HTA's standards for licensed organ donation and transplantation centres

Donor and organ characterisation	
CT1	Where a donor is deceased, a registered medical practitioner (or 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
CT2	Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive
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
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
CT5	Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation
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

Retrieval of organs for transplantation	
R1	Procurement is only carried out after all the requirements relating to consent have been met
R2	Material and equipment used in retrieval meet the requirements of the Medical Devices Regulations 2002, where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with
R3	Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented
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

Organ preservation	
P1	Material and equipment used in organ preservation meet the requirements of the Medical Devices Regulations 2002, where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with
P2	Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented
P3	Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms

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
TP2	The organ shipping container is suitable for transport of the specified organ
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
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
TP5	Arrangements are in place to ensure that any organisation transporting organs on behalf of the licence holder meets the requirements for transportation and serious adverse event and reaction reporting specified in the framework document

Implantation of an organ	
I1	The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior to proceeding to implant an organ, and there is an operating procedures in place to demonstrate how this requirement is complied with
I2	Compliance with the conditions of preservation and transport outlined in the Framework document are verified prior to proceeding to implant an organ
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

Traceability	
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
TC2	There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it
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

SAEARs	
S1	Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction
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
S3	Third parties, such as those undertaking tests or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery

General	
GN1	Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitability qualified or trained to perform their tasks
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
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