

DIRECTIONS TO LICENSED ESTABLISHMENTS IN THE ORGAN DONATION AND TRANSPLANTATION SECTOR, GIVEN UNDER THE QUALITY AND SAFETY OF ORGANS FOR TRANSPLANTATION REGULATIONS 2012 (S.I. 2012 NO.1501) AS AMENDED

Directions requiring establishments in the Organ Donation and transplantation sector to submit a compliance update to the Human Tissue Authority (HTA)

Ref: 003/2019

These Directions are:

General Directions

Regulations providing for these Directions:

Regulation 6

These Directions come into force on:

02 September 2019

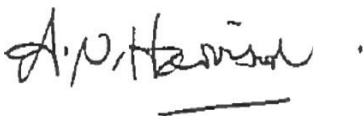
These Directions remain in force:

Until the Directions are revoked

1. These Directions are given in relation to licences Organ Donation and Transplantation sector establishments under Regulation 6 of the Quality and Safety of Organs for Transplantation Regulations 2012 (S.I.2012 NO.1501) as amended.
2. The Directions require licensed Organ Donation and Transplantation establishments to submit information about licensable activities being undertaken.
3. Submissions must be made to the HTA no later than **18 October 2019**.
4. Detailed instructions for completing the submission are provided in a separate document, which is available on the HTA website at:
<https://www.hta.gov.uk/policies/guide-submitting-compliance-updates-using-hta-portal>
5. The information required by these Directions will be used to:
 - a. Ensure each establishment's continued suitability to be licensed
 - b. Inform the scheduling of site-visit inspections
 - c. Inform the HTA's regulatory approach to the Organ Donation and Transplantation sector

Dated 05 August 2019

Signed



Nicolette Harrison
Director of Regulatory Delivery