Site visit audit report on compliance with HTA requirements

Portsmouth Hospitals NHS Trust

HTA licensing number 40020

Licensed for

- **<u>Procurement Activities</u>: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)**

- **<u>Transplantation Activities</u>: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)**

Under the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012

26 November 2013

Summary of Audit findings

Portsmouth Hospitals NHS Trust (the establishment) was found to have met all assessment criteria. Advice has been given with respect to living donor follow up, return of forms to NHSBT and serious adverse event and adverse reaction classification.

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

The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and any requirements imposed by directions made under these Regulations.

The assessment criteria reflect the requirements of the statutory conditions outlined in schedule 1 and the HTA's directions. They are designed to promote the safe use of human organs and ensure traceability is maintained between donor and recipient. The HTA audits establishments it licences against eight groups of assessment criteria:

- Donor characterisation and organ characterisation
- Retrieval of organs for transplantation
- Organ preservation
- Making arrangements to transport an organ
- Implantation
- Traceability
- Serious adverse events and serious adverse reactions
- General (apply to all licences)

Reports of HTA audits are published on the HTA's website.
Throughout the audit process, the HTA assesses the establishment against the assessment criteria. Where the HTA determines that an assessment criteria is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 1: Classification of the level of shortfall). Where HTA assessment criteria are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided in this report.

Licensable activities carried out by the establishment – Procurement activities

Organ type	Kidney
Adult living	**DC, OC, P, T, R**
Adult deceased*	**OC, P, T, R**

Procurement Activities: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)

*The establishment does not routinely undertake organ retrievals from deceased donors and does not participate in the National Organ retrieval Service (NORS). However, in the past and on rare occasions, maybe once per year, the establishment's surgical team may undertake a local organ retrieval if the designated NORS team were unable to attend the retrieval centre as a result of other retrieval commitments

Licensable activities carried out by the establishment – Transplant activities

Organ type	
Adult living	**OC, P, T, I**
Adult deceased	**OC, P, T, I**

Transplantation Activities: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)

Background to the establishment and description of audit activities undertaken

The establishment carries out deceased donor kidney transplants in adult patients. Live donor kidney retrievals and transplants are also performed at the establishment. Living donor work up and organ retrieval surgery takes place at the establishment. The establishment participates in paired and pooled transplants using organs from living donors which are sent onto other implanting centres. The establishment also retrieves kidneys from altruistic living donors which again may be used internally at the establishment or sent onto other centres.

Tissue typing and cross matching are performed by an external laboratory with current CPA accreditation. Other characterisation tests such as additional histopathological tests and donor serology testing are performed by the establishment's pathology laboratory and hospital testing laboratory respectively, which also have current CPA accreditation.

The establishment is not responsible for transporting organs which is undertaken by couriers working under a contract with other HTA licensed establishments.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.	The establishment is not responsible for obtaining information relating to a deceased donor. This will be carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence.	**N/A**
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This criterion is fully met. The establishment is not responsible for the collection of information specified in Part A of the Annex to the Directive. For deceased donor organs, characterisation is carried out at the retrieval centres by another licensed establishment. For living donors, the establishment has developed a 'Living Donor Transplant' protocol which acts as an SOP for living donor coordinators and clinicians to follow and includes details of mandatory tests. This SOP is supplemented by the additional 'living donor characterisation' forms which the establishment has developed. These forms act as a checklist for establishment staff to follow and contain details of all of the questions asked of living donors. Potential living donors are asked medical and social history questions as part of their early assessment, including questions on IV drug use, previous malignancies and recent travel.	**None**

CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Part B of the Annex to the Directive.	This criterion is fully met. For deceased donor organs additional characterisation tests will usually be arranged by the SN-OD under NHSBT's licence. These tests are performed at the retrieval centre. If necessary however, extra tests, most commonly histopathological analysis, may be undertaken at the establishment upon receipt of the organ. The establishment does not have access to 24 hour histopathology services and if necessary, implantation will not proceed until appropriate analysis can be undertaken. For living donor cases, if additional tests are required, these will be carried out at the establishment as part of the living donor work up.	**None**
CT4) All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has adopted NOP006 and has made adaptations to suit local practice. The adapted NOP006 states that all relevant information will be kept for 30 years as required. Notes containing relevant information are microfiched by the Trust and stored as part of the Trust's records.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The CPA accreditation status of all laboratories used by the establishment for donor and organ characterisation was reviewed during the audit. All laboratories had current, non-conditional accreditation.	**None**

CT6) Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Characterisation information for living kidney donors is gathered during donor work-up by the nephrologist. Donors complete a Living Donor Assessment and Consent form under the guidance of a transplant coordinator. This form includes the mandatory donor medical history and lifestyle questions. When all assessments have been completed the nephrologist reviews all of the donor characterisation information including the donor's medical history provided by their GP. The establishment has developed a checklist to help assure themselves that all relevant characterisation tests have been completed. Living donors are then discussed at multidisciplinary meetings which include the establishment's surgical staff. The establishment then use an in-house developed surgical checklist which again includes details of the tests performed and prompts relating to the various discussions to be held with the donor. If sending organs from a living donor to another implanting centre then the establishment will send the nephrologist's and the surgeon's checklists to the implanting centre in addition to the NHSBT's documentation. For deceased donor kidneys the establishment is alerted to a potential donor by NHSBT. The coordinator uses the donor's unique number and logs onto NHSBT's electronic offering system (EOS) to collect initial donor and organ characterisation information. The coordinator then calls the implanting surgeon to discuss the information. If the surgeon has any additional questions at this stage then the establishment may contact the SN-OD at the donor centre. The establishment's internal database is then checked to ensure that there is a suitable recipient. The recipient's referring nephrologist is also consulted about the organ offer and is included in the decision to accept or reject the organ offer. If the organ is acceptable for a particular recipient the offer is accepted. The organ arrives at the establishment's renal ward when the receiving nurse will check the accompanying paperwork, donor details and ice levels within the organ box.	**None**

	Prior to implantation the donor's core donor data form is printed off from EOS and reviewed by the implanting surgeon. The implanting surgeon verifies the details received with the organ against the EOS information to ensure that they match and are correct. The organ is then examined and re-perfused prior to implantation.	

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Retrieval of Organs for transplantation		
R1) Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.	This criterion is fully met. The establishment does not routinely undertake organ retrievals from deceased donors and does not participate in the National Organ retrieval Service (NORS). However, in the past and on rare occasions, maybe once per year, the establishment's surgical team may undertake a local organ retrieval if the designated NORS team were unable to attend the retrieval centre as a result of other retrieval commitments. If the establishment does undertake a local retrieval, surgical staff follow the Trust's WHO surgical safety checklist which includes checks on donor identity and consent. These checks would be performed prior to a retrieval taking place. The same WHO surgical safety checklist which includes checks on donor identity and consent is also used by the establishment if retrieving an organ from a living donor.	**None**

R2) Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment does not routinely undertake organ retrievals and does not participate in the National Organ retrieval Service (NORS). However, if undertaking a local retrieval the establishment's surgical team use equipment from their own Trust. The establishment has adopted NOP004 which details requirements and the management of medical devices used during transplant surgery. In addition, the establishment had an email from the Trust's procurement team which confirmed that all devices and equipment purchased by the Trust must be CE marked and meet the requirements of the Medical Devices Regulations.	**None**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. The audit team reviewed certificates demonstrating that the Trust's decontamination services department had been assessed as meeting the accreditation requirements for sterilisation processes.	**None**
R4) Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.	This criterion is fully met. Live kidney donors are seen by the retrieving surgeon after surgery. The surgeon then reviews the donor at two weeks and six weeks post surgery. The donor is then seen at the establishment's renal clinic at three and six months post surgery. Following these assessment visits the donor then is reviewed annually in the establishment's renal clinic. Donors can undertake the annual reviews by a nephrologist at their local hospital. If seeing a local nephrologist the establishment writes to the relevant clinician at the donor's local hospital with details of live donor follow up assessments. The establishment also writes to the donor's GP to alert them that they have been a live kidney donor. Donors are encouraged by the establishment to visit their GP on a six monthly basis. Advice has been given to the establishment (see below) with regards to amending the letter sent to living donors' GPs when discharging living donors.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Organ preservation		
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Refer to R2	**None**
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. Refer to R3	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is fully met. During the audit a review of transplant related records was undertaken. As part of this exercise, HTA-A and HTA-B forms were reviewed and evidence was seen that the establishment is recording the details of perfusion fluid being used. The audit did identify one case however where details of the perfusion fluid had not been recorded on the HTA-B form. Advice has been given to the establishment as to whether an additional checking step of the HTA-B forms would detect cases where perfusion fluid details had not been recorded so that all documents are fully completed.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Making arrangements to transport an organ		
TP1) The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment does not routinely send organs elsewhere. However, if the establishment is sending an organ to another implanting centre either following rejection of an organ received by the establishment or sending on an organ from a living donor as part of a paired/pooled transplant or an altruistic donor, then organs are packed and sent on using NHSBT's contracted courrier. The establishment has adopted and adapted NOP003 which gives details on how to pack organs for transport. Additionally, as the establishment uses NHSBT's kidney transport boxes for transporting organs, instructions are also contained within the box labelling kit on how to pack organs.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. If sending organs to other implanting centres, the establishment uses NHSBT's kidney transport boxes which are suitable.	**None**
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in paragraph 68 of the framework document, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has adopted NOP003 which details the iinformation specified in paragraph 68 of the framework document which should be included on the transport packaging.	**None**
TP4) Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. When receiving an organ from a deceased organ donor via the national organ offering process, donor and organ characterisation information is received via EOS. If sending an organ from a living donor to another implanting establishment the organ is accompanied by paperwork containing donor and organ characterisation information.	**None**

TP5) Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.	This criterion is fully met. Organs from deceased donors are transported to the establishment by NHSBT using their contracted courier under NHSBT's licence. When sending organs from living donors to other implanting centres the establishment uses NHSBT's contracted courier.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Implantation		
I1) The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has adopted and adapted NOP002 which contains details of the characterisation information that must be reviewed by the implanting surgeon prior to implanting the organ. Additionally the establishment has developed some in house forms to collate some characterisation information and to act as a checklist so that the implanting surgeon can check that all of the required information has been collected. The additional forms also contain a prompt for the implanting surgeon to undertake a risk benefit analysis should any data be missing or if any risks are identified.	**None**
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	This criterion is fully met. Prior to commencing the implantation of the kidney the surgeon verifies that the organ has been correctly packed and has sufficient ice to preserve the organ as part of the benching process.	**None**

I3) Where any of the information specified in Annex A of the Directive is not available; a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.	This criterion is fully met. If the implanting surgeon considers there to be any potential risks associated with the organ, they will undertake a risk-benefit analysis. The surgeon will assess the risk associated with the organ against the benefit to the recipient including the risk to the recipient of not going ahead with the transplant. If any risks have been identified the surgeon will discuss these with the recipient and record the conversation in the recipient's clinical notes. See also I1 regarding prompts for the surgeon to undertake a risk benefit analysis.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Traceability – (*these criteria apply to all licensed activities*)		
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has adopted NOP006 which details the relevant timeframes for the return of the forms to NHSBT. Once completed forms are returned to NHSBT by the transplant coordinators. The coordinators use special delivery for the return of forms through the post.	**None**
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.	This criterion is fully met. Deceased donors are traceable by their NHSBT donor number, available in EOS. For recipients, living donors and living donor organs the establishment uses a four point identification system including name, date of birth, hospital number and NHS number.	**None**
TC3) A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information.	This criterion is fully met. The EUODD form developed by the establishment is used to record the receipt of all organs from either deceased or living donors. The form records details of the date and time of arrival in addition to details of the donor centre and the courier driver. These forms are stored for 30 years in line with the transplant unit's policy and NOP006 which has been adopted by the establishment.	

Assessment Criteria	Audit findings	Level of Shortfall
Serious adverse events and reactions (SAEARs) – (*these criteria apply to all licensed activities*)		
S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.	This criterion is fully met. The establishment reports any incidents using the Trust's internal incident reporting procedure. These are followed up in line with the normal Trust process for investigating incidents.	**None**
S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has adopted NHSBT's updated SOP3888/2 which describes the process for reporting serious adverse events and reactions (SAEARs) to NHSBT within the required timeframe. Staff at the establishment also demonstrated an awareness of the need to report SAEARs to NHSBT. During the audit and a review of incidents by the audit team, an example of damage to an organ was found. A kidney from a deceased donor had been received by the establishment; however, on inspection of the organ by the implanting surgeon, it was discovered that the kidney had suffered ureteric damage which the surgeon decided meant that the organ was untransplantable. The establishment reported this incident immediately to NHSBT by phone but did not report this as a serious adverse event via the online reporting tool. Upon investigation by the audit team it was found that when considering reporting the incident the establishment felt that it did not meet the criteria of a serious adverse event and therefore did not report it to NHSBT. Advice has been given below to the establishment to include the SAEARs guidance document to the establishment's governance documentation. This document gives further guidance and practical advice regarding incidents that initially may not appear to meet any of the SAEARs categories.	**None**

S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.	This criterion is fully met. The establishment described their close working relationship with the testing laboratories through which they would be made aware of any SAEARs. Transport of organs from deceased donors is not the responsibility of the establishment as another licensed establishment's courier is used. If transporting a locally retrieved organ the organ is accompanied by the establishment's surgical staff who would report any SAEAR.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
General – (*these criteria apply to all licensed activities*)		
GN1) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks.	This criterion is fully met. Although there is no formal internal training for transplant coordinators, the establishment uses the National Skills Framework which contains competencies relevant to the transplant unit's activities. All staff are encouraged to attend additional training and attend national transplant related meetings. Staff also attend the south west transplant meetings through which information and learning relating to transplant activity are shared. All staff attend mandatory training such as health and safety, fire training and training on blood transfusions. All staff also receive annual mandatory appraisals. Surgical staff are also appraised. The establishment's Trust designate suitably qualified appraisers that are not related to the activity to appraise surgical staff. Surgeon's appraisals include reviews of surgical outcome audits, any complaints and all critical incidents.	**None**
GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.	This criterion is fully met. Refer to GN1	

GN3) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.	This criterion is fully met. The establishment has adopted NOP005 'Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation' which describes how activities are performed under the advice and guidance of a registered medical practitioner.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	R4	Where a live donor is being discharged by the establishment following donation, the establishment sends a letter to the donor's local clinician to alert them that their patient has been a live organ donor. The establishment is advised to amend this discharge letter so that it includes a reminder notice to a local clinician of the requirement to alert the establishment should the donor present with any indication that may have consequences for the recipient, such as development of a malignancy or transmissible infection, or be as a result of the retrieval surgery.
2.	P3	The licence holder is advised to consider whether an additional check step may be required prior to returning HTA-A and HTA-B forms to NHSBT. During a review of HTA-B forms as part of the audit one case was identified where details of the perfusion fluid had not been recorded on the HTA-B form. The licence holder may consider that an additional check of the HTA-B forms prior to their return would detect cases where perfusion fluid details had not been recorded and help to ensure that all documents are fully completed.
3.	S3	The licence holder is advised to include the SAEARs guidance document (http://www.hta.gov.uk/_db/_documents/Guidance_-_SAEARs.pdf) into the establishment's governance documentation which will give more guidance on the types of serious events and reactions that should be reported to NHSBT via the online reporting tool. This will help to ensure that all events that should be reported are reported.

Concluding comments

During the audit, evidence was seen that the establishment has reviewed procedures to assess compliance with the Regulations. The establishment has taken a pro-active approach to governance and has adopted and adapted many of the NOPs to provide the necessary operating procedures that are required under the Regulations. In addition to adopting and adapting the NOPs, the establishment has also developed in-house documents and checklists to support the NOPs and to help act as further guidance and records for establishment staff.

The establishment has considered its supplementary documentation and appears to have gone through a process to identify important additions, check or prompts. This is exemplified by the addition of a prompt on the in- house forms used both to collate some characterisation information and to act as a checklist for the implanting surgeon These supplementary forms also contain a prompt for the implanting surgeon to undertake a risk benefit analysis should any data be missing or if any risks are identified.

The establishment also undertakes a number of governance meetings such as the fortnightly renal histopathology meetings and the monthly transplant group meetings. During these meetings the previous year's transplants are reviewed to help assure the establishment that its systems are working as expected. Additionally, adverse incidents and any other transplant issues are discussed. This helps to share the learning from incidents to all establishment staff.

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

Report sent for factual accuracy: 8 January 2014

Report returned with comments: 16 January 2014

Final report issued: 28 January 2014

Appendix: Classification of the level of shortfall

Where the HTA determines that an assessment criterion 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 assessment criterion, 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 the quality of an organ intended for transplantation or which poses a significant direct risk of causing harm to a donor or recipient.
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 quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient
or
A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient;
or
A shortfall which indicates a major deviation from the **Human Tissue (The Quality and Safety of Organs Intended for Transplantation) Regulations 2012** or the **Documentary Framework for the Quality and Safety of Organs Intended for Transplantation**;
or
A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting quality and safety of an organ intended for transplantation or the safety of a donor or recipient;

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 audit 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 audit.
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 audit 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 audit 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 audit
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit audit.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.