Site visit inspection report on compliance with HTA minimum standards

UK Stem Cell Bank

HTA licensing number 22502

Licensed for the

- **processing, testing, storage, distribution and import/export 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**

2 May 2013

Summary of inspection findings

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

The UK Stem Cell Bank (the establishment) was found to have met all applicable HTA standards. However, a number of areas of working practice should be reviewed prior to the commencement of licensable activities to ensure regulatory compliance, including the establishment's current approach to environmental monitoring during cell processing to ensure that it meets the requirements set out in Directions 003/2010 and Annex I of the EU Guidelines to Good Manufacturing Practice. Documentation relating to the reporting of Serious Adverse Events and Reactions (SAEARs) should also be updated to accurately reflect the reporting requirements set out in the HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.

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.

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

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Stem cells		**E***	**E***	**E***	**E***	**E***	**E***

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by the UK Stem Cell Bank (UKSCB). The establishment operates as part of the National Institute for Biological Standards and Control (NIBSC), which recently became a new centre of the Medicines and Healthcare Products Regulatory Agency. The establishment is licensed for the processing, testing, storage, distribution and import/export of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. It is also licensed for the storage of relevant material which has come from a human body for use for a scheduled purpose under the Human Tissue Act 2004. The establishment has been licensed by the HTA since January 2008 and has been inspected on two previous occasions. This report describes the establishment's third routine site visit inspection which took place on 2 May 2013.

The UKSCB provides a repository for human stem cell lines of all types, and has been established to supply well-characterised cell lines under appropriate and accredited quality systems both for basic research and for the development of clinical applications. The establishment operates in accordance with strict governance principles laid down by the Steering Committee for the UK Stem Cell Bank and the use of Stem Cell Lines ("the Steering Committee"). The establishment reports to and is overseen by the Steering Committee and works under a Code of Practice drawn up by the Steering Committee. Although this is a voluntary regime, the Code of Practice addresses areas also covered by the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

At the time of the inspection, no licensable activities were being undertaken by staff at the establishment, nor had been since the licence was first issued. However, the establishment anticipates accessioning their first cell lines intended for human application in the near future. Such cell lines, termed "European Union Tissue and Cells Directives (EUTCD)-grade" lines by the establishment, will go through the organisation's internal due diligence process prior to being accepted to ensure that they meet EUTCD requirements with respect to the procurement, testing and initial processing. Subsequent processing of the cell lines at the establishment will be performed using the systems developed for the handling of research-grade cell lines. As a result of this, the inspection focused primarily on these procedures to assess their suitability for use in relation to EUTCD-grade cell lines.

The current processing facility comprises a suite of Grade 'B' cleanrooms, each of which is accessed via a Grade 'C' corridor. A two-stage change permits entry to this clean corridor, whilst large equipment can be moved in and out of the facility via a separate access system. Cell culture is performed in each laboratory within Class II microbiological safety cabinets which are operated in such a way as to provide a Grade 'A' environment during processing. All critical systems, including air handling units, incubators, liquid nitrogen storage, and clean-room status (pressures and particle counts) are continuously monitored and alarmed. This monitoring is controlled by a specialised electronic facility monitoring system linked to the NIBSC Building Management System which alerts establishment staff to any system failures.

The inspection included interviews with key members of staff working under the licence, including the Head of Technology Development and Infrastructure (TDI), who is also the Designated Individual (DI), the Operations Manager, the Head of Quality (NIBSC) and the UKSCB Quality Coordinator, and one of the establishment's Stem Cell Scientists. A review of documentation relevant to the establishment's activities and a visual inspection of the areas of the establishment where sample processing and storage take place were also conducted as part of the inspection.

An audit of two samples held in storage was performed. The samples chosen were intended for research use only and, as such, were outside the licensing requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007. However, the system used to track the samples will be employed for any EUTCD-grade cell lines held by the establishment in the future and so an audit was performed so that its suitability could be assessed. No discrepancies were found.

In addition to the planned work involving stem cell lines intended for human application, the UKSCB also undertakes research aimed at improving cell culture, preservation, cell characterisation and safety testing. This work involves the use of cell lines which have been created outside the human body. The cell lines are not classified as relevant material for the purposes of the Human Tissue Act 2004 and so the regulation of this research falls outside of the HTA's remit. At the time of the inspection, no other relevant material was being stored under this licence for use in a scheduled purpose as defined by the Human Tissue Act 2004. Consequently, the establishment's systems relating to the storage and use of such material were not assessed during this inspection.

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

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the DI to consider the following to further improve practices and to ensure compliance once the carrying out of licensable activities is initiated:

No.	Standard	Advice
1.	GQ1b	The DI is advised to update the standard operating procedure (SOP) relating to environmental monitoring within the cleanrooms to ensure that it accurately captures the current requirements for particulate monitoring, as set out in Annex I of the EU Guidelines to Good Manufacturing Practice. In particular, references to the sampling of 'not less than one cubic foot' of air should be amended to reflect the current requirement for a minimum sample volume of 1 cubic metre to be collected for classification purposes.
2.	GQ4e	The DI is advised to consider archiving, or in some other way backing up, the establishment's 'Accession Book' after an appropriate period of time in use to mitigate the risks associated with the loss of, or damage to, this record.
3.	GQ7a	The establishment has in place a number of policies, SOPs and agreements that make reference to Serious Adverse Events and Reactions (SAEARs) reporting requirements. However, they do not consistently include the requirement to report SAEARs to the HTA within 24 hours as set out in the "Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment" which forms the Annex to Directions 003/2010. The DI should update the establishment's documentation accordingly prior to the commencement of licensable activities.
4.	GQ7b	The DI is advised to review the system used to monitor, receive and distribute HTA regulatory alerts to ensure that relevant communications are shared with staff working under the licence.
5.	GQ8a	The DI is advised to review the establishment's risk assessment documentation to ensure that acceptable risk levels are clearly defined. Residual risk levels that would necessitate implementation of additional control measures should be

		specified in SOPs, guidance documents or on the risk assessment forms themselves.
6.	PFE2	The DI is advised to review the storage of consumables on the bottom shelf of the trolleys used in the 'Grade B' cleanrooms as samples stored there are very close to the floor and to staff feet when seated at the microbiological safety cabinet, so increasing the potential contamination risk. The DI should also review the use of folders and notebooks within the 'Grade B' areas to ensure that the risks of introducing contamination into this area of the cleanroom are appropriately controlled.
7.	PFE2b	Prior to commencing work on EUTCD-grade cell lines, the DI is advised to review the establishment's approach to environmental monitoring within the cleanrooms to ensure that cells intended for human application are processed in an appropriately monitored environment. This should include provision for microbiological monitoring during all cell processing which meets the requirements set out in Directions 003/2010 and Annex I of the EU Guidelines to Good Manufacturing Practice. SOPs relating to this activity should be updated accordingly.
8.	PFE2d	The DI is advised to review the headgear used within the cleanroom to ensure that it is consistent with the requirements set out in Annex I of the EU Guidelines to Good Manufacturing Practice and the intended room classifications set out in the establishment's documentation.
9.	PFE3a	Although the establishment has put in place a number of systems to mitigate the risk of cross-contamination during storage, including the use of separate storage tanks for research and EUTCD-grade cell lines, the DI is advised to further review the establishment's procedures relating to this activity to ensure that they adequately mitigate the risk of cross-contamination given the wide variety of cell lines that could potentially be stored in the stem cell bank. The review should include consideration of how best to store/separate cell lines grown on xenogeneic/non-xenogeneic feeder cells, cell lines grown in the absence of feeders, and cell lines with known contamination.
10.	PFE4a	The DI is advised to ensure that the release procedure for EUTCD-grade cell lines includes adequate provision for the review of any environmental monitoring data generated during in-house processing of the cell lines. The release process should also include a review of the cell line files associated with any feeder cells used during the processing of clinical-grade cells.

Concluding comments

The HTA saw numerous examples of good practice during the course of the inspection.

The establishment has put in place a robust due diligence process for all cell lines accepted for deposit in the stem cell bank by the Steering Committee and that are intended for human application by their depositors. The process includes a thorough review of the information captured in the establishment's 'Cell Line Information' form and the 'Due Diligence Initial Review' form, which together provide assurance that the derivation, culture and storage of the cell lines prior to deposit in the UKSCB was conducted in accordance with all relevant regulatory requirements.

A number of effective policies and procedures relating to the use of the cleanrooms were also noted during the inspection, including provision for the use of dedicated areas within the facility for the full duration of cell line processing prior to banking. The facility itself is well designed and maintained, and is effectively monitored through the organisation's building management system. A number of well-thought out safeguards, both physical and operational, have also been incorporated into the cell line storage room to help mitigate the risks associated with working in this area.

Staff are supported in their roles by an effective training program and were clearly very committed to the further development of the systems and practices associated with the banking of stem cells for both research and clinical use.

The HTA has given advice to the Designated Individual to help ensure regulatory compliance once the carrying out of licensable activities has commenced. This includes advice on environmental monitoring that should be performed during the processing of cell lines intended for human application, and the information that should be included in SOPs and agreements that deal with SAEARs reporting. Advice has also been offered to the DI with a view to helping the establishment further develop their working practices and governance systems. This includes the information that should be reviewed during the release procedure for EUTCD-grade cell lines, and the information that should be captured during routine environmental monitoring of the cleanroom. The HTA has also advised that the DI review the current storage arrangements for cell lines to ensure that they continue to adequately mitigate the risk of cross-contamination of cell lines held by the bank.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 31 May 2013

Report returned from DI: 12 June 2013

Final report issued: 13 June 2013

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.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
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.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
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.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
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.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
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.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
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.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.

f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
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.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

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.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
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.
d) There is a documented, specified maximum storage period for tissues and / or cells.
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.

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.