**Site visit inspection report on compliance with HTA minimum standards**

**Institute of Neurology, UCL**

**HTA licensing number 12198**

**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**

**26 & 27 November 2014**

## Summary of inspection findings

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

Although the HTA found that Institute of Neurology, UCL (the establishment) had met the majority of the HTA standards, shortfalls were found, particularly in relation to Consent, Governance and Quality Systems (GQ) and Premises, Facilities and Equipment (PFE). The shortfalls relate to the recording of consent, SOPs, traceability, audits and risk assessments. Advice has also been given relating to the Consent, GQ and PFE standards.

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

## The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

## Background to the establishment and description of inspection activities undertaken

The Institute of Neurology, University College London (the establishment) is an academic research institute undertaking research into a variety of neurological disease types. The HTA licence covers the storage by five independent research groups consisting of two tissue collections and three Research Tissue Banks (RTBs). The tissue collections and one of the RTBs are located at the hub site, with the other two RTBs located at the satellite site. Each of the research groups has an assigned Person Designate (PD) under the licence who reports to the DI on matters relating to licensable activities.

The RTBs have NHS Research Ethics Committee (NHS REC) approval.

Individual research projects that have NHS REC approval are exempt from the licensing requirements of the HT Act. However, tissue collections associated with these research projects are subject to licensing by the HTA if they continue to be stored after the NHS REC approval has lapsed.

All human tissue is stored for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'. The establishment has been licensed by the HTA since August 2007. This report describes the first, routine, site visit inspection of this establishment in November 2014. The timetable for the site visit inspection was developed in consideration of the establishment's licence application, compliance update information and

pre-inspection discussions with the DI. The site visit inspection included a visual inspection of the storage areas, a review of documentation and meetings with establishment staff. The inspection team conducted interviews with the DI, PDs, Tissue Bank Manager and Tissue Bank Technician. An audit of traceability records, including paper-based and electronic databases, and storage locations was conducted for each of the tissue collections held under the HTA licence. All samples were chosen at random by the inspection team. Anomalies were found in traceability records for the Epilepsy Society Brain and Tissue Bank

Two tissue collections and the three RTBs were inspected. A summary of each of the individual research groups is as follows:

Medical Research Council (MRC) Prion Unit:

The MRC Prion Unit works closely with the National Prion Clinic and stores human tissue which has been donated from patients attending the clinic and post mortem samples obtained from mortuaries. The MRC Prion Unit is located within the hub site at the Institute of Neurology on floors 2, 3 and 4. Some of the material is held under one of the twenty one recognised Research Ethics Committee approvals and is therefore outside the coverage of the HTA licence. The research group hold a total of approximately 22,000 samples, including tissue samples, which consists of brain, cerebrospinal fluid (CSF), spleen, appendix and nasal mucosa.. Samples are stored as frozen, formalin-fixed, paraffin-embedded and tissue sections on slides. Samples are assigned an unique identifier upon receipt which is recorded in both paper and electronic records.

Consent is not sought by researchers directly but by third parties such as clinicians and nurses from the National Prion Clinic.

Epilepsy Society Brain and Tissue Bank (ESBTB):

The ESBTB is located at the hub site on the first floor of the Institute of Neurology within the department of Neuropathology. It is a repository for collections of biological samples from patients with epilepsy and normal controls. Samples are obtained from both the living and deceased. The repository has recently obtained RTB status (12/SC/0669) and has a part-time RTB Manager, for whom the DI is the line manager. Material is generally received into the department of Neuropathology as diagnostic or coroner's case post mortem samples which are then released to the ESBTB if consent has been granted for research. Surgical material is allocated a NH number and post mortem material a NP number, both of which are generated by the electronic database system CoPath.

The RTB holds approximately 1000 brain samples which consist of tissue from both the living and deceased. Surgical tissue is stored as formalin-fixed, paraffin-embedded, frozen and tissue sections on slides. All material is stored within the diagnostic archives. Post mortem tissue is stored as formalin-fixed, paraffin-embedded and tissue sections on slides in the post mortem tissue bank archive located in the basement of the establishment hub site.

Consent for diagnostic surgical samples is obtained generally in advance by the Clinician caring for the patient. This sometimes occurs retrospectively but consent is still taken by Clinicians. Consent for retention of post mortem samples following a coroner's inquest is obtained generally by the ESBTB manager. However, there was evidence of consent for retention of tissue for research being obtained by the Coroner's officers at the time of the Coroner's inquest. Relatives are initially contacted by post with an information leaflet and consent form detailing tissue donation to the ESBTB. This is followed-up two weeks later with a phone call by the ESBTB manager.

MRC Centre for Neuromuscular Diseases Biobank London (MRC CNMD):

The biobank is located at the hub site on the ground and first floor of the Institute of Neurology. The biobank works closely with the Muscle Biopsy Service at the Institute of Neurology where tissue is taken primarily for diagnostic use. The majority of material is collected through Great Ormond Street Hospital for Children. Excess diagnostic tissue for which consent has been obtained for research is released to the MRC CNMD Biobank. The biobank holds approximately 200 samples from the living, consisting of muscle, skin and urine as frozen samples and tissue sections on slides. Each sample has a unique biobank identifier.

Small pieces of tissue are released from the biobank for processing into cultures to the Dubowitz Neuromuscular Unit located at the Institute of Child Health under the ethically approved project 06/Q0406/33. The MRC CNMD biobank does not hold ethical approval as a Research Tissue Bank; this option was not available at the time. As such, the MRC CNMD biobank does not have generic approval for other research projects and therefore samples may only be released to research projects with existing ethical approval in place. The MRC CNMD London Biobank has a counterpart located in Newcastle. In May 2010 both biobanks were approved to join the EuroBioBank. Consent is not sought by researchers directly but by third parties such as clinicians and nurses.

Queen Square Brain Bank (QSBB):

The QSBB is located on the ground floor and basement of the satellite site of 1 Wakefield Street in the department of Molecular Neuroscience, Institute of Neurology. It holds a national collection of brains donated by individuals with a variety of neurological disorders including Parkinson's disease, multiple system atrophy, progressive supranuclear palsy and corticobasal degeneration. Tissue is held in a RTB which has been established since 2008. Recently the QSBB RTB has merged much of its governance with the NeuroResource RTB, and these RTBs now have joint REC approval which was granted in September 2013.

They receive material from all over the UK via their donor system. Upon receipt of the tissue, it is booked into a database and assigned a P number which is generated manually. Eighty-percent of material received is fresh and is flash-frozen or fixed by the establishment. The remainder are received as fixed material from the mortuary. The majority of all material received is for research, only rarely are brains received as part of a Coroner's inquest. Approximately 2000 brain samples are held as frozen, formalin fixed, paraffin embedded or tissue sections on slides.

Consent is sought by tissue bank staff and was originally taken only from relatives following the person's death; however, the consent-seeking process has recently been updated to include consent obtained in life from the donor. A trained member of staff is on call twenty four hours a day, seven days per week. They liaise with the hospital mortuary nearest to the deceased to arrange removal of the brain. They have a number of Service Level Agreements in place with a number of hospital mortuaries throughout the UK.

NeuroResource Tissue Bank (NRTB):

The NRTB is located in the basement of the satellite site of 1 Wakefield Street in the department of Neuroinflammation, Institute of Neurology. The Tissue Bank accepts donations of CNS tissues from patients who have multiple sclerosis, motor neurone disease, stroke, brain tumours, migraine or chronic pain as well as healthy controls.

The NRTB has recently been merged with the QSBB from a REC approval perspective and it shares many of the receipting procedures with this group. Following receipt into QSBB and

initial processing, samples are released to the NRTB where they are assigned a unique B-number. Samples are tracked using a variety of electronic and paper based records. The consenting procedure for the NRTB is separate from the QSBB. A trained member of staff is responsible for the taking of consent. Many of the procedures relating to obtaining and transfer of the brain from the deceased to the NRTB are shared with the QSBB.

## Inspection findings

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

## Compliance with HTA standards

### Consent

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent. | MRC CNMD – Internal consent procedures are not being followed. Two consent forms for the two samples tracked as part of the audit lacked information about the Participant Information Sheet given to the donor, despite the consent form stipulating this information. One of the consent forms was also completed with ticks rather than initialling as requested on the form (see also advice item 2). | **Minor** |

### Governance and Quality

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process. | NRTB – At the time of inspection samples were tracked through the NRTB using multiple electronic and paper-based records. However no existing SOP covered this procedure in sufficient detail (see also advice item 3).<br><br>ESBTB – In general, SOPs are not sufficiently detailed and so do not accurately reflect agreed practices (see also advice item 7).<br><br>Taking all the findings across the groups covered by the licence into account, this constitutes a minor shortfall. | **Minor** |

| | | |
|---|---|---|
| GQ2 There is a documented system of quality management and audit. | Although the establishment has put in place a range of robust audit procedures, a number of inconsistencies were noted in the way in which audit findings were documented and followed-up. For example, actions arising from audits were not always assigned to members of staff for implementation and time limits for the completion of corrective measures were not always defined. Furthermore, audit records did not always capture the fact that corrective measures had been taken. | **Minor** |
| GQ5 There are documented procedures for the distribution of body parts, tissues or cells | ESBTB – there is no documented procedure for the transfer of custody of material from Neuropathology to ESBTB. No SOP was in place to detail how both post mortem tissue and diagnostic tissue with consent for research is accessed and moved around the building. | **Minor** |
| GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail. | ESBTB – anomalies were identified during the audit trail: one block from post mortem tissue was not found and there is no recording system for post mortem tissue received from Neuropathology, making it difficult to identify whether errors in records are administrative or from the misplacing of tissue samples. | **Minor** |
| GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately. | QSBB – A number of risk assessments have not been updated since 2011 (see also advice item 11).<br>ESBTB and NRTB – Although the tissue banks have put in place a range of risk assessments relating to the work carried out by the ESBTB and NRTB, these focus primarily on health and safety issues. A number of risk assessments have been performed in relation to the work being conducted under the authority of the establishment's HTA licence. However, at the time of the inspection, risk assessments were not in place for all such activities, including, for example, the maintenance of sample traceability, the receipting of tissue or the obtaining of informed consent (see also advice item 9). | **Minor** |

## Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | C2 | The DI is advised, where possible, that information leaflets and consent forms sent out to relatives of potential donors should be available in a variety of languages and formats. This should support the seeking of informed consent from donors from a range of ethnic groups and those with specific communication needs. |
| 2. | C3 | CNMD - Consent-seekers should be trained to follow local procedures to ensure consent forms are completed in accordance with agreed procedures. |
| 3. | GQ1 | The NRTB traceability system is complicated, increasing the risk of a loss of traceability. It would be advisable to review and simplify the system, where possible, to reduce this risk. |
| 4. | GQ1 | Many of the policies and procedures for human tissue displayed on the UCL website (e.g. the SOP 'Adverse Event and Incident Reporting'), and the name of the Corporate Licence Holder contact (CLHc) in the quality manual used by one of the groups at the establishment, are several years out of date. Links from the Institute of Neurology website go to the out of date policies and procedures for human tissue found on the UCL website. Therefore, in partnership with the CLHc, the DI is advised to review the HTA page of the UCL website to ensure that the contents are fit for purpose:<br>http://www.ucl.ac.uk/slms/research/human-tissue-act/ |
| 5. | GQ1 | The HTA licence encompasses six relatively large tissue collections, each controlled by independent research groups. The establishment has recently increased the frequency of HTA governance meetings in the lead up to this inspection. The DI is encouraged to continue to hold frequent meetings and use these governance meetings to share best practice between groups and aid her oversight of all licensed activities. |
| 6. | GQ1 | The QSBB identify critical samples on both the freezer maps and the storage location records. This good practice is however not recorded in an SOP. They are therefore advised to record this process in the relevant SOP. |
| 7. | GQ1 | The DI is advised that the ESBTB SOPs which have been recently developed should be reviewed. They currently lack detailed key information to reflect the current procedures which are being conducted. |
| 8. | GQ8 | The DI is advised to review the content of the minutes from the Prion Unit's risk management meetings to ensure that sufficient information is recorded to clearly identify the specific risks that are discussed during the meetings, and that the basis for any decisions taken to tolerate activities classified as 'high risk' is also documented. |
| 9. | GQ2 | Previously, reciprocal audits between groups holding tissue collections under the HTA licence were conducted on a regular basis. The DI is advised to reinstate these audits, recording all findings and implementing corrective and preventative action plans. This will allow all groups to share best practice, review working practices from a different perspective and help the DI to have improved oversight of licensed activities. |

| | | |
|---|---|---|
| 10. | GQ2 | Audit findings should be consistently recorded, with corrective and preventative action plans implemented as appropriate. Actions should be time-bound and assigned to individuals, with a consistent procedure for signing off actions that have been completed. It is advised this process should be overseen by the DI or the PD and discussed at HTA-related governance meetings. |
| 11. | GQ8 | Generally, the establishment's risk assessments are authored and signed-off by the same person. The DI is advised to consider implementing a system whereby risk assessments are signed off by a third party, possibly herself or a PD, and discussed at HTA-related governance meetings. This should allow the DI to be aware of the associated risks for each of the tissue collections held under the licence. |
| 12. | GQ8 | Prion Unit – a single digit error was found in the score range; specifically, a numerical overlap. The error identified should be corrected.<br><br>QSBB - Risk assessments should be subject to regular review and updated where necessary. |
| 13. | PFE1 | Due to the age and infrastructure of the buildings, the storage facilities for the QSBB, NRTB and the ESBTB are reaching full capacity. In collaboration with CLHC, the DI is advised to identify alternative suitable and appropriately licensed storage facilities to store historical material held by these tissue banks. |
| 14. | PFE2 | The wet tissue archive area for the ESBTB is located adjacent to the brain cutting room in the basement of the hub site. Access to the archive area is shared by multiple groups including the Prion Unit. There is currently no marked boundary between the cutting room and the archive area, and staff can traverse between the two. There is a risk that staff could contaminate the archive area, as well as the outside corridor, with infectious material. The DI is advised to consider how to manage this risk. A clear boundary line between these two areas should be considered, as should an associated policy. |
| 15. | N/A | The DI is currently contracted to work, on a part-time basis, as a Neuropathologist within the Institute of Neurology. The HTA licence covers the storage of relevant material by six independent research groups, consisting of one tissue collection and five RTBs. This is a relatively large and complex establishment for the DI to oversee and be responsible for. The Licence Holder should consider how the DI can be optimally supported and resourced so that the required changes identified as a result of this inspection are implemented. |

## Concluding comments

This report outlines the first HTA site visit inspection of Institute of Neurology, UCL. There were a number of areas of good practice observed during the inspection. The establishment as a whole demonstrated a strong commitment to the continual improvement of practices and compliance with the Human Tissue Act (HT Act). Each of the individual groups demonstrated areas of good practice which include:

- ESBTB – a compassionate and thorough approach to the seeking of consent from the families of deceased patients.
- Prion Unit – detailed and informative risk assessments for the majority of procedures.
- MRC CNMD – a detailed procedure recording the commencement of custody of relevant material.
- QSBB – a simple yet effective traceability system for the stored relevant material.

Staff spoke of discussions where procedures and good practice have been shared and implemented by the individual groups. Staff demonstrate a conscientious approach to the handling and traceability of relevant material and a compassionate approach to the seeking of consent. The Designated Individual has a challenging role in overseeing such a multifaceted establishment; however, she is managing the role and is well supported by the PDs located in each of the groups. The DI has implemented regular HTA governance meetings with the PDs to enable her to have oversight of licensable activities undertaken at the establishment and to share working practices between groups. There is clearly a good level of interaction and communication which occurs between the DI and those carrying out licensed activities.

There are a number of areas of practice that require improvement, including five minor shortfalls. The HTA has given advice to the Designated Individual with respect to consent, governance and quality systems and premises, facilities and equipment.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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: 18 December 2014**

**Report returned from DI: 09 January 2015**

**Final report issued: 17 March 2015**

**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: 16 October 2015**

## 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** |
| • Consent forms comply with the HTA's Code of Practice<br>• Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose<br>• If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice<br>• Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice<br>• Consent procedures have been ethically approved |
| **C2 Information about the consent process is provided and in a variety of formats** |
| • Standard operating procedures (SOPs) detail the procedure for providing information on consent<br>• Agreements with third parties contain appropriate information<br>• Independent interpreters are available when appropriate<br>• Information is available in suitable formats, appropriate to the situation<br>• Consent procedures have been ethically approved |
| **C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent** |
| • Standard operating procedures (SOPs) detail the consent process<br>• Evidence of suitable training of staff involved in seeking consent<br>• Records demonstrate up-to-date staff training<br>• Competency is assessed and maintained |

| Governance and quality system standards |
|---|
| **GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process** |
| • Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body<br>• Appropriate risk management systems are in place<br>• Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes<br>• Complaints system |
| **GQ2 There is a documented system of quality management and audit** |
| • A document control system, covering all documented policies and standard operating procedures (SOPs).<br>• Schedule of audits<br>• Change control mechanisms for the implementation of new operational procedures |
| **GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills** |
| • Qualifications of staff and training are recorded, records showing attendance at training<br>• Orientation and induction programmes<br>• Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training<br>• Training and reference manuals<br>• Staff appraisal / review records and personal development plans are in place |
| **GQ4 There is a systematic and planned approach to the management of records** |
| • Documented procedures for the creation, amendment, retention and destruction of records<br>• Regular audit of record content to check for completeness, legibility and accuracy<br>• Back-up / recovery facility in the event of loss of records<br>• Systems ensure data protection, confidentiality and public disclosure (whistle-blowing) |
| **GQ5 There are documented procedures for distribution of body parts, tissues or cells** |
| • A process is in place to review the release of relevant material to other organisations<br>• An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return |

**GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail**

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

**GQ7 There are systems to ensure that all adverse events are investigated promptly**

- Corrective and preventive actions are taken where necessary and improvements in practice are made
- System to receive and distribute national and local information (e.g. HTA communications)

**GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately**

- Documented risk assessments for all practices and processes
- Risk assessments are reviewed when appropriate
- Staff can access risk assessments and are made aware of local hazards at training

**Premises, facilities and equipment standards**

**PFE1 The premises are fit for purpose**

- A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose
- Policies in place to review and maintain the safety of staff, authorised visitors and students
- The premises have sufficient space for procedures to be carried out safely and efficiently
- Policies are in place to ensure that the premises are secure and confidentiality is maintained

**PFE 2 Environmental controls are in place to avoid potential contamination**

- Documented cleaning and decontamination procedures
- Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination
- Appropriate health and safety controls are in place

**PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.**

- Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination
- Contingency plans are in place in case of failure in storage area
- Critical storage conditions are monitored and recorded
- System to deal with emergencies on 24 hour basis
- Records indicating where the material is stored in the premises

**PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination**

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

**PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored**

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

**Disposal Standards**

**D1 There is a clear and sensitive policy for disposing of human organs and tissue**

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

**D2 The reason for disposal and the methods used are carefully documented**

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

## 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.