Site visit inspection report on compliance with HTA licensing standards

Royal Brompton and Harefield NHS Foundation Trust

HTA licensing number 12388

Licensed under the Human Tissue Act 2004 for the

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

22-25 August 2017

Summary of inspection findings

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

Although the HTA found that Royal Brompton and Harefield NHS Foundation Trust (the establishment) had met the majority of the HTA's standards, one major and three minor shortfalls were found. The major shortfall was in relation to sample traceability (T1(c)). The minor shortfalls were in relation to: (i) governance arrangements for the removal licence (GQ1 (a)); (ii) governance arrangements for one of the research tissue banks (GQ1(a)); and (iii) temperature monitoring of satellite storage facilities (PFE2(c)).

Advice has been given relating to the Consent, Governance and Quality systems, Traceability, and Premises, Facilities and Equipment standards, as well as advice on licence management.

Particular examples of strength 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 (DI) is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of 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 the activities carried out by Royal Brompton and Harefield NHS Foundation Trust (the establishment). The establishment's arrangements under this licence cover a hub and four satellites sites. The hub (Royal Brompton Hospital, RBH) and one of the satellites (Harefield Hospital, HH) are part of the Trust. Three other satellites (Sir Alexander Fleming Building ['SAF'], Emmanuel Kaye Building ['EK'], and Guy Scadding Building ['GS']) are part of Imperial College London Faculty of Medicine. The establishment was issued an HTA licence in February 2007 and was last inspected by the HTA in October 2012. The current inspection was a routine site visit to assess whether the establishment is continuing to meet the HTA's standards.

The establishment is licensed under the Human Tissue Act 2004 for the removal of relevant material from the deceased for use for a scheduled purpose and the storage of relevant material for use for a scheduled purpose. Relevant material from living and deceased donors is currently being stored for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body' ('research'). Although the activity of removal of relevant material from deceased donors for the scheduled purpose of research was added to the licence in July 2014, there was no evidence during the inspection that this was taking place and no documentary evidence to support this procedure (see shortfall against GQ1(a)).

The DI supervising activities taking place under the licence is the Trust Director of Research, the Corporate Licence Holder (CLH) is the Royal Brompton and Harefield NHS Foundation Trust and the CLH Contact (CLHC) is the Trust Medical Director. There are currently eight Persons Designated (PDs) working under the licence; including three active ones at the hub and one active one at each of the satellites (see *Advice*, item 1).

Licensed collections include: Research Tissue Banks (RTBs); sample sets previously stored under NHS Research Ethics Committee (REC) project-specific approval (or those previously stored as part of UK Ethics Committee Authority, UKECA-approved clinical trials) where the approval has expired; and imported samples. Sample sets stored under current REC or UKECA approval do not fall under the HTA licence.

Samples originate from adults, children and foetuses, and include both tissue and bodily fluids. Relevant material includes tissue samples: formalin-fixed, paraffin wax-embedded material (blocks and sections on glass slides), isolated cellular preparations (e.g. peripheral blood mononuclear cells), fresh frozen tissue and frozen tissue sections on glass slides. Bodily fluids include urine, saliva and whole blood. Several of the collections also contain other material (e.g. plasma and serum). In total, there are approximately 140,000 human samples stored under the licence.

Samples are obtained from patients during clinical consultations within the Trust, from surgical operations, from patients undergoing heart and lung transplants (explant samples), from the Trust diagnostic pathology archives and from healthy volunteers. Samples are also received from collaborators both within and outside the UK.

The establishment contains three ethically-approved RTBs: the Cardiovascular Clinical Research Centre (CCRC) RTB; the Respiratory Clinical Research Centre (RCRC) RTB and the Diagnostic Archive RTB.

The CCRC and RCRC RTBs contain surgical biopsies, explanted tissue and bodily fluids (whole blood, urine, and saliva). Each RTB holds approximately 50,000 samples. They are governed by separate Tissue Management Committees, which review applications to the RTB, review results from each study, and approve release of samples. Samples are released on a 'linked-anonymised' ('pseudonymised') basis; in other words, the researcher cannot know the identities of the donors. Each Tissue Management Committee includes the DI, specific PDs, a Tissue Bank Manager, senior clinicians and scientists, and a lay representative. The Tissue Bank Manager completes the annual returns to the Health

Research Authority (HRA) summarising requests to the RTB and the tracking of material sent out.

The Diagnostic Archive RTB contains surgical and post-mortem formalin-fixed, paraffin wax-embedded blocks and slides and frozen tissue sections. There is no formal governance structure for the management of the Diagnostic Archive RTB (see shortfall against GQ1(a)).

The hub and satellite sites also contain 17 research groups holding collections of tissue and bodily fluids that fall under the licence (approximately 25,000 samples). Each research group contains a number of principal investigators.

The RTBs and research groups that were inspected are summarised in Table 1.

Table 1: Tissue collections and research groups inspected.

Site	Collection					
Royal Brompton Hospital (RBH; Hub)	Cardiovascular Clinical Research Centre (CCRC) RTB – RBH	Respiratory Clinical Research Centre (RCRC) RTB	Laboratory Medicine (Haematology/ Biochemistry)	Laboratory Medicine (Histopathology Core Facility)	Cardiac Morphology Unit	Muscle Group (RBH)
Harefield Hospital (HH; Satellite)	Heart Valve Biology Laboratory	Muscle Laboratory (HH)	Genetics and Genomics Facility	Cardiovascular Clinical Research Centre (CCRC) RTB – HH		
Sir Alexander Fleming Building (SAF; Satellite)	Allergy and Clinical Immunology	Inflammation Repair and Development	Respiratory Pharmacology	Molecular Medicine		
Emmanuel Kaye Building (EK; Satellite)	Respiratory Epidemiology/ Public Health	Gene Therapy				
Guy Scadding Building (GS; Satellite)	Airways Cellular Biology	Molecular Genetics	Cardiothoracic Pharmacology	Novel Therapies		

Consent

Consent for donation is sought by a clinician or specialist nurse, who have received detailed training in the consent process, either Good Clinical Practice (GCP) training or consent training provided by the Trust. There are standard operating procedures (SOPs) for the consent process. For the CCRC and RCRC RTBs, there are age-specific information leaflets and consent and assent forms for paediatric donors, along with separate leaflets and

consent/assent forms for adult donors. For the research groups there are project-specific information leaflets and consent forms (see *Advice*, item 2).

Tissue preparation and movement

Fresh tissue for the CCRC and RCRC RTBs is sent to the Trust's Histopathology Department, where research material is dissected away from diagnostic material, and then to the RTB. Bodily fluids go directly to the RTB or to the relevant research group.

There are material transfer agreements covering relevant material provided by outside organisations and material released by the CCRC and RCRC RTBs.

Tracking and labelling system

The establishment is aiming towards using a new electronic tracking system and database for recording the details of all stored relevant material, which will generate a unique identification number and label for each sample. However, this is not yet fully operational and there have been several problems with its implementation. As a result, the system currently used is a mixture of the new database and various electronic spreadsheets held by research groups.

Storage

Samples are stored in secure areas in lockable liquid nitrogen storage vessels (cryovessels), freezers (-80°C and -20°C) and refrigerators. There are also dedicated areas for controlled ambient temperature storage. Cryovessel, freezer and refrigerator space is available as a contingency.

Some, but not all, storage facilities are linked to continuous temperature-monitoring units, which feed into an automated, wireless callout system (see shortfall against PFE2(c)).

Temperature excursions outside the set ranges trigger both local audible alarms and the callout system but the system is not tested regularly (see *Advice*, item 13). While several groups, such as the Cardiac Morphology Unit, did label freezers indicating steps to be taken if the audible alarms sound, the majority of groups across the licence did not (see *Advice*, item 14).

There are oxygen depletion monitors in the liquid nitrogen storage facilities linked to an alarm system. In these facilities, samples are generally stored in the vapour phase above the liquid nitrogen but several CCRC RTB samples are stored within the liquid nitrogen itself (see *Advice*, item 8).

The storage facilities are under maintenance contracts and there are regular service visits.

Disposal

Samples for disposal (e.g. those without consent documentation, those where consent has been withdrawn and those where sample quality has been compromised) are disposed of according to a documented procedure and disposal records are kept on the tracking database or within various spreadsheets. The reason for disposal is not always recorded (see *Advice*, item 11).

Description of inspection activities undertaken

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection report, compliance update information and communications with the HTA. The inspection included a visual inspection of all five sites (hub and four satellites), discussions and interviews with key staff, and a review of documentation. Interviews were held with the DI, the CLHC and one of the PDs (the Tissue Governance Manager), and there were roundtable discussions involving PDs and other staff at each of the sites. Audits of traceability were also carried out.

- Traceability audits were performed on 16 stored sample sets (70 samples in total), including samples from the CCRC and RCRC RTBs, along with 14 research groups. The samples were randomly selected from each sample set and labelling and location details were compared to the electronic and paper records. Completed consent forms associated with each sample were also reviewed. On a few occasions, samples were traced from the paper records to the storage location. There were a number of discrepancies noted (see shortfall against T1(c)).
- During the inspection, the RCRC RTB Manager brought to the attention of the inspectors a sample set of 100 samples that appeared to be lacking appropriate consent. In addition, the Tissue Governance Manager brought to the attention of the inspectors an additional sample set (RBH Muscle Group) of unknown quantity, tissue type, consent or ethical approval status (see shortfall against T1(c)).

Inspection findings

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

Compliance with HTA standards

Governance and Quality sytems

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		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	The establishment applied for a removal licence to allow the retrieval of lungs from deceased donors for research, as part of a project approved by an NHS REC. Although the establishment has not yet carried out this activity, there is no evidence of: • Communication between the DI and the responsible PD. • Details of the premises where the retrieval will take place. • Records of staff involved in seeking consent and those carrying out the retrieval. • Relevant documentation, including SOPs for consent and tissue handling. Further details of this project have been requested and are currently being followed up with the HRA.	**Minor**

a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	The Diagnostic Archive RTB was approved by the HRA (South Central – Hampshire B REC) in December 2015 (REC Ref: 15/SC/0569). However, there is no evidence to demonstrate how the Diagnostic Archive RTB is being governed. For example: • There is no evidence of a Tissue Access Committee (or equivalent). • There is no evidence of a Tissue Bank Manager (or equivalent). • There are no records of applications to the RTB and release of samples from the RTB. • There are no records of annual returns to the HRA. This is currently being followed up with the HRA.	**Minor**

Traceability

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		

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.	During the inspection, two sample sets were brought to the inspectors' attention: Inflammation, Repair and Development (SAF): 100 RCRC RTB samples (out of 246) collected on behalf of the RTB were not recorded on the database and there were no records of consent. This is currently being investigated by the establishment, which will report to the HTA. Muscle Group (RBH): An archival collection of material previously collected under REC approval was investigated. Staff were not aware of sample numbers, types of sample or status of the REC approval. This is currently being investigated by the establishment, which will report to the HTA. In addition, discrepancies in four of the sample sets audited were noted: CCRC RTB (RBH): Discrepancies in 3/7 samples selected (incorrect location on the new tracking database, discrepancies due to software problems). Molecular Medicine (SAF): Discrepancies in 2/3 records selected due to incomplete recording of storage location following transfer of samples to a new storage facility. This is currently being investigated by the establishment, which will report to the HTA. Gene Therapy (EK): Discrepancy in 1/5 samples selected (incorrect transcription onto electronic spreadsheet). Airways Cellular Biology (GS): Discrepancy in 1/4 samples selected (no consent documentation). This is currently being investigated by the establishment, which will report to the HTA.	**Major**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue		

c) Storage conditions are monitored, recorded and acted on when required.	During the inspection, it was noted that the continuous temperature monitoring system did not cover any of the storage facilities at the GS satellite and some of the storage facilities at the EK satellite. Although temperatures of the identified storage facilities in these buildings are monitored, there is no temperature monitoring at weekends. The establishment has not risk assessed the current arrangements for monitoring and recording temperatures and the effects that storage temperature deviations would have on the quality of samples stored.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The DI is advised to consider appointing a PD for the RCRC RTB, to assist him in the role. The DI is also advised to consider reviewing the role of PDs in relation to the different licensed areas. The HTA should be notified of any additions or removal of PDs.
2.	C1(a)	During the inspection, it was noted that there were inconsistencies in the instructions for completing consent forms. Examples included: I. 'Obtaining informed consent – CCRC RTB' (SOP.CRC.004, v 3). Unclear instructions for completion of boxes on giving consent for removal of multiple tissue types and bodily fluids. II. 'Obtaining informed consent – Cardiac Morphology Unit. While informed consent documents had been signed, 2/4 documents had not been completed with a contact name or last date for withdrawal of consent. The DI is advised to consider incorporating patient information sheets and consent forms into the audit schedule.
3.	GQ1(a)	The DI is advised to ensure that all staff read and understand the relevant SOPs.
4.	GQ1(b)	During the inspection, it was noted that certain documents were incomplete, for example: 'Withdrawal of Consent' (SOP CRC004, v 5). Page 7/8 had text that referenced 'SOP-XX-Destruction'. The SOP number had not been added. The DI is advised to consider incorporating consent SOPs into the audit schedule.
5.	GQ1(d)	There are regular meetings where governance matters relating to licensed activities are discussed. In the light of: (i) a new DI being in place (January 2016); and (ii) new HTA Codes of Practice having been introduced, it is important that the DI attends these meetings as a sitting member, as well as the CLHC (when available).

		The DI may also wish to consider whether to include representatives from other departments (e.g. Clinical Governance, Information Technology, Estates) to help develop the establishment's working practices.
6.	GQ1(d)	Joint governance meetings, involving DIs across the different sectors, are a feature in several other organisations that hold multiple HTA licences. The Trust is CLH on four HTA licences and the CLHC is the representative on all four licences. There are currently no meetings between DIs and individuals named on these licences. The CLH is advised to consider setting up joint governance meetings involving staff on all of these licences, to ensure consistency of good practice.
7.	GQ2(a)	The Tissue Governance Manager carries out an annual high-level audit of each RTB and research group on all sites and shares the audit findings. The DI is advised to ensure that the audit schedule is extended to involve PDs, principal investigators and different research group members carrying out audits at a local level so that the full range of samples and activities is covered.
8.	GQ6(a)	There is an extensive suite of risk assessments provided by the Tissue Governance Manager to all research groups. The DI is advised to consider covering the possible risks of liquid nitrogen storage in this suite.
9.	GQ6(c)	The DI is advised to ensure that all staff have access to risk assessments.
10.	T1(b)	The Tissue Governance Manager is developing a master register of all licensed sample sets, including existing holdings. The DI is advised to consider how sample sets currently under REC and UKECA approval could be integrated within the register so that expiry dates of ethically approved projects can be monitored.
11.	T2(b)	The reason for disposal is recorded for most sample sets, in line with the establishment's SOP. To ensure consistency, the DI is advised to ensure that this practice applies to all disposed material.
12.	PFE2(c)	The DI is advised to ensure that the set temperature ranges for the alarm system are documented and are recorded on labels on cryovessels, freezers and refrigerators.
13.	PFE2(c)	The DI is advised to consider regular testing of the temperature alarm callout system to ensure that it is functioning correctly.
14.	PFE2(c)	The DI is advised to consider placing labels on freezers and refrigerators to summarise procedures to take when the audible temperature alarms are activated.
15.	PFE2(c)	The DI may wish to consider initiating a programme by which, at suitable timeframes, the temperature plots from the monitoring system are reviewed. This may help to identify a potential failure of the system before it occurs.

Concluding comments

During the inspection, areas of strength and good practice were noted:

- The Tissue Governance Manager is the focal point of the licence. He audits all

research groups annually, provides regulatory training, provides advice and ensures consistent governance across the establishment.

- Each research group works to its own 'master file', which contains generic and local SOPs, audit schedules, training records, incident logs and risk assessments.
- The Medical Research Council (MRC) 'Research and Human Tissue Legislation e-learning Module' is included in the training programme for all staff.
- The 'Procedure for reporting research incidents' (TG-SOP003-R) is comprehensive, giving a detailed list of a wide range of research incidents in the Annexe.
- Some research groups have used photographs of contingency storage areas and storage boxes to assist staff in moving samples as part of the contingency plan.

There are a number of areas of practice that require improvement, including one major shortfall and three minor shortfalls. The HTA has given advice to the DI with respect to the Consent, Governance and Quality systems, Traceability, and Premises, Facilities and Equipment standards, as well as advice on licence management.

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

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: 22 September 2017

Report returned from DI: 10 October 2017

Final report issued: 6 November 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: 4 February 2019

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 that 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 either which will usually be assessed by the HTA by desk based or site visit inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. 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.