Site visit inspection report on compliance with HTA licensing standards

Queen Mary University of London

HTA licensing number 12199

Licensed under the Human Tissue Act 2004 for the

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

17 – 20 July 2017

Summary of inspection findings

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

Although the HTA found that Queen Mary University of London had met the majority of the HTA's standards, two shortfalls were found in relation to audits and governance meetings.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual 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 Designated Individual 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 site visit 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.

Background to the establishment
This report refers to activities carried out at Queen Mary University of London (the establishment). For the purposes of licensing, Queen Mary University of London (Barts and the London School of Medicine and Dentistry) is the hub site; St Bartholomew's Hospital, a satellite; Queen Mary University of London, Mile End Hospital, a second satellite; and the Blizard Institute, a third satellite.

The establishment is licensed for the storage of relevant material which has come from a human body for use in a scheduled purpose, under the Human Tissue Act 2004 (HT Act). Human samples are stored for use in the scheduled purpose of 'research in connection with disorders, or functioning, of the human body'.

The establishment has been licensed since 2007 and this was the second routine site visit inspection. The last inspection was in 2010. There are 10 Research Tissue Banks (RTBs) under the licence that have approval to collect, store, distribute and use human tissue for research. In addition, there are a number of collections of relevant material that are being stored for research that has been approved by recognised NHS Research Ethics Committees (RECs), including samples stored as part of clinical trials. Samples stored under recognised REC approval are exempt from the licensing requirement of the HT Act for the duration of the approval, after which the samples will then fall under the remit of the HTA licence.

The DI supervising activities taking place under the licence is a Tissue Bank Manager, the (Corporate) LH (CLH) is Barts Health NHS Trust and the CLH Contact (CLHc) is a Clinical Director of Pathology. The establishment has two Persons Designated (PDs) listed on the licence, one at the hub, the Barts Cancer Institute (BCI) Tissue Bank Operations Manager and one at the Blizard Institute satellite, a Institute Laboratory Manager (see Advice, item 14).

The total material held under the licence is approximately 140,000 samples.

The hub
At the hub there are seven RTBs and a recent BCI restructure has resulted in the streamlining of governance of the majority of RTBs, including the location of the freezers, consent procedures and temperature monitoring (see Table 1). In addition to the RTBs, there are four collections of relevant material being stored for research that has been approved by recognised RECs (see Table 2).

Tissue sources: consent, procurement, receipt and storage
A wide range of relevant material is stored under the licence, including: breast tumour tissue; whole blood; lymph nodes; biopsies (e.g. atria, appendages); plasma: urine; saliva; ovarian tissue; omentum; endometrium; buffy coat red blood cells; serum clot; pancreatic tumour tissue; prostate biopsy; testis; kidney; penile tissue; DNA samples from children with growth hormone deficiency and other material (serum). Tissue samples are from both the living and

the deceased. Samples are stored at a range of temperatures, including room temperature; -80°C and liquid nitrogen (see Advice, items 11 and 12).

Patients are predominantly recruited from local hospitals (St Barts and the Royal London); however, two RTBs (Breast Cancer Now and Pancreatic Cancer Research Fund Tissue Bank) also collect from, and collaborate with, other hospitals in London and across the United Kingdom (UK). Specific details for each RTB can be found below. Clinicians and staff involved in seeking consent must complete GCP training, shadow colleagues seeking consent, and be observed seeking consent before being deemed competent. In addition, some staff undergo the 'Sage and Thyme' training provided by Macmillan Cancer Support which provides staff with the appropriate tools for seeking consent, and listening to patients who are extremely ill. Patients are given an opportunity to discuss the proposed research, as well as some time to consider participating. Patients recruited for the Gynae Tissue Bank, Barts Pancreas Tissue Bank and Metastatic Cancer Tissue Banks meet with Tissue Acquisition Officers (TAO) who are trained in seeking consent and have a dedicated room in the Royal London where they meet with patients.

Samples are collected and transported to the hub either by courier or by a member of the research team using contracted taxi companies. Groups use different types of software products - including proprietary sample tracking software, online databases and spreadsheets - to track tissue. The BCI Tissue Bank Operations Manager aims to implement a unified tracking system which will be used by all Barts Cancer Centre (BCC) groups working under the licence in the hub.

Requests for tissue

Researchers at the establishment wishing to use tissue from any of the RTBs must submit a request, detailing their intended research to RTB staff. Depending on the nature of the research, the request will be reviewed by a committee of clinicians, oncologists, pathologists, lab managers, tissue bank managers, lay members or go to patient advisory groups. Tissue is not usually returned to the RTBs, and researchers must confirm with Tissue Bank Managers that the tissue has been disposed of following completion of the research.

Occasionally requests are made from researchers external to Queen Mary University of London. In these instances, a request form must be completed and the Joint Management Research Office (JMRO) or a committee will review these requests and draft a Material Transfer Agreement (MTA).

Governance documents

Each group inspected had a folder of the documents relevant for licensable activities. The level of detail in these folders, and the standard operating procedures within, varied greatly. Some overarching documents have been developed with regards to storage of relevant material, however, not all groups were working to these documents (see Advice, item 2).

Collaborations
At the hub, a number of RTBs collect for, or hold samples in collaboration with, other centres in the UK. Further details of these RTBs are listed below.

Breast Cancer Now Tissue Bank & Barts Cancer Institute Breast Tissue Bank
The breast cancer RTB is one of five national centres to supply tissue and data to the Breast Cancer Now Tissue Bank. Every two weeks, representatives from each centre meet to discuss external tissue bank requests, and monthly to discuss operations. Following collection, samples are divided between the Breast Cancer Now Tissue Bank and the Barts Cancer Institute Breast Tissue Bank, with priority given to samples for the Breast Cancer Now Tissue Bank.

Barts Cardiovascular Registry
The Barts Cardiovascular Registry works in conjunction with the NIHR National Biosample Centre (NIHR-NBC). Following collection, samples are duplicated and divided between the RTB at the establishment and the UK Biobank. NIHR-NBC provides software for recording sample location.

Barts Pancreas Tissue Bank
This Barts Pancreas Tissue Bank consists of two RTBs – the Pancreatic Cancer Research Fund Tissue Bank (PCRFTB), and Barts Pancreas Tissue Bank (BPTB). The establishment is one of four centres who supply tissue and data to the PCRFTB. Currently, the establishment is the only site able to undertake sample collection; however, recruitment at the other sites is imminent. At the Barts collection centre samples are collected and divided between the BPTB and PCRFTB, with priority given to the PCRFTB. At the other five sites either 100% or 50% of samples collected will be sent to the PCRFTB.

Orchid Tissue Bank
In addition to the RTB, there is also a separate collection (British Testicular Panel Collection) of approximately 4000 blocks and slides from the 1950's. These blocks and slides are not subject to the consent requirements of the HT Act; however, they are subject to the licensing requirements.

Site	**Collections inspected**
Queen Mary University of London	• Breast Cancer Now Tissue Bank & Barts Cancer Institute Breast Tissue Bank • Barts Cardiovascular Registry • Barts Pancreas Tissue Bank

(Barts and the London School of Medicine and Dentistry)	• Orchid Tissue Bank • Barts Gynae Tissue Bank • Metastatic Cancer Tissue Bank • Paediatric Endocrinology
The Blizard Institute	• Digestive Diseases Bioresource • Amaze study

Queen Mary University of London, Mile End Hospital (satellite)
Two collections are held at the Queen Mary University of London satellite site. A collection of approximately 100 teeth collected prior to 2005 and stored in 70% alcohol is held as part of the Dental School. Teeth are no longer being collected, and this collection is used for teaching and research purposes. Once provided to a researcher, teeth do not return to the collection, and the researcher must confirm disposal with the Principle Investigator (PI) responsible for the collection.

A second collection - comprising of cartilage, amniotic membrane, tumour tissue and tendons - is held in the Biomedical Engineering department in -20 and -80°C freezers and at room temperature. Further details can be found in the 'other collections' section of this report, below.

St Bartholomew's Hospital (satellite)
Samples from two collections are stored in the satellite in one -80°C freezer (see Advice, item 11). One collection has approval from a recognised REC for the storage and use of the tissue, and the second is held under the governance of the licence. In both collections recruitment for the studies is no longer being performed. Samples held include tumour tissue, blood and serum. Sample locations are recorded using proprietary sample tracking software. The DI has received requests for two additional studies which will be stored in the hub in the future. At the time of inspection, no new samples had been added to or removed from the freezer for a number of years.

The Blizard Institute (satellite)
One RTB and four collections of relevant material are held in the Blizard Institute. As with the hub site, a number of overarching documents are in the process of being developed for researchers working with relevant material (see Advice, item 2).

Digestive Diseases Bioresource
The Digestive Diseases Bioresource RTB encompasses a number of groups including surgery, Immunology and Infectious Disease. Samples are collected from patients, both adult and paediatric, undergoing investigation or treatment for a number of digestive-related diseases, including Crohn's disease and irritable bowel syndrome. The majority of groups

working under the governance of the RTB use tissue immediately following collection, however some groups, do store tissue for use in their own projects and collaborations.

Patients are recruited and identified from the surgical, endoscopy, out and in-patients lists of mainly the Royal London and St Barts Hospitals. Consent is sought either by the researcher, or by the consultant clinical teams treating the patient. A single consent form has been developed and distributed to all groups working under the RTB structure. Staff seeking consent include researchers and clinicians, and all have completed GCP training and are trained in the SOP's of the RTB.

Researchers wishing to use samples stored in the RTB must submit a request, including intention of study and relevant protocols. This is peer-reviewed by two independent reviewers, external to the department.

Samples are held at room temperature and -80°C (see Advice, items 11 and 12). Samples include urine, biopsies and saliva.

Amaze study
Samples from this study originated in Zambia and have been brought to the UK for further analysis. They will be transferred to another HTA-licensed establishment for analysis in due course. Samples are blocks and slides stored at room temperature. As these samples are imported, they are not subject to the consent requirements as set out in the HT Act, however the DI has assurance that appropriate consent has been sought. Samples are not currently logged on a tracking system (see Advice, item 8).

Other collections
In addition to the collections detailed above, eight other collections were inspected (Table 2). These collections included samples surplus to diagnostic requirements from surgical procedures; biopsies of various types; blood; urine; and tumour tissue. Samples are sourced from St Barts and the Royal London, and in some instances other hospitals around the UK are collaborating with the groups. Samples are stored at a variety of temperatures, including room temperature, -80°C, and liquid nitrogen. Consent for all samples was sought by the treating clinician, or by a researcher specific to the group. In all instances, staff seeking consent had received GCP training.

During the inspection, these collections were inspected by the HTA and, following the audit, it became clear that each of these collections are covered by REC approval from a recognised REC, either NHS or UKECA, and as such, exempt from the HTA licensing requirements.

Table 2: Tissue collections inspected with approval from a recognised REC

Site	Collections inspected

Queen Mary University of London (Barts and the London School of Medicine and Dentistry)	• Experimental Medicine and Rheumatology • Cancer Prevention • Molecular Endocrinology • Haemato-Oncology
The Blizard Institute	• Cutaneous Research • Paediatrics • Neurology ALS Biomarkers
Queen Mary University of London (Mile End Hospital)	• Biomedical Engineering • Dental collection

Description of inspection activities undertaken

The inspection comprised of roundtable discussions with members of staff working under the licence, visual inspections of the laboratories where human tissue is stored under the licence, a review of governance documentation and interviews with:

- the BCI Tissue Bank Operations Manager (PD)
- a Laboratory Manager (PD)
- a Medical Laboratory Assistant
- a Professor of Oral Biology
- a Laboratory Manager
- a Professor in Medical Engineering and Deputy Director of Taught Programmes
- a Laboratory and Workshop Manager
- a Technician
- the Clinical Director of Pathology (CLHc)
- the DI

In addition, traceability audits were carried out for a total 87 samples stored across varying temperatures including room temperature, -80°C and liquid nitrogen. Samples were identified from their storage location and traced to the relevant documents, in addition to being selected from the human tissue inventory and traced to the storage location. Minor discrepancies were noted in two consent documents where the date had not been completed and where the form had been ticked instead of initialled (see Advice, item 4).

Inspection findings

The HTA found the Licence Holder, the Designated Individual and the premises to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.	A large number of staff work with relevant material held under the licence. However, there are no formal meetings where staff come together to discuss matters relating to the HTA licence, including audits or incidents. *See Advice, item 3*	**Minor**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits covering licensable activities.	The following collections held under the licence are not subject to a regular schedule of audit: • Barts Gynae Tissue Bank • Metastatic Cancer Tissue Bank • Orchid Tissue Bank • Paediatric Endocrinology • Breast Cancer Now Tissue Bank & Barts Cancer Institute Breast Tissue Bank • both collections at St Bartholomew's Hospital • both collections at Queen Mary University of London, Mile End • Digestive Diseases Bioresource • Amaze study Audits of sample traceability; consent; and documentation for content and accuracy are not currently undertaken. There is no schedule of audits in place. *See Advice, item 4*	**Minor**

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	C1(d)	While the majority of consent forms and patient information sheets used by researchers detail how a participant may withdraw consent, consent forms and patient information sheets related to the Breast Cancer Now Tissue Bank & Barts Cancer Institute Breast Tissue Bank are significantly less detailed. The DI is advised to review all documentation used to support the seeking of consent to ensure that information about consent withdrawal is sufficiently detailed and includes the relevant contact details.
2.	GQ1(a)	Not all standard operating procedures are sufficiently detailed to optimally reflect current practices. Where overarching documents are in place, the DI should ensure that all groups have and work to these. Where group-specific documents are in place the DI should assure himself that these are adequately detailed and consider all practices related to human tissue.
3.	GQ1(d)	Some staff working under the licence meet on an ad hoc basis. However, all staff working under the licence should be aware of the governance arrangements in place, and they should be represented at governance meetings. Formal meetings should be minuted and the actions should be noted and followed up. Documented minutes of meetings should be distributed to all

		relevant staff to help to ensure that they are aware of all important information relating to licensed activities at the establishment. The HTA recommends that the CLHc attends the first few meetings held.
4.	GQ2(a)	Audits are undertaken at the establishment; however, with the exception of one group, licensed activities are not currently included. The DI is advised to create a schedule of audits to demonstrate compliance against the HTA standards. Vertical audits of records and specimens should allow the establishment to assure itself that specimens and records are fully traceable from consent to disposal. Records, including records of consent, should be audited regularly to ensure completeness, accuracy and legibility. Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. Audits should be carried out on a periodic basis, or following a change in process. Shortly after receiving the first batch of samples the DI is advised to conduct an audit of all processes and procedures related to the samples. This will provide assurance that the systems in place are working as expected. Audits should be performed by colleagues working in different research groups and the findings shared at meetings.
5.	GQ2(b)	The DI is advised that audit findings and corrective and preventative actions should be recorded, and should include timeframes for completion. The DI may wish to develop a form to record audits so that they are consistently captured and followed-up.
6.	GQ5(a)	The DI has developed an incident reporting SOP which has been circulated to some but not all groups working under the licence. The DI is advised to ensure all groups are aware of this document. Individual groups may have their own procedures in place; however, the DI needs to be assured that incidents are captured and escalated appropriately. The DI should consider updating the document to include examples of what an incident related to human tissue may be, for example: • specimen loss; • missing or incorrect documentation; • security breach; • abnormalities in storage temperature readings; • inappropriate disposal.
7.	GQ6(a)	A risk assessment matrix has been developed, which addresses the potential risks to relevant material; however, not all groups have updated this matrix to reflect all the risks specific for each group. The DI is advised to ensure that all groups have undertaken and documented appropriate risk assessments.
8.	T1(c)	While the majority of collections held under the licence use a tracking system to ensure the audit trail is maintained of samples, not all collections have such a system. The DI is advised to ensure that all collections are

		recorded on a system which is auditable and can trace the sample from storage to use to disposal.
9.	T1(c)	The establishment also stores non-human material. To avoid the risk of sample confusion, and to ensure that human tissue samples are handled in line with the regulatory requirements under the HT Act, the DI should assure himself that all freezers and containers holding human tissue are labelled appropriately. Where possible, non-human material should be stored on a separate shelf to human material.
10.	T2(b)	The DI has created a documented procedure for the disposal of relevant material in accordance with the HTA's Codes of Practice. Amongst the groups inspected some variation was noted in terms of the use of this document as well as in the recording of date, reason and method of disposal. The DI should assure himself that all groups are recording the same information when disposing of tissue.
11.	PFE2(c)	The majority of freezers and liquid nitrogen tanks inspected are linked to a remote call out system, which will alert relevant staff to temperature deviations. However, freezers in paediatric endocrinology (in the hub), Queen Mary University of London (satellite) and St Bartholomew's Hospital (satellite) were not linked to a remote call out system. To ensure consistent coverage, the DI is advised to link all freezers used to store relevant material to a remote call out system or, at least, to undertake a documented risk assessment if a consistent approach cannot be adopted.
12.	PFE2(c)	All freezers and liquid nitrogen tanks are on maintenance contracts and are routinely service: however, the alarms are not challenged. The DI is advised to implement a schedule where freezer alarms are tested to ensure the call out system triggers and contacts the appropriate people. This test should be documented and any failures in procedure followed up. This will provide assurance that the system is working as expected.
13.	PFE2(d)	Currently, there are contingency arrangements in place in the event of a storage failure; however, the majority of these are informally agreed. The DI is advised to ensure contingency arrangements are documented, which will provide more formal assurance that samples will be safe in the event of a storage failure.
14.	N/A	To provide assistance in the governance of the licence, the DI is advised to nominate more PDs, with a recommendation that there is one PD per collection. PDs should attend governance meetings, and should perform audits of other collections. The HTA must be notified of the PDs, including contact details and job titles.

Concluding comments

In terms of good practice, in the Barts Cardiovascular Registry group, an audit is completed of consent records of those deemed competent. The Cancer Prevention group had also performed a detailed audit against the HTA standards and documents were held under the respective HTA standards, which demonstrated a good understanding of the requirements.

There are a number of areas of practice that require improvement, including two minor shortfalls.

The HTA requires the Designated Individual 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.

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.

Report sent to DI for factual accuracy: 16 August 2017

Report returned from DI: 25 August 2017

Final report issued: 31 August 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 23 February 2018

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
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
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.
c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
b) A register of donated material, and the associated products where relevant, is maintained.
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.
f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice.
b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity.
b) Where relevant, storage arrangements ensure the dignity of the deceased.
c) Storage conditions are monitored, recorded and acted on when required.
d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
c) Staff are provided with suitable personal protective equipment.

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 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 Human Tissue Act 2004 (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:

   (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 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 CoPs, 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 or site visit.

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. You 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 site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

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