HTA themed inspection evidence template: PM establishments

When completed, please file this document with the establishment's licensing records.

Name of Inspector	
Name(s) of other attendee(s)*	

*please attach any 'Conflict of interest' questionnaire(s)

Name and address of establishment	
HTA licensing number	
Designated Individual and contact phone number	
Licence Holder Contact	
Persons Designated	
Date of inspection	
Time inspection starts	
Time inspection finishes	

Information reviewed pre-inspection

Reviewed (Y / N / N/A)	Reference	Key information / issues for inspection follow-up
	Previous inspection report	
	General Directions Self-assessment 2011	
	Audit summary report 2010	
	Compliance report June 2010	
	Serious Untoward Incidents	
	Compliance assessment score	
	DI Training completed	
	Other:	

Themes	HTA Standards	HTA Codes of Practice
Theme 1: Appropriate consent is in place for post-mortem examinations not under the Coroner's jurisdiction and in the event that tissue is to be retained for future use. Where there is no consent for retention, tissue must be disposed.		
Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice.	C1	C: 74-96, 105-107 PM: 27-40, 82-88, 99-106
Information about the consent process is provided and in a variety of formats.	C2	C: 62-64, 97-99 PM: 107-113
Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	C3	C: 43-55, 100, 105-107 PM: 32-39, 50-55, 89-98,115
Theme 2: Governance and quality systems promote robust traceability systems, reducing the risk of serious untoward incidents.		
All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process.	GQ1	PM: 137, 138
There is a documented system of quality management and audit.	GQ2	PM: 140
A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	GQ6	PM: 123-126, 142-144
There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	GQ7	PM: 146
Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	GQ8	PM: 138, 139
Theme 3: Fridges and freezers safeguard the integrity of the deceased.		
There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	PFE3	PM: 158, 166

HTA licensing standards

Theme 1: Appropriate consent is in place for post-mortem examinations not under the Coroner's jurisdiction and in the event that tissue is to be retained for future use. Where there is no consent for retention, tissue must be disposed.

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice	
There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.	
Standard assessed during inspection:	YES / NO / N/A
Name / job title of staff member HTA standard was discussed with:	
Evidence:	

C2 Information about the consent process is provided and in a variety of formats	
Relatives are given an opportunity to ask questions. Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. Information on the consent process available in different languages, or there is access to interpreters/translators. Information is available in different formats (e.g. Braille, DVD).	
Standard assessed during inspection:	YES / NO / N/A
Name / job title of staff member HTA standard was discussed with:	
Evidence:	

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent	
There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. Refresher training is available (e.g. annually). Attendance at consent training is documented. If untrained staff are involved in consent taking, they are always accompanied by a trained individual.	
Standard assessed during inspection:	YES / NO / N/A
Name / job title of staff member HTA standard was discussed with:	
Evidence:	

Theme 2: Governance and quality systems promote robust traceability systems, reducing the risk of serious untoward incidents.

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process	
Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include: • post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases • record keeping • receipt and release of bodies, which reflect out of hours arrangements • lone working in the mortuary • transfer of bodies and tissue (including blocks and slides) to other establishments or off site • ensuring that tissue is handled in line with documented wishes of the relatives • disposal of tissue (including blocks and slides) *(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)* Policies and procedures regularly reviewed (for example, every 1-3 years). There is a system for recording that staff have read the latest versions of these documents. Deviations from documented SOPs are recorded and monitored. Mortuary staff regularly attend meetings where issues relating to the licensed activities are discussed.	
Standard assessed during inspection:	YES / NO / N/A
Name / job title of staff member HTA standard was discussed with:	
Evidence:	

GQ2 There is a documented system of quality management and audit	
There is a quality manual which includes activities in the mortuary. Policies and SOPs are version controlled (and only the latest versions available for use). There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits). Audits include compliance with documented procedures, records (for completeness) and traceability. Audit findings document who is responsible for follow up actions and the timeframe for completing those actions. Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.	
Standard assessed during inspection:	YES / NO / N/A
Name / job title of staff member HTA standard was discussed with:	
Evidence:	

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	
Bodies are tagged/labelled upon arrival at the mortuary. There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records). Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded: material sent for analysis on or off-site, including confirmation of arrival receipt upon return to the laboratory or mortuary number of blocks and slides made repatriation with a body return for burial or cremation disposal or retention for future use. Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.	
Standard assessed during inspection:	YES / NO / N/A
Name / job title of staff member HTA standard was discussed with:	
Evidence:	

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly	
Staff are trained in how to use the incident reporting system. Staff know how to identify incidents and near-misses which must be reported. The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents. The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed. Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.	
Standard assessed during inspection:	YES / NO / N/A
Name / job title of staff member HTA standard was discussed with:	
Evidence:	

GQ8 Risk assessments of the establishments practices and processes are completed regularly and are recorded and monitored appropriately	
All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed. Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks. Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years. Risk assessments include how to mitigate the identified risks; this includes outstanding actions which need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.	
Standard assessed during inspection:	YES / NO / N/A
Name / job title of staff member HTA standard was discussed with:	
Evidence:	

Theme 3: Fridges and freezers safeguard the integrity of the deceased.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	
There is sufficient capacity for storage of bodies, organs and tissues. Temperatures of fridges and freezers are monitored on a regular basis. There are documented contingency plans in place should there be a power failure, or overflow.	
Standard assessed during inspection:	YES / NO / N/A
Name / job title of staff member HTA standard was discussed with:	
Evidence:	

Assessment of suitability of the Designated Individual (if suitability is required to be assessed)

Assessment of compliance with HTA Standards

Assessment of compliance with outstanding conditions

Interview record 1

Designated Individual:	
Interview started at:	
Interview finished at:	

- Introductions and thank the interviewee for sparing the time to attend the interview.
- Outline the aims of the interview, giving a clear indication of the length of time you expect to spend on the interview and in the department in total.
- Interview is not about individual performance but more about establishing what systems and processes are in place. Advise the interviewee that information from the interview would not itself lead to regulatory action and will not be attributed to individuals in the feedback meeting or the inspection report.
- Provide an explanation of the role of the HTA in providing advice and guidance role.
- Explain that you will be taking notes in order to contribute to the inspection report and clarify the issues to be covered

Suggested interview topics:

- Role and responsibilities
  - In relation to the licensed establishment
  - In relation to the organisation as a whole
- arrangements for overseeing licensed activity
- How do you satisfy yourself that you have suitable persons to carry out that activity and that they use suitable practices?
- How often do you meet staff working under the licence? What kinds of issues do you discuss? What changes have resulted?
- What is your involvement in the QMS?
- Management and reporting of SUIs
- CLHC support for effecting change

Interview Record 2

Corporate Licence Holder Contact:	
Interview started at:	
Interview finished at:	

- Introductions and thank the interviewee for sparing the time to attend the interview.
- Outline the aims of the interview, giving a clear indication of the length of time you expect to spend on the interview and in the department in total.
- Interview is not about individual performance but more about establishing what systems and processes are in place. Advise the interviewee that information from the interview would not itself lead to regulatory action and will not be attributed to individuals in the feedback meeting or the inspection report.
- Provide an explanation of the role of the HTA in providing advice and guidance role.
- Explain that you will be taking notes in order to contribute to the inspection report and clarify the issues to be covered

Suggested interview topics:

- Role and responsibilities
  - In relation to the licensed establishment
  - In relation to the organisation as a whole
- Arrangements for overseeing licensed activity?
- Support for DI to fulfil his/her statutory responsibilities?
- Frequency of meetings with DI
- How do you effect change in the event that significant expenditure is required to comply with HTA requirements?

Visual inspection notes:

Visual inspection notes:

Visual inspection notes:

Audit trail notes:

Audit trail notes:

Documentation review notes:

Documentation review notes:

Feedback notes:

Feedback notes:

Additional notes:

Shortfalls

Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall

A shortfall which poses a significant direct risk of causing harm to a living or deceased patient;

or

A number of 'major' shortfalls, which individually do not pose a direct risk of harm to a a living or deceased patient, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

1. A notice of proposal being issued to revoke the licence
2. Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
3. A notice of suspension of licensable activities
4. Additional conditions being proposed
5. Directions being issued requiring specific action to be taken straightaway.

2. Major shortfall

A non-critical shortfall:

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a living or deceased patient;

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a living or deceased patient;

or

A shortfall which indicates a major deviation from the Human Tissue Act 2004, the **Human Tissue (Quality and Safety for Human Application) Regulations 2007 or HTA Directions as applicable**;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues or cells or a failure on the part of the designated individual to fulfil their legal duties;

or

A combination of several ‘minor’ shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

3. Minor shortfall

A shortfall which cannot be classified as either critical or major that can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA at the time of the next inspection.