Site visit inspection report on compliance with HTA licensing standards

University of Surrey

HTA licensing number 12365

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**

16 to 18 July 2019

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 the University of Surrey had met the majority of the HTA's licensing standards, 8 major shortfalls and 14 minor shortfalls were identified against standards in all four of the HTA's standards groups.

Advice has also been given across a range of HTA standards.

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

The University of Surrey (the 'establishment') is an academic institution that has a current student cohort of around 17,000 in undergraduate and post-graduate courses. The University of Surrey is split over two campuses - Stag Hill and Manor Park - and also includes Surrey Research Park, which has 116 companies.

The establishment has been licensed since September 2007. The hub is in the Faculty of Health and Medical Sciences (FHMS), School of Biosciences at Stag Hill campus. There are four satellite sites at Manor Park Campus: the Leggett Building (since September 2007); the Surrey Clinical Research Centre (SCRC, since September 2007); the School of Veterinary Medicine (since March 2019) and the Veterinary Pathology Centre in the School of Veterinary Medicine (since October 2016). This is the establishment's second routine inspection; their previous inspection was carried out in May 2013.

Description of inspection activities undertaken

The inspection timetable was developed after consideration of the activities conducted under the licence, compliance update information and discussions with the Designated Individual (DI) and the Corporate Licence Holder contact (CLHc). The inspection team reviewed the establishment's procedures for conducting activities under the licence. This involved interviews and group discussions with staff involved in consent seeking, quality management and sample management. The inspection also included a visual inspection of all areas where relevant material is stored under the licence. Audits of sample traceability were also conducted on randomly selected samples covering a range of storage areas:

- Forty-two tissue samples stored in -80°C freezers
- Eleven tissue samples stored in -20°C freezers
- Six tissue samples stored in liquid nitrogen
- Seven formalin-fixed paraffin-embedded (FFPE) tissue samples stored at room temperature (RT)

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

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes 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.	Consent forms for imported samples had a 'yes' or 'no' box for a question regarding future use in genetic analysis. The 'yes' box had been crossed through. It was not clear if this indicated 'yes' to the question or, having been crossed through, this indicated 'no'. One sample obtained from a private clinic did not have a corresponding consent form, as there was no matching record of that patient identifier at the clinic. The establishment conducts numerous NHS Research Ethics Committee (REC) approved studies. The signed patient consent forms from REC approved studies were not sufficiently scrutinised to ensure these samples could be held under licence, for use in future research after the study is completed. There was no evidence that signed patient consent forms are checked for completeness and validity, for samples held directly under licence. There was no evidence that checks are conducted on imported samples to provide assurance that these samples have been obtained with the appropriate mechanisms in the country of origin.	**Minor**
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.	There were tissue samples that had been acquired from a research collaborator in a European Country. The Patient Information Sheet (PIS) and consent form were available; however, these were in another language and no English translation or other assurances had been sought.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) Competency is assessed and maintained.	There is a lack of competency assessment and refresher training for consent seekers.	**Minor**

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		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	There are SOPs that cover licensable activities. There are Material Transfer Agreements (MTAs) for both incoming and outgoing tissue samples from the establishment. The 'University of Surrey Human Tissue Governance Document' is limited in scope and is not sufficient in providing overall governance of HTA related activities. There is a lack of overarching governance, guidance and information at the hub, the four satellite sites and the research tissue bank for staff working under the licence. There is inconsistent implementation and of all documents relating to licensable activities.	**Minor**
c) There are change control mechanisms for the implementation of new operational procedures.	A document control system is used for some documentation covering licensable activities but there are no change control mechanisms for the implementation of new operational procedures. In the absence of change control mechanisms, there is no evidence that any planned changes, validation or training could be implemented for new operational procedures by staff.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	There is a documented audit schedule. While there is 'HTA Audit schedule for 2017 to 2020', the entire schedule from November 2017 to 2020 makes reference to the former HTA licensing standards (C3, GQ7, GQ8, PFE4, PFE5, D1 and D2) despite this schedule being compiled after the publication of the updated standards and guidance for research (Code E) in April 2017.	**Minor**
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	Audits have been conducted in line with the establishment's document, 'HTA audit schedule 2017-2020'. While audit findings, outcomes and actions have been undertaken, these have not been conducted against the updated standards and guidance for research (Code E) published in April 2017.	**Minor**

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.	There is a 'Staff learning and development policy', but it does not make reference to training for research activities relevant to human cellular material held under the HTA licence. There was a list of staff who had attended external courses for Good Clinical Practice (GCP), and use of human tissue. It is not evident if all the staff had undertaken the most appropriate training for their research activities. There is a University 'Human Tissue and Governance Document (dated March 2019) and a 'Human Tissue in Research' leaflet (second edition 2017). It is not clear if the staff are aware of these documents and understand how the information they contain should be applied. It was evident during the inspection that staff had a lack of awareness of the Human Tissue Act 2004 and HTA Research standards and guidance (Code E). It was also evident during the inspection that staff had a poor understanding of the difference between 'recognised REC approval' and relevant material held under licence. There is no evidence that meetings or refresher training sessions are held for staff and students, to ensure they are up to date with policies and procedures.	**Major**
b) There are documented induction training programmes for new staff.	There is an 'FHMS Health and Safety Induction checklist B' which has a section on 'working with human tissue' that makes reference to 'online training courses to be completed' but does not specify which. There is a lack of specific training and guidance for relevant new staff and students that addresses the requirements of the Human Tissue Act 2004 and the HTA's Codes of Practice.	**Minor**

c) Training provisions include those for visiting staff.	There is a 'Visiting Academic Staff appointment policy'. There is no reference to asking if working with human material and a lack of specific training and guidance for relevant visiting staff and students that addresses the requirements of the Human Tissue Act and the HTA's Codes of Practice.	**Minor**
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.	There is an absence of an overarching policy or SOPs detailing record creation, records access, amendment, retention and destruction of records for the entire establishment. The Research Tissue Bank (RTB) sample register is maintained only using hand written documentation. During the inspection, it was evident that across the establishment, records were not reviewed or amended to reflect current holdings. A patient withdrawal of consent in the RTB had missing information for sample disposal, demonstrating a lack of review and amendment of records. There was a lack of records detailing all the locations across the establishment where relevant material is held.	**Major**
b) There are provisions for back-up / recovery in the event of loss of records.	There are no centralised records held by the establishment. Tissue registers and holdings are held at the individual sites and across a number of research groups. One site has an electronic system to record all of their tissues. This system was created locally and was not supported by the establishment's IT department. The RTB has only paper documentation of the sample register. There is no electronic back-up and no archived copies. There was no evidence that the individual tissue registers and records have provisions for back-up and recovery in the event of loss of records.	**Major**

GQ5 There are systems to ensure that all adverse events are investigated promptly		
a) Staff are instructed in how to use incident reporting systems.	In the Health and Safety Handbook (October 2017), there is section on incident reporting. In the Faculty of Health and Medical Sciences (FHMS) Health and Safety manual, 'Section 5.3 Incident reporting' states that incidents are to be reported to line managers and provides a link to an online reporting system. There is evidence of one HTA related incident that was entered through the online system, logged by the personal assistant to the DI. There is a supplementary document providing details of the incident, but there is no date or indication of who created it. This is not sufficient evidence that staff working under the licence are aware of how and when to report HTA related adverse events. *Standard GQ5(b) could not be assessed.*	**Minor**
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.	'SOP HTA02 – Storage and tracking of human samples (traceability)' section 11.0 lists identifiable risks to tissue. In 'TRA-269 Working with human tissue in the pathology laboratory of the Veterinary School of Pathology' there is a section on working with human tissue from handling to the disposal of samples under the Human Tissue Act. There are several 'University of Surrey Description and risk assessment for research projects involving human material' which are reviewed by the Human Tissue Governance Group. These are all project specific and are insufficient to cover all of the risks that would need to be assessed for HTA-related activities across the licensed premises. In all of the specific project documents reviewed, there was a lack of a risk assessment in the event of a donor withdrawing their consent. There is a lack of overarching documented risk assessments for all practices and processes requiring compliance with the Human Tissue Act and HTA's Codes of Practice.	**Major**

b) Risk assessments are reviewed regularly.	The project-specific 'University of Surrey Description and risk assessment for research projects involving human material' documents were insufficient to evidence meeting this standard. Some of these documents lacked any date for when these were effective; a number of these documents had expiry dates but review arrangements were unclear. *Standard GQ6(c) could not be assessed.*	**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		
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.	Unique codes are not consistently applied to all samples stored under the licence. A single unique code is often used for samples divided into multiple aliquots and multiple samples received from the same donor. This creates the risk of a lack of traceability for all samples from a donor and impairs the ability to identify individual samples. This also impedes the ability to ensure all samples can be identified if consent for continued storage and use is withdrawn. It was evident during the inspection that staff were not aware that unique identifiers are required for samples held under the licence. It was also observed that labels were peeling off the storage vials for a few samples in one of -80°C freezers.	**Major**

b) A register of donated material, and the associated products where relevant, is maintained.	There are a number of registers for donated material at each site. During the traceability audit for the RTB, there were a few samples that were not in the paper records. For example, one donor had withdrawn consent for the use and storage of their samples. The paper records did not show evidence when or where these samples had been held, or when they had been disposed of (or that this had been carried out within an appropriate timeframe). The RTB could only provide verbal assurance that the samples had been removed and disposed in accordance with the HTA's Codes of Practice. An RTB consent form stated that 'samples will be destroyed for future research use if a cancer diagnosis is not made.' There is no formal process to ensure that these samples are removed and this is recorded in the tissue register. One satellite site conducts a large number of REC-approved studies. Consent forms for expired REC studies are sent to off-site archives. Records were not kept with regards to consent decisions for future storage and use in research beyond the study closure. Across the establishment, sample storage location was inconsistent with tissue registers. Sample locations were not specific enough to demonstrate where the samples were actually stored.	**Major**

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 sample traceability audits that were undertaken, it was identified that the physical storage locations of some samples did not match those recorded on the electronic database. Samples which had been recorded as stored in one freezer location were found in another freezer, having recently been moved, and the records not updated. During the sample traceability audits, three vials of fluid containing tissue (unlabelled as to tissue or fluid in vial) were observed to be stored in a cupboard. These were not recorded on the tissue register, and it was unclear if these vials had provided tissue to create some of the existing wax blocks. At one site, tissue had been received from a private clinic undertaking a (now completed) study, to process the tissue for histological slides (Histopathological service business). The slides had been sent back to the clinic, but the clinic had asked that the site retain the wax blocks (for an undefined period). The consent forms had not been checked to ensure that these samples were being held with the appropriate consent. The PhD student using the samples had now left the establishment. The site processing slides did not maintain the same level of traceability when slides and blocks had been returned to researchers in the establishment, compared to requests for histological services from external researchers (there is a detailed application form when samples are received and sent out from site). The RTB sent a number of tissue samples to researchers at an external establishment. Included in this set of samples was the anonymised donor number of a patient who had withdrawn their consent for their tissue to be stored by the RTB. There was a lack of evidence in the paper records to show that this patient's tissue sample(s), had been removed from the RTB before this set of tissue samples were sent to the researchers. The RTB staff could provide only an oral assurance that the sample had been withdrawn and was not sent out of the RTB after patient consent was withdrawn. During the inspection, there were a number of times when staff were unsure if their samples were stored under the authority of a REC approval or the HTA licence.	**Major**

T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and the method used are documented.	The date, reason for disposal and the method used are inconsistently documented or absent in the individual registers of relevant material held by researchers across the establishment. For example, one donor that had withdrawn their consent for use and storage of their samples in the RTB. There was no record of whether these samples had been disposed (date, method or reason). It was evident during the inspection that not all staff were aware that records of disposal should be kept in order to provide a complete audit trail from donation through to disposal.	**Major**

Premises, Facilities and Equipment

Standard	**Inspection findings**	**Level of shortfall**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
d) There are documented contingency plans in place in case of failure in storage area.	While there is a Business Continuity Management Policy, and Business Continuity Plans, for both the School of Biosciences & Medicine and the School of Veterinary Medicine, these do not specify the contingency arrangements for the storage of samples held under licence (either on-site or off-site). The Incident Response Plan for each school states first point of contact and escalation process with respect to incidents (including equipment failure (i.e. freezers) There is no centralised register or list, of the storage locations across all five sites where samples are held under licence.	**Minor**

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.	In general, freezers were not optimally maintained by staff and some were found to be 'iced up'. Defrosting schedules were inconsistent across the establishment. There was evidence during the inspection that one -80°C freezer door seal was in need of replacement (falling off the door) There is evidence of a few freezers being challenged to test the accuracy of internal temperature probes (by opening freezer doors). However, freezers fitted with an external alarm system are not deliberately challenged by users to ensure that they are working to required specifications. Freezers that are monitored using only integral temperature probes are not compared to a calibrated temperature probe. There is only one site where temperature trends are reviewed by staff.	**Minor**
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.	There is no evidence of a process to report an equipment problem.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(b)	Signed paper consent forms are archived off site. The DI is advised that staff should have access to the consent forms where appropriate, have secure and encrypted electronic copies or have information pertaining to the appropriate use of all relevant material held under licence, as authorised by the donor.
2.	GQ1(b)	The DI is advised that the document control system at (site) is implemented across all documents relating to licensable activities.
3.	GQ2(a)	The DI is advised to increase the frequency of audits and to conduct horizontal audits of staff involved in the processes, to ensure SOPs accurately reflect actual practices.

4.	T1(c)	To raise awareness and facilitate traceability, the DI is advised to consistently use the university template for external signage on all equipment where human samples are stored under the licence.
5.	T1(c)	The DI is advised to improve the governance of, and traceability of samples associated with, all REC approved studies. This is important if the intention is to store these samples under HTA licence after the REC approval has expired. The HTA recommends that establishments adopt a harmonised approach to sample management as there are risks of varying practices where samples being stored for REC-approved projects are managed differently to samples subject to HTA's licensing standards.
6.	PFE1(c)	The DI is advised that where University estate and facilities staff clean any of the premises, this is documented at each site.
7.	PFE2(a)	The DI is advised to implement an appropriate racking system to help with sample storage location, and for the samples to be stored in appropriate vials/containers that help preserve the integrity, prevent damage or loss to tissue samples.

Concluding comments

The establishment staff were engaged and acknowledged that, while some of the HTA standards were met, there are a few significant areas that require improvement. Since the last inspection in 2013, two satellites sites have been added to the licence which now constitutes a large licence of five sites (one hub and four satellites). Four of the sites are active under the licence, while the fifth site is just about to begin to conduct licensable activities. With the increase in size and activity under the licence, the absence of centralised and overarching governance has contributed to a significant lack of compliance. However, there are systems and processes currently in place at the establishment, which could be shared and utilised across all the five licensed sites. Eight major shortfalls and fourteen minor shortfalls, were identified across all the HTA's standard groups.

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: 15/08/2019

Report returned from DI: 29/08/2019

Final report issued: 19/09/2019

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: 18/05/2020

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.