**Site visit audit report on compliance with HTA requirements**

**Papworth Hospital NHS Foundation Trust**

**HTA licensing number 40033**

**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**

**31 July 2013**

**Summary of Audit findings**

Papworth Hospital NHS Foundation Trust (the establishment) was found to have met all assessment criteria.

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

| **Adult Deceased** | |
|---|---|
| **Heart** | **DC, OC, P, T and R** |
| **Lung** | **DC, OC, P, T and 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)

## Licensable activities carried out by the establishment – Transplant activities

| **Adult Deceased** | |
|---|---|
| **Heart** | **OC, P, T and I** |
| **Lung** | **OC, P, T and 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 is part of the National Organ Retrieval Service (NORS) for cardiothoracic organs (hearts and lungs) and implants cardiothoracic organs at Papworth Hospital. This was the establishment's first, routine audit.

The NORS team typically consists of a surgeon, donor care physiologist (DCP), transplant practitioner and scrub nurse. Trainees and surgical fellows also go on retrievals. Surgical fellows may be observed by a consultant, especially in the case of marginal donors (donors assessed at the lower or higher end of the acceptable donor selection criteria ranges).

The transplant unit has a team of transplant coordinators working with recipients before implantation. They are supported by a team of three data officers, to prepare and maintain paperwork.

When an offer comes in through NHS Blood and Transplant's (NHSBT) Electronic Offer System (EOS), the transplant coordinator discusses the offer with the on-call surgical fellow who will liaise with the on-call transplant consultant. The consultant will discuss the donor features with another consultant surgeon or physician, to make a decision based on a double consultation. The establishment will respond within the required 45 minutes if accepting the offer. The transplant coordinator then contacts the recipients at an early stage and may organise a vehicle to transport the recipients to the establishment. Throughout the assessment process potential recipients are warned about the possibility of false alarms.

Retrieval and implantation are conducted by separate teams. At the start of the retrieval, the preservation fluid is prepared by the transplant practitioner. Cannulation of the organ is performed by the retrieval surgeon. DCPs monitor the donor and organ function during the retrieval. Once the organs are retrieved they are packaged for transport for cold, static preservation in line with NORS guidance.

The retrieval team reports to the recipient transplant team when leaving the donor hospital, on the way to Papworth and 15 minutes before arrival, to allow the recipient team to make a timely decision on removal of the recipient's organs. Once the retrieval team returns to Papworth, the organ is taken straight to theatre. Tissue typing is performed by a laboratory at another HTA licensed establishment. Any additional donor or organ characterisation testing required, such as histopathology, virology and biochemistry is performed by the laboratories on site.

In addition to transporting organs on ice in cooler boxes, the establishment occasionally also uses organ cases, which are machines that perfuse hearts and lungs. The organ cases keep the hearts and lungs supported in a normothermic state (at body temperature). The establishment would be unable to reoffer hearts and lungs, due to the short ischaemic times acceptable for these organ types. Reoffer is theoretically possible with organs preserved using organ cases, but not likely. If an organ was to be donated for research or disposed of, the team would check the consent and organise this through the correct channels.

## 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. | This criterion is not applicable.<br>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.<br>The establishment has the *Papworth adapted operating procedure National Operating Procedure (NOP)001, Donor and organ characterisation, assessment and allocation in deceased donation transplantation* in place. Adaptations include referencing the *FRM4194, Cardiothoracic donor information form*.<br>The establishment also prints all the core donor data from EOS to refer to all necessary donor and organ characteristics. Extra functional data for organs are also available on the *Donor care practitioner's log*.<br>The *Transplant operation: donor and recipient data form* records all the minimum mandatory data in the one place. | **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.<br>Refer to CT2. The establishment staff stated that due to the nature of the organ types, more information is needed to make a clinical decision to use an organ, apart from the mandatory and complementary data set. The establishment follows guidance from the UK Cardiothoracic Advisory Group in gathering all necessary organ and donor data. | **None** |

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| 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.<br>The establishment has *Papworth adapted operating procedure NOP006 Transfer and storage of donor and organ characterisation information and storage of traceability data* in place.<br>The transplant coordinators keep files with all donor and organ characterisation information in a secure office indefinitely. The traceability information is backed up on a transplant database which includes recipient information, donor number, virology details, HTA A and B core data, timing information and cross-matching results. | **None** |
| CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation. | This criterion is fully met.<br>The establishment's laboratories have full Clinical Pathology 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.<br>The establishment has *Papworth adapted operating procedure NOP002 Verification of donor identity, consent and organ and donor characterisation in deceased transplantation* in place.<br>Transplant coordinators keep a *Transplant log* to clearly document the decision-making process. | **None** |

| **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 not applicable.<br>Consent is taken by the SN-OD. The establishment also confirms consent is taken when checking the EOS printout. | **N/A** |
| 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.<br>The establishment has *Papworth adapted operating procedure NOP004 Management of procurement material and equipment in deceased and living donation and transplantation* in place.<br>Compliance with the Medical Devices Regulations 2002 is reinforced at Trust level in *DN420 Medical device acceptance and installation procedure* and *DN416 Medical device procurement and selection procedure.* | **None** |

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| 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.<br><br>The establishment has an in-house Sterile Services Department (SSD). There is a *DN166 Decontamination Procedure* in place.<br><br>Cleaning for specific reusable instruments is also done according to specific procedures, such as *Transoesophageal Echo (TOE) Probe cleaning, disinfection and processing quick guide.* There is a *Donor run bronchoscope information form* to track sterilisation.<br><br>The ice-machine was also validated by a consultant microbiologist. A sanitisation record is kept.<br><br>The following certificates were seen during the audit, as evidence of validation of the SSD procedures:<br><br>• British Standards Institute (BSI) / UK Accreditation Services (UKAS) washer / disinfector quarterly test certificates – report number: 970, 978, 1650 and 1638.<br><br>• BSI / UKAS porous load quarterly test – report number: 001953, 1337, 13122 and 001959.<br><br>• Audit Certificate for SSD Papworth Hospital: BSI / UKAs FS399.36; Certificate number: BSENISO9001:2008 for the washer, disinfectors and porous load steriliser. | **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 not applicable.<br><br>The establishment does not have a living donor programme. | **N/A** |

| 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.<br>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.<br>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.<br>The establishment has *Papworth adapted operating procedure NOP006 Transfer and storage of donor and organ characterisation information and storage of traceability data* in place.<br>Perfusion batch numbers were seen on an HTA A Form.<br>The *Donor procurement perfusion manual* contains images of HTA A and B forms to indicate the correct sections to fill in.<br>The establishment is highly unlikely to reperfuse an organ, so perfusion fluids would be unlikely to be recorded on the HTA B Forms. The establishment may only reperfuse an organ if a pair of lungs transported on a portable support machine is split, with the first lung being implanted and the second lung re-perfused and re-packed in ice. | **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.<br>The establishment has *Papworth adapted operating procedure NOP003 Packaging, labelling and transport of organs in deceased donation and transplantation* in place.<br>The establishment also has a *Transport record of procured organs between donor hospital and Papworth hospital form*. This records the hospital, theatre number, date, retrieval team, organ type, clamp time, time the organ left the theatre, the mobile time, whether the organ came by road or by air, the time of arrival in theatre and the name and job title of the person who receives the organ and confirms the integrity of the packaging.<br>The *Donor procurement perfusion manual* also includes packaging instructions. | **None** |
| TP2) The organ shipping container is suitable for transport of the specified organ. | This criterion is fully met.<br>The establishment continues to use its cool-boxes while NHSBT source an alternative box that is compliant with the regulations. The establishment has participated in a recent trial for new boxes validated by NHSBT.<br>All organ cases used for machine preservation are CE marked. All data are held on the machine itself and also in paper form. The information is phoned in to the recipient transplant centre. | **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.<br>The establishment has *Papworth adapted operating procedure NOP003 Packaging, labelling and transport of organs in deceased donation and transplantation* in place.<br>The *Donor procurement perfusion manual* includes instructions on labelling. Examples of labels were observed. These contained all the mandatory information such as contact details for the NHSBT duty office, donor hospital and address and organ type. | **None** |

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| 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.<br>The establishment has *Papworth adapted operating procedure NOP003 Packaging, labelling and transport of organs in deceased donation and transplantation* in place.<br>The *Donor procurement perfusion manual* also includes labelling instructions. An example of a label was seen which contained all the necessary 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.<br>The establishment has *Papworth adapted operating procedure NOP003 Packaging, labelling and transport of organs in deceased donation and transplantation* in place.<br>The Service Level Agreement in place with the transport provider references Standard Operating Procedure (SOP) 3888/1, which requires reporting of incidents to NHSBT. | **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.<br>The establishment has *Papworth adapted operating procedure NOP002 Verification of donor identity, consent and organ and donor characterisation in deceased transplantation* and *Papworth adapted operating procedure NOP003 Packaging, labelling and transport of organs in deceased donation and transplantation* in place.<br>Rapid processing and relaying of information is especially necessary due to short cold ischaemic times for hearts and lungs. While in most cases, the implanting team will comprise of different staff from the retrieval team, there may be some cross-over of staff. There is constant communication between the two teams.<br>The *Transplant coordinator transplant log* supports communication between individual members of staff and teams by clearly documenting decisions made through the organ pathway. The *Donor care practitioner's log* provides further functional data. | **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.<br>The establishment has *Papworth adapted operating procedure NOP002 Verification of donor identity, consent and organ and donor characterisation in deceased transplantation* and *Papworth adapted operating procedure NOP003 Packaging, labelling and transport of organs in deceased donation and transplantation* in place.<br>The *Transplant coordinator transplant log* further supports communication between individual members of staff and teams by clearly documenting decisions made through the organ pathway. | **None** |

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| 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.<br>There was evidence seen of conversations with recipients about receiving organs from marginal donors recorded in patient notes.<br>The *Transplant coordinator transplant log* further supports communication between individual members of staff and teams by clearly documenting decisions made through the organ pathway. | **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.<br>The establishment has *Papworth adapted operating procedure NOP001 Donor and organ characterisation, assessment and allocation in deceased donation transplantation* and *Papworth adapted operating procedure NOP006 Transfer and storage of donor and organ characterisation information and storage of traceability data* in place.<br>The transplant team is well-supported by a group of data officers in administration tasks. The *Administration procedure manual* requires return of HTA A and B forms to NHSBT within three days. | **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.<br>The establishment uses three demographic details to identify the recipient: hospital number, name and date of birth. The donor identification number and hospital is used to identify donors and organs. | **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.<br>There is a *Transport record of procurement organs between donor hospital and Papworth hospital form* used to track the timing of the organ along the pathway.<br>All records related to the transplant are kept by the transplant coordinators in a secure office. The information is backed up on an electronic database. | **None** |

| 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.<br>The establishment has adopted the NHSBT SOP3881/1 *Reporting an organ donation or transplantation incident to NHSBT*.<br>All internal incidents are reported through Datix. There is an internal procedure, *DN70 Procedure for the reporting of accidents / adverse events / incidents and defects* in place.<br>The establishment has not reported any serious adverse events or reactions to NHSBT. This was confirmed on audit by reviewing the establishment's register of 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.<br>Refer to S1. | **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.<br>The establishment's contract with the transport provider references SOP3881/1. | **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.<br>Evidence was seen of sign-off of competency for staff in tasks relevant to their role. For example, the Transplant On-Call Assessment Sheet for Scrub Nurse to Demonstrate Knowledge of Procedure and Ability to Scrub Competently for an Organ Retrieval Procedure – both Adults and Paediatric. This relates to the *Association for Perioperative Practice 2007 standards and recommendations for safe perioperative practice*. | **None** |

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| 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.<br>Refer to GN1. The transplant coordinators' training document clearly articulates the whole process and possible scenarios. Training for transplant coordinators is for a minimum of one year, to take into account all the possible variables that might influence a transplant. | **None** |
| 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.<br>The establishment has *Papworth adapted operating procedure NOP005* in place. The Donor Procurement Perfusion Manual and *DN215 Management of the transplant patient*, also define roles and ensure medical 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. | N/A | The establishment has all policies and procedures in place, as required by the relevant regulations. The HTA advises the establishment to continue with its work and ensure quality documents continue to be reviewed and updated as necessary, to ensure they remain in line with the establishment's processes. |

## Concluding comments

There were a number of strengths and areas of good practice observed during the audit. The establishment has excellent communication and documents in place, developed through a strong team-based approach to its work. The diverse clinical team, includes surgeons, nurses, transplant coordinators and donor care practitioners, supported by a team of data officers. There is a weekly meeting held to discuss cases and incidents or for education, to further support communication across the team. In addition to adapting national operating procedures to reflect local protocols, the establishment has its own documents in place which further facilitate clinical processes and demonstrate a strong commitment to compliance with clinical standards and relevant regulation.

The HTA would advise the establishment to continue to maintain its current high standards of documentation and continue to make improvements to its documents.

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

**Report sent for factual accuracy: 23 August 2013**

**Report returned with comments: 5 September 2013**

**Final report issued: 12 September 2013**

## 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.