

Site Inspection Report for:

Mid Essex Hospitals Trust

Licensing number: 12441

Licensed for the making of a post mortem examination; and

the removal from the body of a deceased person (otherwise than in the course of carrying out an anatomical examination or making a post mortem) of relevant material of which the body consists or which it contains, for use for a Scheduled Purpose other than transplantation; and

the storage of the body of a deceased person, or relevant material which has come from a human body, for use for a Scheduled Purpose

28 January 2010

Introduction

1. The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes such as research, transplantation, and education and training. The requirements of the HTA are set out in the Human Tissue Act 2004 (HT Act) and the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. There are supplementary requirements for those establishments storing tissue for transplantation and they are summarised in HTA Directions 001/2006.
2. As part of the regulatory framework, the HTA licenses establishments and undertakes inspections to assess compliance with expected standards.
3. Under the HT Act, the HTA has a statutory responsibility to make judgements about the suitability of the Designated Individual, Licence Applicant (Holder), premises and practices in relation to the licensed activities. These responsibilities are set out in Schedule 3 to the HT Act, which is the framework for the HTA's approach to licensing and inspection.
4. The HTA must satisfy itself that the Designated Individual (DI) is a suitable person to supervise the activity to be authorised by the licence and that they will undertake the following duties:
 - secure that other persons to whom the licence applies are suitable persons to participate in the licensed activities;
 - secure that suitable practices are used in the course of carrying on the activity; and
 - secure that the conditions of the licence are complied with.
5. The HTA must satisfy itself that the applicant for the licence is a suitable person/entity to be the holder of the licence.
6. The HTA must satisfy itself that the premises are suitable for the activity to be authorised by the licence.
7. To fulfil its statutory responsibilities, the HTA must be able to assess whether an establishment is suitable to carry out one or more of the activities regulated by the HTA. Suitability is assessed through a process of inspection. Inspections can be routine or risk based, announced or unannounced.

Inspection Process

8. HTA defines inspection as a process encompassing desk-based review, on-site assessment and analysis of relevant written, numerical, verbal and visual information to evaluate the establishment's compliance with expected standards. Desk-based reviews, described as phase one inspections, focus on the evaluation of the compliance report submitted by the Licence Applicant and Designated Individual, as well as any additional information provided by the establishment at the request of the HTA. On-site assessments, described as phase two inspections, focus on a review of the establishment's operational policies and procedures, inspection of its premises and scrutiny of its practices. Where the inspection process identifies that a standard is

not being met, additional conditions may be placed on an establishment's licence to ensure that appropriate action is taken to address the non-compliance/s.

9. Both desk-based review and on-site assessments may lead to advice and guidance for improving practice in one or more areas.

Judgements

10. To enable the HTA to make effective judgements about the suitability of the DI and the Licence Holder, the suitability of the premises and the suitability of the practices taking place on the premises under the supervision of the DI, the HTA standards were developed under four high-level headings:
 - Consent
 - Governance and Quality
 - Premises, Facilities and Equipment
 - Disposal
11. The evidence gathering during inspection focuses on these standards, with particular emphasis on any areas identified as requiring special attention in phase one of the inspection, as detailed above.
12. Throughout the inspection process, standards are assessed using the same four-point numerical scale used by the DI in the completion of the initial compliance report.

Numerical scale	Interpretation
1	Standard not met
2	Standard partially met
3	Standard almost met
4	Standard fully met or exceeded

13. The information gathered throughout the inspection process informs the HTA's licensing decisions within the regulatory framework. Where the HTA is not presented with evidence that the establishment meets the requirements of a standard/s, it works on the premise that a lack of evidence indicates non-compliance. There are varying degrees of non-compliance. The action an establishment will be required to make following the identification of a non-compliance is based on the HTA's assessment of risk to patient safety and/or tissue integrity and/or a breach of the HT Act or associated Directions.

The Inspection Report

14. The inspection report represents the findings from the evidence supplied during phase one and phase two of the inspection process, that is from the initial compliance report any additional documentation provided prior to the site-visit and the evidence obtained through interview and observation during the site-visit. Future inspections may identify other areas of non-compliance if new evidence is obtained. Where full compliance with a standard has been established, this is noted. Where standards have been found to be non or partially compliant, details are included of the evidence for this finding.
15. Once the factual accuracy of the report has been agreed with the establishment, it may be published on the HTA website.

Inspection Report for Mid Essex Hospitals Trust (MEHT) (Licence number: 12441)

16. The scope of this inspection was the Department of Histopathology of the Mid Essex Hospital Services NHS Trust (MEHT), Pathology Directorate. The histopathology department encompasses the mortuary and histopathology services operating from Broomfield Hospital, Chelmsford. The Broomfield Hospital Mortuary carries out post mortem (PM) examinations, primarily, under the direction of HM Coroner and, on occasion, under the direction of MEHT clinicians. In addition, visiting pathologists use the facilities for forensic post mortems.
17. Approximately 600 PM examinations are undertaken at the establishment each year. The vast majority of these are under the direction of one of two Coroners. Approximately 10 to 15 hospital PM examinations are carried out, each year, under the direction of MEHT clinicians. High risk and paediatric cases are referred to other establishments. There are demonstrably good links with the Coroner's office through the recently appointed Coroner's Service Manager.
18. The Department of Histopathology has a very sound quality management ethos. The department is a participant of the CPA accreditation programme. The most recent cycle of accreditation, in November 2009, resulted in certification, incorporating ISO15189. The establishment is also inspected by the Medicines and Healthcare Products Regulatory Agency (MHRA) with respect to the blood transfusion operations.
19. A phase two inspection of Broomfield Hospital Department of Histopathology was carried out on 28 January 2010.
20. The inspection team comprised:
 - [REDACTED], Lead Inspector
 - [REDACTED], Support Inspector
21. This is the first on-site inspection of this establishment. The timetable for the site visit was developed with due consideration of the results of the phase one assessment process and pre inspection discussion with the establishment. As a first on-site inspection, focus was on a high level review against all HTA standards in order to verify working compliance.
22. As part of the inspection process, the labelling of two bodies in storage was checked to ensure it matched details in the mortuary register. In addition, the audit trail exercise traced tissues from mortuary records through to histopathology systems, processes and documentation. Details are provided under standard GQ6 below.

Compliance with standards, Codes of Practice and Directions

Consent

Standard	Assessment	Score
<p>C1 Consent is obtained in accordance with the requirements of the HT Act 2004 and as set out in the Code of Practice.</p>	<p>This standard is partially met.</p> <p>There is a process of witnessed consent for hospital PM examinations.</p> <p>The two forms that are available:</p> <ul style="list-style-type: none"> • “Agreement to a Post Mortem Examination” • “Consent to a post mortem examination of an adult” <p>do not meet the requirements of the HT Act or the HTA codes of practice and need to be updated or replaced. The Trust’s current policy, procedures and consent forms allow the retention of blocks and slides without consent</p> <p>Refer to proposed additional condition 3 (section 29)</p> <p>Refer to advice and guidance 1 (section 30)</p>	<p>2</p>
<p>C2 Information about the consent process is provided and in a variety of formats.</p>	<p>This standard is partially met.</p> <p>As described in C1 above there is a need to update, or replace, the consent forms and associated literature to ensure that information reflects the requirements of the HT Act 2004 and HTA codes of practice.</p> <p>Refer to proposed additional condition 3 (section 29)</p> <p>Refer to advice and guidance 1 (section 30)</p>	<p>2</p>
<p>C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.</p>	<p>This standard is partially met.</p> <p>Consent training is carried out as part of the Trust’s induction process.</p> <p>The Trust’s current consent training does not reflect the requirements of the HT Act 2004 or the HTA codes of practice.</p> <p>Consent training policy and procedure will need to be revised to reflect the Trust’s updated consent policy, procedures and consent form(s). The revised training will need to be rolled out to staff involved in seeking consent.</p> <p>Refer to proposed additional condition 4 (section 29)</p> <p>Refer to advice and guidance 1 (section 30)</p>	<p>2</p>

Governance and Quality

Standard	Assessment	Score
<p>GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.</p>	<p>This standard is fully met.</p> <p>Should the plans to recruit a trainee mortuary technician progress it is worth taking advantage of the opportunity to review ways of working versus existing standard operating procedures.</p>	<p>4</p>
<p>GQ2 There is a documented system of quality management and audit.</p>	<p>This standard is fully met.</p> <p>There is a schedule within Q-Pulse 5 that will drive formal review of audits and any resultant actions.</p> <p>The establishment is working towards an umbrella quality management structure that satisfies the requirements of HTA, CPA and MHRA. This is a good initiative.</p>	<p>4</p>
<p>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.</p>	<p>This standard is almost met.</p> <p>Overall, this standard is fully met for staff working within the department of histopathology.</p> <p>Porters who have access to the mortuary during out of hours need documented training in how to access the mortuary, complete documentation, deliver the body of the deceased and how to deal with any adverse events, such as an alarm from the fridges / freezer. It is recommended that experienced mortuary staff take part in this training.</p> <p>Refer to advice and guidance 2 (section 30)</p>	<p>3</p>
<p>GQ4 There is a systematic and planned approach to the management of records.</p>	<p>This standard is almost met.</p> <p>The establishment uses the Q-Pulse system which includes procedures for the creation, change, retention and, where applicable, the destruction of records.</p> <p>Whilst there is a clear system and procedure there was some evidence that corrections to the mortuary register were in a manner that obscures the previous entry. Corrections should avoid overwriting or masking so that a complete audit trail of original entry and correction is maintained. Alternative ways of working were discussed, and implemented, during the inspection.</p> <p>Refer to advice and guidance 3 (section 30)</p>	<p>3</p>

<p>GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.</p>	<p>This standard is not applicable.</p> <p>The Trust does not undertake donor selection / exclusion. The Trust does not operate an in-house donor service.</p>	<p>N/A</p>
<p>GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.</p>	<p>This standard is almost met.</p> <p>The audit trail exercise demonstrated that, where tissue is retained on the premises, there are systems in place to ensure traceability to individual blocks and slides. The system covering circumstances where tissue is taken from the premises by visiting forensic pathologists can be improved.</p> <p>Refer to advice and guidance 4 (section 30)</p> <p>The start of the audit trail identified a missing wrist identification 'bracelet' in one out of two examples. In both cases a wrist tag was in place which met traceability requirements. However, the inspection team understand that the establishment's expectation is for two forms of labelling on the wrist – one bracelet and one tag. A third, random, challenge identified another incident of wrist tag but missing 'bracelet'.</p> <p>Refer to advice and guidance 5 (section 30)</p>	<p>3</p>
<p>GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.</p>	<p>This standard is fully met.</p> <p>The establishment uses the 'Datix Common Classification System' reporting tool for adverse incidents. The system drives good practice. Incidents are documented, assessed and reported. The system prompts a review to determine steps that can be taken to prevent recurrence. A record is also retained on Q-Pulse</p>	<p>4</p>
<p>GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.</p>	<p>This standard is almost met.</p> <p>Overall, there is a good system of risk assessment. The establishment is advised to extend the risk assessments across all licensable activities.</p> <p>Refer to advice and guidance 6 (section 30)</p>	<p>3</p>

Premises, Facilities and Equipment

Standard	Assessment	Score
PFE1 The premises are fit for purpose.	<p>This standard is fully met.</p> <p>Overall the premises are fit for purpose. Processes are in place to assure the safety of staff and visitors and to assure the dignity of deceased persons.</p>	4
PFE2 Environmental controls are in place to avoid potential contamination.	<p>This standard is fully met.</p> <p>Staff are provided with appropriate protective equipment.</p> <p>The facilities are designed to minimise risk of contamination.</p> <p>Documented cleaning and decontamination procedures are in place. Records of cleaning and decontamination are retained.</p>	4
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	<p>This standard is almost met.</p> <p>Periodic capacity breach in the mortuary is currently being well managed, monitored and reported.</p> <p>During the last three years this has consistently occurred at Christmas and Easter. During these periods the 65 spaces, within the main building, are supplemented by the addition of a rented controlled storage unit with spaces for up to 16 bodies. The use of the additional storage unit increases the complexity of operations within the mortuary.</p> <p>Refer to advice and guidance 7 (section 30)</p> <p>There are suitable precautions to minimise risk of damage, theft or contamination. There is controlled access to the mortuary and the histopathology laboratories.</p> <p>The controlled storage units are alarmed. Temperature is monitored and recorded.</p>	3
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to its destination.	<p>This standard is almost met.</p> <p>The system and procedure for the transport of body parts, organs, tissues and cells to, for example, the premises of visiting pathologists needs to include a requirement for the recipient to sign for this against a full description of the tissue being taken.</p> <p>Refer to advice and guidance 4 (section 30)</p>	3
PFE5 Equipment is appropriate for	This standard is almost met.	3

<p>use, maintained, quality assured, validated and where appropriate monitored.</p>	<p>Equipment is monitored and performance is documented and documents retained.</p> <p>There is a system for dealing with equipment problems.</p> <p>There is evidence of contingency planning in the event of equipment failure.</p> <p>On the day of inspection the establishment was unable to access documented evidence of a planned preventative maintenance programme for the fridges and freezers or for the ventilation system in the post mortem suite.</p> <p>Refer to advice and guidance 8 (section 30)</p>	
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Disposal

Standard	Assessment	Score
<p>D1 There is a clear and sensitive policy for disposing of human organs and tissue.</p>	<p>This standard is fully met.</p> <p>There is a policy for sensitive disposal. The establishment has a contract with a third party which is appropriate for purpose.</p>	<p>4</p>
<p>D2 The reasons for disposal and the methods used are carefully documented.</p>	<p>This standard is partially met.</p> <p>The coroner's office uses a tissue disposal form which must be completed and signed by a relative of the deceased before the body is released.</p> <p>The mortuary has procedures in place to flag circumstances where specific information on disposal has been received from relatives of the deceased. This includes a flag to identify that histology tissue is to be returned to the body.</p> <p>Following post mortem, and after the Coroner's authority ends, blocks and slides are routinely kept without consent. Where consent for their continued retention for a scheduled purpose is not given, these must be respectfully disposed of in accordance with establishment procedures. The detail of the disposal must be recorded.</p> <p>Refer to proposed additional condition 5 (section 29)</p>	<p>2</p>

Conclusions

23. During the inspection process, the HTA has made judgements about the suitability of the Designated Individual, the Licence Holder, the premises and the practices taking place on the premises under the supervision of the Designated Individual.

Suitability of DI and LH

24. The Designated Individual (DI), [REDACTED], is a consultant physician and Service Director, Emergency Care and Clinical Sciences. The HTA is satisfied that D [REDACTED] is suitable for the role of DI. However, during the inspection the possibility of appointing a DI from within the Department of Histopathology was discussed. [REDACTED] [REDACTED] has the opportunity to reassign the role of DI to the Head of Department, Histopathology. This potential change will bring the DI closer to the operational management of regulated activities. The HTA will support such a change and, if needed, will provide advice and guidance on the process involved. Mid Essex Hospitals NHS Trust is the Licence Holder. Under the proposed arrangement, described above, [REDACTED] will continue as the Licence Holder Contact. This represents the HTA preferred model and is suitable.

Suitability of the Premises

25. The HTA is satisfied that the premises are suitable for the licensable activities being carried out. The HTA endorses the plans to address periodic capacity issues that are adding complexity to the ways of working in the mortuary.

Suitability of Practices

26. Overall, the HTA is satisfied that the practices are suitable and comply with the requirements of the HT Act. However, the HTA has concerns about the retention of blocks and slides without consent and about the, resultant level of compliance with disposal standards. The HTA also has concerns about the need for the establishment to update policy, procedure and training on consent. The degree of HTA concern is reflected by three proposed additional conditions relating to this issue. These are detailed in section 29 below. In addition, advice and guidance on individual standards is offered to help the establishment enhance its existing systems and processes. These are detailed in section 30 below.

Summary comment

27. The HTA is satisfied that the establishment continues to be suitable to be licensed for the purposes that it has set out.

Conditions (requirements) on the licence at the time of the site visit inspection

28. There were no additional conditions on the licence at the time of inspection. Two additional conditions were placed on the licence as a result of the phase one, desk based, inspection process. These two additional conditions were placed on the licence in December 2007. They were removed from the licence, identified as 'closed and met', in April and May 2008.

Proposed additional conditions (requirements) related to areas of non-compliance identified during the inspection process

29. The regulatory reference is noted so the DI can refer back to relevant standards in the Human Tissue Act 2004, the Compliance Report and Directions or Codes of Practice.

No	Regulatory reference	Conditions (including reasons for conditions)
3	<p>C1, C2</p> <p>HTA code of practice 1 (consent)</p> <p>HTA code of practice 3 (post mortem examination)</p>	<p>Condition</p> <p>By 31 August 2010, the Designated Individual shall ensure that appropriate consent is obtained, in accordance with the Human Tissue Act 2004 and HTA Codes of Practice, for all material, including blocks and slides, stored under the licence for scheduled purposes, and that this is reflected in the Trust's documented policy, procedures and consent forms.</p> <p>The DI shall notify the Regulation Directorate in writing when the condition has been met, setting out details of compliance. This information should be sent to: licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason</p> <p>The establishment currently stores blocks and slides, containing tissue removed during post mortem for scheduled purposes, without appropriate consent. Specific consent must be obtained to store and use tissue, including blocks and slides, for any of the scheduled purposes listed in the Human Tissue Act 2004.</p>
4	<p>C3</p> <p>HTA code of practice 1 (consent)</p> <p>HTA code of practice 3 (post mortem examination)</p>	<p>Condition</p> <p>By 31 August 2010, the Designated Individual shall ensure that individuals obtaining consent for hospital post mortem examinations are appropriately trained in accordance with the Trust's updated policy, procedures and consent forms and that this training is documented.</p> <p>The DI shall notify the Regulation Directorate in writing when the condition has been met, setting out details of compliance. This information should be sent to: licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason</p> <p>The establishment's current consent requirements for hospital post mortem examinations do not reflect the consent requirements of the Human Tissue Act 2004, the HTA code of practice on consent (code 1) and the HTA code of practice on post mortem examination (code 3).</p>

5	D2 HTA code of practice 5 (disposal)	<p>Condition</p> <p>By 31 August 2010, the Designated Individual shall ensure that all material which does not have appropriate consent is carefully disposed of and that the method and reason for disposal is documented in accordance with the HTA Codes of Practice and applicable establishment operating procedures.</p> <p>The DI shall notify the Regulation Directorate in writing when the condition has been met, setting out details of compliance. This information should be sent to: licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason</p> <p>The establishment currently stores blocks and slides without consent. This practice, which is in breach of the Human Tissue Act 2004, covers all such material which has been retained, without appropriate consent, after 1 September 2006.</p>
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Advice and guidance

30. Below are matters which the HTA advises the DI to consider.

No	Regulatory reference	Advice
1	C1, C2, C3	<p>The DI is advised that the HTA has published a model consent form which provides a suggested format for NHS Trusts obtaining consent for the PM examination of adults in line with the requirements of the Human Tissue Act 2004.</p> <p>The PM examination consent form is available at:</p> <p>http://www.hta.gov.uk/_db/_documents/Post-mortem_examination_consent_form_200912073732.doc</p>
2	GQ3	<p>The DI is advised to assure that porter staff receive appropriate, documented, training for the aspect of their role that comes under licensable activities. It is recommended that experienced mortuary staff be involved in providing this training. The DI is advised to assure that training in checking the minimum identification requirements for bodies of the deceased admitted to the mortuary is included as part of this exercise.</p>
3	GQ4	<p>The DI is advised to assure that documentation practices within the mortuary consistently meet the minimum standards required by the Trust. In particular, the DI is advised to assure that corrections to data are made in a manner that ensures that an audit trail of the previous record is retained and that corrections are accompanied by a reason for the change and are initialled and dated. The DI is advised to include a review of documentation practices and standards as part of the rolling schedule of audits.</p>
4	GQ6, PFE4	<p>The DI is advised to assure that there is a robust system and associated procedure(s) for visiting forensic pathologists who are involved with PM examinations. The DI is advised to consider the need for visiting forensic pathologists to sign for receipt of body parts, organs, tissues or cells that are taken from the premises for processing or examination at other premises. This will help</p>

		ensure that the audit trail providing traceability of body parts, organs, tissues and cells taken at post mortem is maintained whilst under the supervision of the DI.
5	GQ6	The DI is advised to assure that there is a robust system and procedure for checking the minimum identification requirements for bodies of the deceased admitted to the mortuary. The DI is advised to assure that standard operating procedures exist, and are followed, so that any deviations / discrepancies are fed back to staff on the wards and, if indicative of systemic failings, escalated to ward management.
6	GQ8	The DI is advised to extend risk assessments to cover all aspects of risk to bodies and tissue. This should include, but should not necessarily be limited to, all aspects of mortuary operations. For example: <ul style="list-style-type: none"> • the risk to bodies brought into the mortuary by porters; • the risk that a body could be released without all tissue being returned in accordance with consent; • the risk of the wrong body being released; • the risk to the integrity of bodies caused by equipment failure.
7	PFE3	The DI is advised that the HTA endorses the business case that was prepared during 4 th Quarter 2009. This business case looks to address the occasional, but regular, mortuary 'capacity breach' issue, mitigating the need for the use of a rented storage unit. The plan to add an additional ten storage units within the existing mortuary storage area will reduce the complexity of operations in times of increased storage needs.
8	PFE5	The DI is advised to assure that documented evidence of planned preventative maintenance for quality critical equipment is routinely made available to the histopathology department from the estates department.

Report sent to DI for factual accuracy: 25 February 2010

Report returned from DI: 8 March 2010

Final report issued: 25 March 2010