Site visit inspection report on compliance with HTA minimum standards

MTS Cryo Stores UK

HTA licensing number 22499

Licensed for the

- **storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007; and**

- **storage of relevant material which has come from a human body for use for a scheduled purpose under the Human Tissue Act 2004**

30 May 2013

Summary of inspection findings

MTS Cryo Stores UK (the establishment) was subject to a themed site visit inspection. The themes selected for inspections in this sector for 2013 / 2014 include quality management, contingency planning and risk management.

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

Although the establishment had met the majority of the HTA standards, eight minor shortfalls were found with regard to the Governance and Quality Systems (GQS), Premises, Facilities and Equipment (PFE), and Disposal (D) standards. The shortfalls were in relation to standard operating procedures, governance meetings, audit, contingency planning, transport and disposal of tissue. Advice has also been given relating to the GQS, PFE and D standards, as well as in the area of licence management.

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

The HTA's regulatory requirements

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

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

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

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

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

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

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

Licensable activities carried out by the establishment

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out (see below).

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
-	-	-	-	**E***	-	-	-

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by MTS Cryo Stores UK (the establishment). This was the third site visit inspection of the establishment since it was issued an HTA licence in January 2008 (the last inspection was in May 2011). It was a routine 'themed' inspection to assess whether the establishment is continuing to meet the HTA's standards.

Although the establishment holds storage licences under both the Human Tissue Act 2004 (the HT Act) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the HT Quality and Safety Regulations), until now the establishment has only undertaken the storage of relevant material for use for a scheduled purpose (research) under

the HT Act. It now wishes to expand its activities to include storage under the HT Quality and Safety Regulations.

The establishment is a tissue storage facility currently housed on two floors within a secure warehouse. Storage facilities include -20°C, -40°C, -80°C and -150 °C freezers, and liquid nitrogen tanks.

The establishment provides emergency storage for HTA-licensed establishments. This is its 'Disaster Recovery Plan' service provided for customers. The DI also runs an ultra-low temperature refrigeration repair business. Continuous and on-going maintenance is therefore provided to the sample storage facility.

MTS Cryo Stores has entered into service level agreements (SLAs) with other HTA-licensed establishments for storage on their behalf, of relevant material for use for a scheduled purpose. It now also intends to develop SLAs with other HTA-licensed establishments for storage on their behalf, of tissue and cells for patient treatment (*see Advice item 1*). The establishment currently stores samples involved in clinical trials and research studies (including kidney and muscle biopsies, buffy coats and urine).

Following the previous site visit inspection of the establishment, a minor shortfall was found in the area of the documentation of risk assessments for licensable activities. This was assessed as being met following submission of evidence by the establishment in 2012.

The present site visit inspection included a visual inspection of the storage area. Interviews were conducted with: the Designated Individual; the Person Designated (Biosafety Consultant); the Business Development Consultant; and the Operations Manager. A documentation review and audit trail were carried out.

For the horizontal audit, four samples were selected from the freezers and the location and labels were compared with the paper and computer records; no anomalies were found. For the vertical audit, three samples were traced from receipt to dispatch; no anomalies were found.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	Some procedures still need to be created and developed. *See Advice item 2*.	**Minor**
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	There is no existing regular governance meeting, which covers HTA issues, for staff working under the licence. *See Advice item 3*.	**Minor**
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.	The establishment uses dedicated courier services for the transport of samples but has not yet used these for the transport of tissue and cells for human application, and appropriate agreements have not yet been developed. *See Advice item 4*.	**Minor**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	Staff perform ad hoc sample audits but there is no full audit schedule. *See Advice item 5*.	**Minor**
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	The establishment does not yet have a regular independent audit to verify compliance with protocols and HTA standards.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.	There is no written agreement with another HTA-licensed establishment to transfer traceability records and raw data in the event of termination of licensable activities.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination.		
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.	The establishment has not yet shipped samples for human application from its own premises back to customers. There are no specific procedures for this. *See Advice item 8*.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human body parts and tissues.		
a) The disposal policy complies with HTA's Codes of Practice.	Although the establishment has not yet disposed of any tissue and cells, provisions should be made for situations when material cannot be returned to customers. *See Advice item 9*.	**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 ensure that, under the HT Quality and Safety Regulations, the SLA with supplying HTA-licensed establishments confirms that the supplying establishments are responsible for: • ensuring that appropriate consent has been obtained • ensuring that mandatory donor test results and microbiology test results have been recorded. • confirming sample storage temperature requirements. • labelling sample primary packaging with the information required by the Directions: http://www.hta.gov.uk/_db/_documents/Annex_-_Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf

		• receiving back samples in the event of termination of the MTS Cryo Stores' licensed activities (or allowing MTS Cryo Stores to dispose of the samples). In addition, the establishment itself should confirm that there are authorised receiving personnel in place to ensure that tissue or cells received for human application have undergone the required donor serology tests.
2.	Principally GQ1(b) but also relevant to standards GQ4(a), (h) and (i); PFE2(c) and PFE5(f)	The DI is advised to develop Standard Operating Procedures (SOPs) to cover the following areas: • record creation, access, amendment and destruction. • retention of critical raw data (for 10 years) and traceability records (30 years). • cleaning and decontamination.
3.	GQ1(c)	In other establishments, regular governance meetings have covered items such as: reportable incidents, changes to SOPs, audits, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items).
4.	Principally GQ1(p-s) but also relevant to standards PFE4(c), (e), (f)	When creating a third party agreement with the specialised courier service, the DI is advised to ensure that: • the courier will inform the establishment in the event of a serious adverse event or reaction. • the courier has a system to ensure that traceability of samples is maintained during transport. • the courier packs and transports samples under conditions that minimise their risk of contamination and ensure their safety and quality. • the courier ensures that any specific transport conditions required are maintained.
5.	Principally GQ2(b) but also relevant to standard GQ4(b)	The DI is advised to divide the audit schedule into small increments, carried out by different team members. This should include horizontal audits to ensure that SOPs accurately reflect current practices and vertical tissue traceability audits, from records of receipt to dispatch. The results of all audit findings, and actions taken, should be formally recorded.
6.	GQ7(b), (c)	The DI currently has an SOP for all 'Emergency Events'. The DI is advised to create a separate SOP specifically for Serious Adverse Events and Adverse Reactions (SAEARs) which details the reporting obligations to the HTA, the receipt of HTA regulatory alerts and which identifies the personnel who should report adverse events and reactions in the DI's absence. The DI is referred to the HTA's website page for further information:

		http://www.hta.gov.uk/licensingandinspections/reportingtothehta/adverseeventandreactionreporting.cfm
7.	GQ8(b), (c)	Having now established a set of risk assessments, the DI is advised to ensure that these are reviewed regularly and that all staff are made aware of risk assessments during training.
8.	PFE4(d), (g), (h), (j)	When creating the SOP for transportation, the DI is advised to ensure that it covers: • that records are kept of transportation and delivery. • that critical transport conditions are defined and documented. • that packaging and containers used for transportation are validated. • that shipping packaging is labelled with the information required by the Directions: http://www.hta.gov.uk/_db/_documents/Annex_-_Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf
9.	Principally D1(b), (c) but also relevant to standards D2(a), (b)	The DI needs to develop a disposal policy or procedure. This should: • comply with Health and Safety recommendations. • ensure that the disposal date, method and reason are recorded. • ensure that, for samples from deceased donors, the HTA 'Code of Practice 5: Disposal of human tissue' – paragraphs 35 and 67 are followed: 'Where practical, human tissue from the deceased should be bagged separately from clinical waste, but disposed of within the same incinerator. It is not necessary for each tissue sample to be disposed of individually': http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code5disposal.cfm
10.	N/A	The current DI is also the licence holder. It would be preferable for the (corporate) licence holder to be MTS Cryo Stores UK and for a separate licence holder contact name to be provided.

Concluding comments

During the site visit inspection of MTS Cryo Stores UK, several strengths and areas of good practice were noted:

- The DI and his staff were found to be enthusiastic and keen to improve.
- Quality management has developed further since the last HTA site visit inspection.
- The individual training folders for each member of staff and the staff training schedule

have been well thought out.

Eight minor shortfalls were identified as a result of the site visit inspection. In addition, the HTA has given advice to the Designated Individual in several areas, including governance and quality systems, premises facilities and equipment and disposal, as well as licence management.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the site visit inspection.

Report sent to DI for factual accuracy: 27 June 2013

Report returned from DI: 10 July 2013

Final report issued: 16 July 2013

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: 13 April 2017

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.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.

b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010

are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.

e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Human Tissue Act 2004 Standards

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

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
GQ2 There is a documented system of quality management and audit
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
GQ4 There is a systematic and planned approach to the management of records
GQ5 There are documented procedures for distribution of body parts, tissues or cells
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail
GQ7 There are systems to ensure that all adverse events are investigated promptly
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
PFE 2 Environmental controls are in place to avoid potential contamination
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
D2 The reason for disposal and the methods used are carefully documented

Appendix 2: Classification of the level of shortfall (HA)

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 direct risk of causing harm to a recipient patient or to a living donor,

   Or

   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 number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   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.

   A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

   or

   A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

   or

   A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

   or

   A shortfall which indicates a breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

   or

   A shortfall which indicates a failure to carry out satisfactory procedures or a failure on the part of the designated individual to fulfil his or her legal duties;

   or

   A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

   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 and, which can be addressed by further development by the establishment.

   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 review or at the time of the next 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.