Inspection report on compliance with HTA licensing standards
Inspection date: **14 January 2024**

Central Mortuary

HTA licensing number 12194

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
Central Mortuary	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*

Summary of inspection findings

The HTA found that Central Mortuary ('the establishment') had not met the majority of the HTA's standards and one critical, 25 major and five minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

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

Compliance with HTA standards

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	There are insufficient refrigerated storage facilities. Due to a backlog of post-mortem examinations the establishment frequently uses unlicensed body store facilities to store bodies awaiting post-mortem. Storage frequently exceeds seven days. Although not in use at the time of the inspection, the establishment's contingency cold room is not fit for purpose *(see shortfalls for PFE1(a) and PFE1(d)).*	**Critical**

Major 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.	Not all mortuary procedures have a documented policy in place. There was no Standard Operating Procedure (SOP) in place for the following activities; - Condition monitoring of the deceased - Mortuary audits - Document control Some SOPs lack detail and do not reflect staff practice. At the time of inspection, some procedures observed by the inspection team were not consistent with that of the SOPs. These include, but are not limited to, SOPs detailing the process for: - Mortuary Security (document 4.10)- which details a burglar alarm system which is non-functional. - Body storage and contingency storage arrangements (document 4.11) - which only provides summary information (some of which no longer takes place) and no robust contingency measures. - Viewing of bodies of persons known to APTs (document 4.2) – which does not detail the current limited arrangements for viewing deceased. This is due to the viewing facility which is not fit for purpose *(see shortfall for PFE2(a)).* Some documents are significantly outdated. For example, the SOP for Post mortems cross references the HTA Code of Practice 3 which was superseded by HTA Code B: Post-Mortem in 2017. Updates were advised at the previous inspection in 2019. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The establishment does not formally monitor the condition of bodies after the initial admission check. One body that was audited during the site visit had extensive purging which was immediately dealt with upon identification.	**Major**

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	There are no formalised arrangements for the review of mortuary SOPs. Many of the documents appear to be reviewed on an 'ad hoc' basis, and some of the SOPs have not been reviewed since the previous inspection in 2019. There is no consistent document control system, and some SOPs are missing key document control information. For example, the SOP for body storage and contingency storage arrangements (document 4.11) does not contain page numbers, version history, date of review, issued to staff date etc. The SOP for Record Keeping & Management, document 4.10 has the same document control reference as the SOP for Mortuary Security that is also document 4.10. Some findings relating to this shortfall were identified on the previous inspection.	**Major**
e) There is a system for recording that staff have read and understood the latest versions of these documents	There were no records available to review indicating staff had read and understood the latest versions of SOPs and risk assessments.	**Major**
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	There are frequent deviations from SOPs that are not recorded or monitored. For example; • There were many instances identified where the SOP for dealing with same/similar names was not being followed. • Visitor logs are frequently not completed with missing information relating to dates of entry and sign out times. • Material that is taken at PM is receipted at the referral establishment however if it is not, this is not followed up and the logs remain incomplete.	**Major**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	There is a very limited audit schedule and no vertical or horizontal audits checking compliance with documented procedures. This shortfall was identified on the previous inspection. Due to the lack of an audit schedule and SOP standards relating to GQ2(b) and (c) could not be assessed.	**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 are no records of staff training or refresher training relating to mortuary activities.	**Major**
c) Staff are assessed as competent for the tasks they perform	The inspection team are not assured that staff who undertake mortuary duties receive competency assessments. There were no documents available to review relating to mortuary staff being assessed as competent for tasks undertaken under the license. This shortfall was identified on the previous inspection.	**Major**
f) There is a documented induction and training programme for new mortuary staff	There is no formalised and documented induction process for mortuary staff. This shortfall was identified on the previous inspection.	**Major**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	The establishment employs locum staff, however there were no documents available to review in support of an induction, training and competency check for external visiting staff. This shortfall was identified on the previous inspection.	**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 SOP for Adverse Event / Incident Leading to a HTA Reportable Incident (document 4.8) has not been reviewed since 2019. There is an incident reporting form (document 4.9) however this is not referenced in the adverse event SOP. Staff were unaware of the SOP, form and any formalised incident reporting system in place. The DI cannot provide assurance that staff are aware and know how to report incidents and be assured that when incidents occur, follow-up actions are completed. This shortfall was identified on the previous inspection. Due to the lack of an incident reporting system standards relating to GQ5(b), (c), (d) and (e) could not be assessed.	**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	Only risks posed to staff are covered in the establishments risk assessments. No procedures related to licensed activities (such as the security, dignity and integrity of bodies) are risk assessed. The risk assessments relating to staff are not regularly reviewed. This shortfall was identified on the previous inspection.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

d) There is system for flagging up same or similar names of the deceased	The establishment has a written procedure in place for flagging same or similar names, however, the inspection team identified inconsistencies in the highlighting of the deceased with a same or similar name in accordance with the written procedure. • There were four instances where deceased with the same surname had not been identified or flagged up. • Same and similar name wristbands were not being attached to the body and were added to fridge doors. • Same and similar name wristbands were attached to fridge doors where the fridge space was empty. • Same and similar names were not highlighted in the mortuary register as per the SOP.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Material that is taken at PM is receipted at the referral establishment however if it is not, this is not followed up and the logs remain incomplete. The procedure is not in line with the SOP for Post mortems (document 4.4). This shortfall was identified on the previous inspection.	**Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	There is no formalised mechanism for the auditing and/or following up of material that is contained within the specimen freezer.	**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	Areas of the mortuary are very old and have not been maintained sufficiently. The ceiling of the body store is cracked, and paint is coming away, this area is adjacent to a toilet which has been decommissioned due to ceiling issues. There are some areas of the PM room floor that are unsealed and require maintenance. Although not in use at the time of the inspection for the storage of bodies, the establishment's contingency cold room is not fit for purpose. There is rust on the trolleys. The mortuary facility is mostly unheated and was very cold. The DI is advised to review, and risk assess the arrangements to ensure that the premises are fit for purpose and safe for staff.	**Major**
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)	CCTV coverage is limited and only covers some of the external mortuary access points. CCTV is only reviewed if there are incidents. CCTV review should form part of the audit schedule, both to routinely monitor visitors, and to mitigate against unauthorised access.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Whilst there are some external CCTV cameras partially covering mortuary access points the lack of cameras does not afford effective oversight of persons entering the mortuary. Out of hours, there is no alarm system.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	Families are led through vacant and dilapidated council buildings to view their loved ones. The area is unheated and mouldy, with damaged walls and non-functional lights. Staff informed the HTA of a recent burst pipe from the room above. During the site visit inspection there was an odour in the viewing room coming from the unventilated body store. The DI is to urgently review whether the area is fit for purpose. *Since the inspection the Coroners Officer has confirmed that viewings are to only take place in exceptional and necessary circumstances, and families are pre-warned about the condition of the facility.*	**Major**
d) Fridge and freezer units are in good working condition and well maintained	The contingency cold room that is detailed as a contingency and may be used if capacity is reached is not regularly maintained.	**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	The establishment does not have low temperature trigger points for the body store fridges. This creates a risk of bodies being inadvertently frozen. The specimen freezer that is in use to store evidence for forensic cases (including swabs and tissues) is not monitored or alarmed. The contingency cold room that may be used if capacity is reached is not monitored or alarmed. There are no consistent records of testing the fridge and freezer alarms. Although some recent records were reviewed, testing had not taken place for the four years prior to May 2024. This shortfall was identified on the previous two inspections in 2015 and 2019.	**Major**
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	The documented contingency plan is not robust and summarises what could be done should capacity be reached. There is a risk that the lack of planning and clear escalation procedures is significantly impacting service delivery and the safeguarding of the deceased during peak periods.	**Major**
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 body store freezer units had ice around the doors due to the door seals having deteriorated. Dirty towels covered the floor underneath the units to soak up the condensation and dripping. This shortfall was identified on the previous inspection.	**Major**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation system is tested monthly however there are some instances where the records do not meet the necessary ten air changes per hour. The reports are signed off by mortuary staff however there is no escalation process and mortuary staff are recommended to 'turn it up'. This is a longstanding problem, about which the HTA provided advice in 2013, 2015 and 2019. The establishment carry out PMs on infectious bodies up to category three and there is a risk to the health and safety of staff working in the PM room.	**Major**
e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation	There is 75 litres of Thanyl-22 (a methanol and formaldehyde mix) that is stored on the body store floor in an unventilated area of the mortuary.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
d) Staff have annual appraisals and personal development plans	There were no documents available to review indicating staff receive annual appraisals and personal development plans.	**Minor**
e) Staff are given opportunities to attend training courses, either internally or externally	Due to workload pressures the staff have not been able to attend any development opportunities or training courses.	**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 SOP for Record Keeping & Management (document 4.10) has not been reviewed since 2019. This document has the same document control reference as the SOP for Mortuary Security that is also document 4.10. The document does not detail how errors in written records should be managed.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
a) Bodies are tagged/labelled upon arrival at the mortuary	The mortuary generally relies on the wristbands that accompany the deceased when they arrive at the mortuary and as such there are inconsistencies with what is included on the identifying band and how it is written (some partially illegible). This increases the risk of misidentification of the deceased.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies	Although it is rare that the establishment admits infants and babies there are no special measures documented or in place should it occur.	**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.	GQ1(a)	The '*Body Receipt and Handling'* SOP (document 4.1) details that *'the deceased must be transferred to a suitably sized tray'*. To make the SOP clearer, the DI is advised to go into more detail on which fridge spaces are to be utilised for bariatric bodies and bodies that are of a shape or position which require a larger space. To further strengthen procedures in the mortuary the larger fridge spaces could be labelled as such.
2.	GQ1(a)	The actual procedures for evisceration and reconstruction of bodies are contained within an Appendix (App10) in the SOP for Post mortems (document 4.4). As this is a fundamental part of the procedure the DI is advised to add it to the main protocol.
3.	GQ1(h)	There are formalised governance meetings that are held every two months. When corrective actions are put into place in relation to GQ2 and GQ5, the DI is advised to include audit findings and incident management as standing agenda items within the meetings.
4.	T1(c)	The *'Release of Bodies'* SOP (document 4.5) details that *'mortuary staff must check that information provided by the undertaker concurs with that held by them and must check the labels on the body/body bag to ensure that the correct body is released'.* The DI is advised to make it clearer that it is the identification band on the deceased that must be checked. The HTA does not advise that identifiers are written on body bags.
5.	T1(c)	The DI should consider expanding the use of the individual mortuary numbers given to each body to be used as an additional identifier.
6.	PFE1(a)	The DI is advised to ensure there is a program of planned preventative maintenance to keep equipment and premises fit for purpose.

Background

Central Mortuary has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent full routine inspection took place in January 2019.

Since the previous inspection, there has been one change to the Corporate Licence Holder contact (CLHc) in June 2023.

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

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

- Consent standards (C1a, C1b, C1c, C1d, C1e, C1f, C1g, C2a, C2b, C2c and C2d) do not apply to this establishment, as all PM examinations are performed under the authority of HM Coroner, and relevant material is not stored for use for scheduled purposes once coronial authority has ended.
- Due to a lack of an audit schedule GQ2(b) and (c) could not be assessed.
- Due to the lack of an incident reporting system standards relating to GQ5(b), (c), (d) and (e) could not be assessed.

Review of governance documentation

Policies and procedural documents relating to licensed activities were reviewed. These included standard operating procedures (SOPs), risk assessments, details of the servicing of equipment and records of servicing, ventilation reports, meeting minutes, and temperature monitoring for the storage units.

Visual inspection

The inspection team carried out an unannounced visual inspection of the mortuary body store areas, PM room and viewing area.

Audit of records

The inspection team undertook traceability audits for four bodies in storage including one in long-term storage. Traceability details were crosschecked between the identification bands on the body and information on the mortuary register and whiteboards. Discrepancies were identified in relation to flagging up same and similar names *(see shortfall for T1(d)).*

Meetings with establishment staff

The inspection team met with staff carrying out activities under the licence, including the Mortuary Manager, Mortuary Technicians, Coroners

Officer, the Head of Environmental Health who is the establishment's DI and the Director of Regulation and Enforcement who is the establishments CLHc.

Report sent to DI for factual accuracy: 5 February 2025

Report returned from DI: 14 February 2025

Final report issued: 24 February 2025

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.