV at Poole Hospital is controlled to prevent inappropriate access or use of images. *See advice item 8*	**Cumulative critical**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	There is no regular CCTV audits against mortuary swipe card access and visitor logs at each site. The current annual review of swipe card access is not sufficient to provide assurance that those who have access to the mortuary continue to be authorised to do so. The mortuary at Royal Bournemouth Hospital is situated close to a busy on-site road and the walkway around the mortuary is frequently used by hospital staff and visitors. There is insufficient screening at the external mortuary door to prevent viewing of mortuary activities or unauthorised access to the mortuary. In addition, the area adjacent to the mortuary viewing room door is currently used to store broken equipment and rubbish which is unsightly and poses a potential risk to relatives viewing the deceased.	

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment's audit schedule is linked to the HTA standards. However, audits of relevant standards are not included. The schedule also includes audits of activities that are not undertaken at the establishment. The audit schedule does not include: • a range of vertical and horizontal audits, to check compliance with documented procedures; • completion of records; • traceability of bodies; • checking of CCTV against swipe card access and visitor logs. The audit schedule is relevant only to Royal Bournemouth and Poole Hospitals. The is no assurance that audits are being undertaken at Christchurch Hospital.	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	There is no documented refresher training in mortuary procedures for mortuary staff (including bank staff), porters or house keeping staff. Porters at Royal Bournemouth Hospital have an electronic record of training in mortuary procedures but it is not clear from the record seen that all staff have up to date training. House keeping staff at Christchurch Hospital do not formally record training of staff in mortuary activities. There is a training presentation for mortuary procedures but it is not clear if or who uses this for training staff. *See advice item 4*	**Major**
c) Staff are assessed as competent for the tasks they perform	Not all mortuary activities are included in competency assessments for mortuary staff. For example, release of adult bodies is not included. In addition, key steps of a procedure are not stated, for example, the checking of three identifiers on a body. Not all mortuary staff (including bank staff) have up to date competency assessments. Although the DI has provided some porters at Poole Hospital with a competency sheet to complete, they cannot be assured that all porters have completed this. House keeping staff are not competency assessed in mortuary activities.	**Major**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly

a) Staff know how to identify and report incidents, including those that must be reported to the HTA	The inspection team identified two HTA reportable incidents (HTARIs) at Poole Hospital: • a freezer failure in the mortuary. • a fridge failure in the maternity unit. Incident logs for the last 12 months for all three sites were requested but not submitted for review. *(as a result standards GQ5(b), (c), (d) and (e) could not be assessed)* *See advice item 5*	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	The risk assessments provided for review do not cover all mortuary activities. The risk assessments that were reviewed are not up to date and review dates are not necessarily in-line with those stated on individual risk assessments. The risk assessment provided for lone working is for laboratory staff and is not applicable for mortuary staff who frequently work alone. The lone working checklists provided for staff working alone at Royal Bournemouth and Poole Hospitals from 2022 identified risks that do not appear to have been addressed. *See advice item 6*	**Major**

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Mortuary staffing levels are not sufficient to cover periods of absence, especially when more than one staff member is absent. The current arrangement of using bank staff who are not necessarily available is not robust. The DI frequently covers mortuary duties during periods of absence. *This shortfall was identified at the previous inspection in 2022.* Following the site visit, the establishment submitted an HTARI under the category 'Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence. The initial report from the establishment states that due to staff absences a full service was not possible at Royal Bournemouth and Poole Hospitals meaning bodies could not be released in to the care of funeral directors. The inspection team are not assured that the lack of freezer storage is on the Trust's risk register.	**Major**
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	Royal Bournemouth Hospital The condition of the premises has deteriorated since the last inspection in 2022. The planned refurbishment to address issues did not go ahead as indicated in the CAPA plan from the previous inspection. The inspection team identified the following: • the flooring is split, lifting and coming away from the walls in places; • the walls are damaged in places, exposing porous plaster; • fridge door seals have not been cleaned. Christchurch Hospital The inspection team identified the following: • the flooring is marked and stained and the seals around the edges adjoining the walls and fridge unit require attention; • the radiator and associated pipework in the body store are rusty; • The door between the viewing area and body store is damaged, exposing underlying porous wood; • Fridge door seals have not been cleaned. These issues require addressing to ensure dignified storage is provided for the deceased *(see shortfall against PFE2(d)).* *See advice item 7*	**Major**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There are no cleaning or decontamination procedures for the mortuary fridges at each site. The fridges at Poole Hospital were recently cleaned but this does not occur regularly and has not been recorded. The fridges at Royal Bournemouth and Christchurch Hospitals have not been cleaned.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment do not have sufficient freezer storage for long-term bodies. The inspection team were informed bodies are not always transferred to freezer storage after 30 days in refrigerated storage.	**Major**
d) Fridge and freezer units are in good working condition and well maintained	<u>Royal Bournemouth Hospital</u> The fridge door seals have continued to deteriorate since the last inspection in 2022. Large areas of rust on the floor of the fridges and fridge racking has not been addressed. The planned refurbishment to address this did not go ahead in 2022 as indicated in the CAPA plan from the previous inspecton. <u>Christchurch Hospital</u> The fridges are old and require attention to remain fit for purpose and provide dignified storage for the deceased.	**Major**
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	Body store fridge alarms are not regularly tested at each site. Where tests have occurred these have not included the lower alarm trigger point, the call out procedure or been recorded. Although the inspection team were informed that body store fridge alarms would trigger at appropriate temperatures should a failure occur, this information contradicts the information provided for the upper alarm trigger in the mortuary SOP. The fridge in the maternity unit at Poole Hospital is located in a room away from the main ward area and does not have a remote alarm should a temperature deviation occur. The fridge alarm is also not tested.	**Major**

f) Temperatures of fridges and freezers are monitored on a regular basis	<u>Poole Hospital</u> A temporary refrigeration unit was in use at the time of the inspection. Review of the temperature monitoring record identified that the temperature of the unit had not been checked and recorded out of hours, including the previous bank holiday weekend. Although the permanent fridges across all sites are remotely temperature monitored, this is managed by the estates department at each hospital. The DI does not have access to this information and cannot be assured fridge temperatures are being reviewed for trends. *See advice item 10*	**Major**

Minor Shortfalls

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 HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP 'Following neonatal death in women and newborn services' does not include who is able to seek consent for post mortem (PM) examination and what training they should receive.	**Minor**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	The training presentation for seeking consent for PM examination refers to out of date HTA codes of practice and is not clear whether it is for adult or paediatric/perinatal cases. *See advice item 2*	**Minor**

b) Records demonstrate up-to-date staff training	The clinician responsible for seeking consent for adult consented PM examinations has not undertaken regular refresher training in this task.	**Minor**
d) Competency is assessed and maintained	The clinician responsible for seeking consent for adult consented PM examinations has not undertaken regular competency assessment in this task.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	The inspection team noted that errors in the mortuary registers were not always amended in-line with the documented procedure.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Condition checks of bodies are not taking place at Christchurch Hospital.	**Minor**
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	<u>Royal Bournemouth and Christchurch Hospitals</u> Body trolleys at both sites have damaged surfaces and require attention. *This shortfall was identified at the previous inspection in 2022.*	**Minor**
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 fridge in the maternity unit at Poole Hospital is not regularly serviced.	**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.	C1(a)	The DI is advised to remove the reference to the HT Act 2004 in section 3.1.1 in the consent for post mortem examination policy as this refers to anatomical examination, not PM examination.
2.	C2(a)	The DI is advised to consider other staff completing training to seek consent for adult consented PM examinations to help ensure that staff are available should the only consent seeker be unavailable.
3.	GQ1(a)	The DI is advised to reduce the length of the current SOP and consider developing shorter procedure specific SOPs for staff to follow. A procedure for all three sites could be included in one SOP but colour-coded to denote which site it is relevant to. The DI is also advised to ensure that any screenshots used do not contain patient identifiable information.
4.	GQ3(a)	The DI is advised to include HTARIs in refresher training for porters, house keeping staff and mortuary staff.
5.	GQ5(a)	The DI is advised to include all relevant HTARI categories in the 'Mortuary incident notification' poster as a visual aid for staff undertaking mortuary activities.
6.	GQ6(a)	The DI is advised to use the HTARI categories to help ensure risk assessments include all mortuary activities. The DI is also advised to distribute completed risk assessments to staff, so they are aware of the risks associated with the activities they undertake.
7.	PFE1(a)	The DI is advised to ensure that where varnished/sealed wooden doors, door frames and other items are in place, these are monitored for damage and repaired or replaced as soon as possible. Unsealed wood is porous and cannot be adequately cleaned or disinfected.
8.	PFE1(d)	The DI is advised to review arrangements for accessing CCTV to ensure that audits of access can be properly undertaken and that any suspicions of inappropriate access can be identified and managed.

9.	PFE1(e)	The DI is advised to conduct mortuary access and security audits at each site on a suitable frequency in line with the retention period of CCTV footage.
10.	PFE2(f)	The DI is advised to increase the frequency of manual temperature monitoring and recording of temporary body store units (when in use) and the fridge on the maternity unit at Poole Hospital to more than once every 24 hours to help ensure that a failure could be detected at the earliest opportunity.
11.	PFE	The DI is advised to organise removal of non-mortuary equipment which is unsuitable to be stored in the bodystores at Royal Bournemouth and Christchurch Hospitals.
12.	N/A	The DI should ensure that all mortuary staff use the lone worker devices at Royal Bournemouth and Poole Hospitals when working alone.

Background

The most recent previous inspection was a Licence Application Assessment Visit which took place in March 2022 in connection with changes to the licence arrangements (hub and satellite changes). This is the first inspection of the establishment under this licence arrangement.

During preparation for this inspection, it was identified that the establishment are removing tissue from the deceased for a scheduled purpose. The activity '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' has now been added to the licence for Royal Bournemouth Hospital and Poole Hospital

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

Standards GQ1(b), GQ2(c), T1(g), T2(a-d), PFE3(c) and PFE3(e) were not assessed as they are not applicable to the activities undertaken. The remaining 63 HTA licensing standards (standards published 3 April 2017) were assessed.

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 for the mortuary were reviewed. Risk assessments, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises at each site which included the mortuary body storage areas, viewing rooms and the decommissioned PM room at Royal Bournemouth Hospital which is used to house a temporary body storage unit, if required.

Audit of records
The inspection team undertook audits of traceability for 12 bodies across all three sites. This included a body in long term storage. Traceability details were crosschecked between the identification bands on the bodies, information on the door of the body store, the mortuary register, paperwork and mortuary spreadsheet. Whilst some minor discrepancies were found with recording the fridge location of bodies in the mortuary register and spreadsheet, these were not sufficient to amount to a shortfall, but oral advice was given to the establishment at the time of the inspection.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including mortuary staff, quality managers, portering staff, house keeping staff, staff involved in the consent seeking process for adult and perinatal PM examination and staff responsible for the removal of relevant material on the paediatric ward at Poole Hospital.

Report sent to DI for factual accuracy: 28 May 2024

Report returned from DI: 31 May 2024

Final report issued: 18 June 2024

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.