Site visit inspection report on compliance with HTA licensing standards

London School of Hygiene and Tropical Medicine

HTA licensing number 12066

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**

25 July 2018

Summary of inspection findings

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

The HTA found that London School of Hygiene and Tropical Medicine (the establishment) had a total of thirteen minor and three major shortfalls across the HTA's four groups of licensing standards relating to Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

The DI has also been given advice on a range of issues.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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

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

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

This report refers to licensable activities carried out at London School of Hygiene and Tropical Medicine (LSHTM) (the establishment). The establishment is licensed for the storage of relevant material that has come from a human body for use for a scheduled purpose, under the Human Tissue Act 2004 (HT Act). Human samples are stored for use for the scheduled purpose of 'research in connection with disorders, or functioning, of the human body'. The establishment has been licensed since June 2007 and this was the third routine site-visit inspection to assess whether it continues to meet the HTA's standards.

The establishment stores relevant material in approximately 60 individual projects that have local ethical approval from the LSHTM ethics committee. Samples include tissue, whole blood and processed blood components, urine, faeces, breast milk and saliva. The establishment also stores human samples for research projects that have project-specific approval from recognised research ethics committees (RECs) and a number of samples held under clinical trial (UKECA) approvals. Although these are exempted from the licensing requirements of the HT Act, there is overarching and harmonised governance of the collections. The DI has robust processes in place to monitor when REC approval is coming to an end and samples are transferred immediately onto the records of material held under the authority of the HTA licence.

Relevant material is stored throughout the LSHTM building in a number of different laboratories, stores, offices and corridors. The building is secured 24 hours a day and only authorised personnel have swipe card access. Visitors must be accompanied and are required to sign in and out at the main entrance. The majority of working collections are stored in freezers located within controlled-access laboratories. There are three freezers containing archived material in the basement. The basement is locked with a key and only authorised personnel have access permission. Due to capacity, some freezers are located within the corridors of the LSHTM building. All of the freezers within open areas are kept locked. The majority of freezers are fitted with automated alarms that are triggered by deviations from the set acceptable temperature ranges (see minor shortfall against standard PFE2(c)). If temperatures go out of range, an external monitoring service alerts relevant members of staff by telephone, 24 hours a day and, in the event of a power failure, they are connected to the emergency supply. The alarm systems are not routinely tested and trends are not reviewed (see *Advice*, item 16). Freezers are not maintained and not subject to servicing (see minor shortfall against standard PFE3(a)). The establishment has contingency arrangements for all temperature-controlled storage; however, these are not documented (see minor shortfall against standard PFE2(d)).

The liquid nitrogen store is located on the second floor of the LSHTM building and, although there is no controlled access, the two tanks that contain relevant material are secured by

locks (see *Advice*, item 14). The servicing of the liquid nitrogen tanks is overdue (see minor shortfall against standard PFE3(a)).

There is a large collection of electron microscopy blocks that are stored at room temperature in the DI's office. The office is secure and locked.

A number of research projects involve samples imported from outside of England, Wales and Northern Ireland. Although the consent requirements of the HT Act do not apply to these samples, the establishment seeks consent as part of good research practice and Material Transfer Agreements (MTAs) with all external establishments are in place. LSHTM also have many collections stored as existing holdings where the current consent requirments also do not apply. For active projects, the Principal Investigators (PIs) and researchers are responsible for seeking consent from volunteers. Although consent training is available, not all consent seekers receive this training and training is not documented or refreshed (see minor shortfall against standard C2(b)). Competency of consent seekers is also not assessed (see minor shortfall against standard C2(c)). Consent is sought using project-specific consent forms that reflect the requirements of the HT Act and the HTA's Codes of Practice and all participants are given a detailed information sheet relating to the research and process.

There are some governance documents; however, not all activities carried out under the licence are covered and there is poor distribution of documents to relevant staff working under the licence (see major shortfall against standard GQ1(a)). Each specific project uses different databases and methods to facilitate the traceability of material (see *Advice,* item 12). It is the responsibility of the PI to update the DI, annually, of activities. Projects and associated collections are not audited (see major shortfall against standard GQ2(a)).

Description of inspection activities undertaken

The inspection timetable was developed in consideration of the activities conducted under the licence, compliance update information, discussions with the DI, previous communications with the HTA and the findings of the previous inspection. The inspection included review of the establishment's procedures for conducting activities under the licence and interviews with staff involved in consent seeking, quality management and sample management. The inspection also included a visual inspection of the areas where samples are stored under the licence and audits of sample traceability. Audits of the following, randomly-selected samples were conducted:

- Seven samples from consent to frozen storage.
- Two samples from frozen storage to consent.
- Three samples from room temperature storage to historical records.
- Six sample disposal records.

- For three collections chosen, the DI was not aware of where samples were located within the laboratories or freezers and, as PIs were unavailable, they could not be audited. The HTA are following up with the establishment as part of the corrective and preventative action (CAPA) plan for the shortfall against T1(c) to ensure that the collections are fully traceable.

For collections where PIs were available, samples were fully traceable. However, three consent forms were not completed as required by the establishment. One had been completed with ticks in the check boxes instead of initials and two forms did not have the consent seekers details filled out (see minor shortfall against standard C2(c)).

Inspection findings

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training.	Consent training is available and addresses the requirements of the HT Act and HTA's Codes of Practice; however, this is not distributed to all relevant staff. The establishment could not provide evidence that staff members who seek consent had received up-to-date training. *See Advice, item 2.*	**Minor**
c) Competency is assessed and maintained.	Competency is not assessed and there are no arrangements to ensure consent-seeking proficiency is maintained.	**Minor**

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.	While the establishment has some standard operating procedures (SOPs) in place, the SOPs do not cover all of the procedures which the establishment is carrying out under its HTA licence. Some of the documented procedures are not being followed. For example; • The 'Informed Consent for Research SOP' states that those who are involved in the consent process are signatories to the consent. An audit of consent forms identified that consent seekers do not always sign consent forms. • The 'Informed Consent for Research SOP' states that consent seekers should have received appropriate training however there is no training relating to consent seeking. *See Advice, items 3 and 4.*	**Major**
c) There are change control mechanisms for the implementation of new operational procedures.	Many members of staff working directly under the licence are not aware of the SOPs that are available and there are no change control mechanisms for the implementation of new operational procedures.	**Minor**
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.	Matters relating the licence are discussed at governance meetings; however, the DI does not meet with Persons Designated (PDs) and PIs who have direct responsibilities under the licence.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	The audit schedule is not being followed and no audits have taken place since 2016. This issue was identified in the establishment's previous two HTA inspections; however, the corrective and preventative actions have not been followed. *See Advice, items 9 and 11.*	**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 no HTA training for staff that are directly working under the licence. *See Advice, item 10.*	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
b) There are provisions for back-up / recovery in the event of loss of records.	The establishment use both paper and electronic records for sample traceability. Some of the paper records of storage locations are not backed up and in the event of loss of paper records, the sample locations could not be identified.	**Minor**
GQ5 There are systems to ensure that all adverse events are investigated promptly		
a) Staff are instructed in how to use incident reporting systems.	There is an incident reporting procedure; however, incidents relating to licensable activities (for example loss of material) are not covered. Staff are unaware of what incidents should be reported to the DI and there is no process in place to investigate adverse events relating to relevant material and licensable activities.	**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	Not all documented risk assessments are followed. For example; • DI oversight is an existing control in the 'loss of traceability' risk assessment. The DI does not have oversight of all samples • No relevant material to be held outside of the external monitoring system is an existing control in the 'maintenance of freezers' risk assessment. There is an unmonitored freezer in the insectary which stores relevant material for the purpose of research in connection with disorders, or functioning, of the human body. Each project has an independent risk assessment. Although hazards are documented, the impact scoring needs review. For example, the impact of a non-compliance with the Human Tissue Act is scored at 1 (low) despite this being an unlawful activity.	**Minor**
c) Staff can access risk assessments and are made aware of risks during training.	Risk assessments have been developed, which address the potential risks to relevant material; however, not all staff working under the licence are aware of them. This issue was identified in the establishment's last HTA inspection and it was advised that staff were to be made aware of risk assessments.	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
b) A register of donated material, and the associated products where relevant, is maintained.	There is a collection of electron microscopy (EM) blocks (approx. 15,000) stored in the DIs office that include animal and human material. There is no record of the individual blocks and incomplete records of the number of blocks in the collection. This issue was identified in the establishment's last HTA inspection; however, the samples remain uncatalogued.	**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.	The freezer policy and procedure states that contents of the freezers are clearly labelled and an accurate inventory maintained. In a number of cases, PIs have failed to follow this and relevant material could not be found by the DI.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	Although the freezer policy and procedure states that all freezers containing HTA relevant material must be monitored by the external monitoring system, not all freezers storing relevant material are alarmed and monitored.	**Minor**
d) There are documented contingency plans in place in case of failure in storage area.	There are contingency storage facilities available; however, plans are not documented and not all staff are clear of what to do in the event of a storage failure. *See Advice, item 17.*	**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.	Freezers storing relevant material are not subject to servicing to cover the maintenance, validation and calibration. The liquid nitrogen tanks storing relevant material are maintained annually; however, the next service is overdue (June 2018). The freezer policy states that PIs and laboratory staff are responsible for checking the freezers on a regular basis; however, checks are not being carried out. During the inspection many of the freezers storing relevant material had a buildup of ice. The DI was advised to develop a maintenance schedule to cover all freezers in the last HTA inspection.	**Major**

Advice

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

No.	Standard	Advice
1.	C1(a)	The consent SOP (LSHTM-SOP-005-03) references the old HTA Code of Practice 1. The DI is advised to update this reference to the Code of Practice A: Guiding principles and the fundamental principle of consent.
2.	C2(a)	To address the shortfalls against C2(b) and C2(c), the DI has a consent training presentation which should be given to all consent seekers. The DI is also advised to make relevant staff aware of the HTA Codes of Practice A (Guiding Principles and the fundamental principle of consent) and E (Research). The Codes provide anyone undertaking activities with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA guidance and standards.
3.	GQ1(a)	To address the shortfall against GQ1(a) it is expected that the establishment will have SOPs covering all licensable activities including but not limited to; • consent; • receipt; • labelling; • specimen preparation / preservation; • storage; • relevant transport arrangements; • cleaning and decontamination; • disposal. SOPs should be a clear and accurate representation of an existing procedure or process, preferably set out in the format of a stepwise guide. SOPs should be drafted in such as way as to enable new staff to follow a procedure from beginning to end.
4.	GQ1(a)	The DI is advised to consider introducing a system to record that staff have read and understood SOPs.
5.	GQ1(a)	The DI is advised to keep under review the establishment's arrangements for lone working to ensure that they are appropriate and protect the safety of staff.
6.	GQ1(a)	The document 'Guidance on taking consent for the removal, storage and use of human tissue in research' details the consent requirements for the removal and use of material from the deceased; however, it does not list the qualifying relationships nor does it refer to the hierarchy. The DI is advised to add this information to the guidance document for clarity.
7.	GQ1(b)	Risk assessments, some SOPs and the Freezer Policy are not controlled. The DI is advised to include the following in these documents; • Revision history and version number • Review date • Author and reviewer names

8.	GQ1(c)	To address the shortfall against GQ1(c), the DI is advised to ensure that all relevant staff are consulted when controlled documents are reviewed. This will help to identify changes required to policies, procedures and forms, including where additional clarification or details of procedures are required.
9.	GQ2(a)	During the HTA audits, although appropriate and valid consent had been given, three consent forms were incomplete, with the consent seeker's name missing and one had ticks in the check boxes instead of being initialled as per instructions. The DI is advised to ensure that the audit schedule includes vertical audits of records and samples, from sample through to consent documentation. Records should be audited regularly to ensure completeness, accuracy and legibility. Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. All audit findings and related corrective and preventative actions should be recorded to allow the establishment to demonstrate compliance with HTA standards and follow-up outstanding actions.
10.	GQ3(a)	The DI informed the HTA that a HTA awareness presentation was being put together for new members of staff. The DI is advised to finalise the presentation and distribute it to all members of staff working under the licence. The DI is also advised to make relevant staff aware of HTA Code of Practice E (Research). The Code provides anyone undertaking activities with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA guidance and standards.
11.	GQ3(a)	The DI is advised that process audits of staff undertaking procedures may also help to identify areas where additional training is required. Process audits may form part of the establishment's process for staff annual review and personal development plans.
12.	T1(a)	With the collections growing, a more streamlined approach to sample management, such as a unified database, may help to reduce the risks associated with loss of traceability.
13.	T2(a)	Disposal is being carried out in accordance with the HTA's Codes of Practice on Research (Code E); however, this is not documented. A disposal SOP should be developed and the quality manual revised to include more detail of the process. The date, reason and method of disposal should be clearly documented so that staff continue to dispose of human tissue in an appropriate manner.
14.	PFE1(b)	The liquid nitrogen dewars that store relevant material are situated in an unsecured room on the third floor of the LSHTM building. The DI is advised to secure this room such that only authorised and trained personal have access.
15.	PFE2(b)	None of the freezers containing relevant material are labelled. The DI is advised to label every freezer that contains human material to increase staff awareness.
16.	PFE2(c)	Most of the temperature-monitored freezers have external alarm and call-out systems. The DI is advised to challenge the alarm systems to ensure that when temperature deviations are detected, the system operates successfully. The DI is also advised to review temperature trends.

17.	PFE2(d)	Currently, there are contingency arrangements in place in the event of a storage failure; however, the majority of these are informally agreed. To address the shortfall against GQ1(a), the DI should ensure contingency arrangements are documented, which will provide more formal assurance that samples will be safe in the event of a storage failure.
18.	N/A	To provide assistance in the governance of the licence, the DI is advised to consider having more PDs. The DI may wish to nominate PIs as PDs on the licence as they have direct oversight of licensed activities. PDs should attend governance meetings, and could perform audits of other collections. The HTA must be notified of any new PDs.
19.	N/A	The DI is advised to make staff aware of the HTA's bi-monthly newsletter, which may help them to keep abreast of relevant information for the areas they work in.

Concluding comments

Although there are a number of areas of practice that require improvement, including thirteen minor and three major shortfalls, 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.

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.

Report sent to DI for factual accuracy: 22 August 2018

Report returned from DI: 28 August 2018

Final report issued: 28 August 2018

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: 14 November 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 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.