Changes in this version

Whole document amended to reflect the change in commissioning accountability (transferred to OTDT NHSBT from 1 April 2022), the new arrangements for monitoring accreditation, and the process for managing issues with disruption in service or accreditation

SOP and INFs updated (section 3)

Policy

NHS Blood and Transplant (NHSBT) holds a Procurement licence (40056) under the Quality and Safety of Organs Intended for Transplantation Regulations (2012); licensed for the activity of 'donor and organ characterisation'.

This legislation requires that laboratories which carry out testing of organ donors are accredited by the United Kingdom Accreditation Service (UKAS) to ISO 15189:2012.

UKAS accreditation also provides NHSBT with assurance that laboratories carrying out donor testing are doing so to accepted standards in relation to staff, facilities and equipment. Such standards reduce the risk of inaccurate results and thereby ensure patient safety.

This policy describes how NHSBT OTDT works within the requirements of the Regulations to endeavour to use UKAS accredited laboratories.

1. Introduction

The Quality and Safety of Organs Intended for Transplantation Regulations (2012), as amended, sets out a requirement that laboratories undertaking screening as part of donor characterisation meet certain standards.

The HTA DIRECTS that tests required for donor and organ characterisation are carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.

The HTA considers that laboratories which hold current accreditation by the United Kingdom Accreditation Service (UKAS) to the internationally recognised standard ISO 15189:2012 will meet the requirement and NHSBT should endeavour to use only UKAS accredited laboratories.

Laboratory accreditation status can be checked here

The HTA Framework document states that there is an expectation that '*licence holders to establish the accreditation status of laboratories that are frequently used for donor or organ characterisation, and to review and update this information on a regular basis'*.

Furthermore '*Licence holders should not use a laboratory with an unknown or unaccredited status unless justified on the basis of risk to the quality and safety of the organ or to the recipient. This should be documented for reference in event of a serious adverse event or serious adverse reaction'*.

2. Operational Implementation

NHSBT OTDT holds a contract with laboratories for deceased donor characterisation which states that laboratories MUST hold ISO:15189 accreditation. The contract also includes a requirement that laboratories MUST notify the OTDT Commissioning Team of any changes in accreditation.

The OTDT Commissioning Team holds a register of all laboratories' accreditation, and will also capture any accreditation losses or suspensions so that these can be risk assessed, monitored and any recurring issues addressed contractually.

3. Operational Disruption

SOP5546 (H&I/Virology Laboratory – Operational Disruption) details the steps to be taken for NHS laboratories, Hub Operations, OTDT Commissioning, QA and SNODs when a laboratory identifies that there is a potential disruption to the testing service provided, which may impact on the organ donation process. Disruption may include, but is not limited to, issues affecting the accreditation status of the laboratory.

INF1466 (Back-up Laboratories for Deceased Donor Tissue Typing Testing) and INF 1583 (Back-up Laboratories for Deceased Donor Virology Testing) provide a list of back up laboratories for deceased donor testing following the identification of potential disruption to the testing service of individual laboratories.