

Human Tissue Authority
Finlaison House
15–17 Furnival Street
London EC4A 1AB

Tel 020 7211 3400
Email enquiries@hta.gov.uk
Web www.hta.gov.uk

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Dear Colleague,

General Directions 003/2010 implementing the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment and revocation of Directions 001/2006, 002/2007 and 004/2007

I am writing to you about General Directions 003/2010 we are issuing today for the human application sector. The new Directions consolidate and clarify the standards required under the Human Tissue (Quality and Safety of Tissues and Cells for Human Application) Regulations 2007.

Background:

HTA Directions 001/2006, 002/2007 and 004/2007 have now been in force for a number of years and feedback given by establishments as well as our own experience have shown us that these Directions needed improving so they would be easier to understand and follow. As of necessity, previous Directions implemented the requirements of the European Tissues and Cells Directive and the technical Directives in a step-wise fashion. This has led to duplications between Directions, in particular between Directions 001/2006 and 002/2007. We now also deem the language of the old Direction as too convoluted. Lastly, increased experience in particular regarding requirements for import and export and with third party agreements means that we are now able to give clearer instructions about requirements.

Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment

The new requirements are published as a Guide which forms the annex to Directions 003/2010. This Guide will be subject to periodic review and updates, which will be implemented by issuing further directions implementing any changes. The aim of this approach is to have a living document as the basis for the requirements for this sector, so that new developments and clarifications can be made more easily and integrated into the existing text.

The content of the Guide consolidates the requirements of Directions 001/2006, 002/2007 and 003/2007 and aims to use Plain English. The draft Guide was subject to review by some of our external stakeholders, who provided valuable feedback on the clarity of the contents.

The Guide is structured broadly according to activities and aims to take the user through the journey of the tissues and cells in a logical step-by-step fashion, starting from general requirements, consent procurement, testing, processing, storage and distribution to end users. The document, in pdf format, is interactive and the index can be clicked to jump to relevant sections directly. Cross references have been inserted with clickable links.

Overall the requirements set out in the Guide are not intended to place additional requirements on licensed establishment and third parties; instead the Guide more clearly reflects guidance already issued to establishments in the course of inspections. The main areas of note are:

- Guidance on third parties and third party agreements aims to be clearer and easier to follow, a template third party agreement is provided (paragraphs 188 to 202 and Annex E)
- We are providing clarification on the donor testing requirements of the European Directives (paragraphs 90 to 94).
- After many attempts to escalate the reporting timelines for serious adverse events and reactions, the HTA is now implementing mandatory reporting timelines of 24 hours from discovery. It is not our intention that establishments should have additional out-of-hours systems in place, but that reports can be made within this time frame during operational hours. Establishments should read paragraphs 171 to 187 carefully.

We are hoping that the new Guide makes adherence to the standards for our licensed establishments in the human application sector easier.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Liz McAnulty'.

Liz McAnulty
Director of Compliance and Enforcement