

EU Tissues and Cells Directive newsletter

Summer 2006

Summer 2006 - Summer edition HFEA EU Tissues and Cells Directive

HFEA Standards for Assisted Conception Centres

In April we sent all centres the new HFEA Standards for Assisted Conception Centres. We would like to thank centres for their comments on this document.

The Standards incorporate the requirements of the EU Tissues and Cells Directive and the measures that clinics will have to meet to demonstrate compliance with the Directive. The requirements of the Directive will be incorporated into the HFE Act 1990 and centres will have to demonstrate compliance from April 2007. Centres therefore have less than a year to put these new requirements in place.

Using the Standards, every centre should now be developing a quality management system, including the appointment of a quality manager, if one is not already appointed. Although the Standards are provisional, pending finalisation of European technical requirements, we are confident that they will not change significantly. Centres should therefore not be tempted to wait until the Standards are finalised.

The guidance which accompanies these Standards answers frequently asked questions and clarifies areas of the Directive which are not prescriptive. This guidance will be updated regularly to clarify any issues which arise. This guidance, and the Standards document, is available at the following address:

<http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy/StandardsforAssistedConceptionCentres>.

Technical requirements

To recap, the European Commission adopted the first Technical Directive (covering donation, procurement and testing) in February 2006, which is available on the HFEA website.

The text of the second Technical Directive (covering processing, preservation, storage and distribution) is still under discussion following the public consultation last summer. It is anticipated that it will be finalised by December 2006, but we do not expect and significant changes to take place before then. It is also anticipated that the European Commission will not implement an EU coding system until September 2008.

Our advice to clinics is to plan their implementation of the Directive against the draft requirements of the Directive which are incorporated into the HFEA Standards for Assisted Conception Centres, as detailed on the left.

For further information visit www.hfea.gov.uk



Licensing and regulations

The Department of Health are currently consulting on the Regulations which will transpose the Directive into UK law (these regulations will amend the Human Fertilisation and Embryology Act 1990). For more information please see the Department of Health website (www.dh.gov.uk)

All centres will need to obtain a licence, under the Directive, from the HFEA by April 2007. It is expected that centres will be issued with licences in March 2007 following the completion of self assessment forms. Formal inspections under the Directive will take place between April 2007 and April 2009. Centres already licensed by the HFEA, under the HFE Act, will receive one inspection to cover existing requirements and the new requirements of the Directive.

Centres will receive detailed instructions around the licensing process and implementation of the Directive later this year. IUI and GIFT

centres will receive extra information regarding how to complete self assessment forms.

EUTD fees for previously unlicensed (IUI and GIFT) centres

All previously unlicensed services will have to apply for a licence, under the EU Tissues and Cells Directive, from the HFEA before April 2007 and there will be an application fee charged to cover the licensing process up to April 2007. The HFEA are currently consulting on the proposals for these application fees.

It is proposed that all previously unlicensed clinics requiring a licence under the EUTD will be charged a flat fee of £975. This will cover the administrative costs of the application process, assessment of applications, and issuing of licences prior to April 2007. Clinics will also be invited to a comprehensive workshop during which further guidance will be provided and participants will have the opportunity to discuss issues with

the HFEA and other clinics. We will contact you again shortly regarding these workshops.

Additionally, clinics will have access to a named contact at the HFEA who will address queries and provide practical advice around the process.

For more details of this proposal please see the HFEA website (www.hfea.gov.uk) and please send your comments to eutdfees@hfea.gov.uk.

Also, there will be a further consultation later in the year to propose the structure for ongoing licence fees after April 2007.

HFEA workshops for IUI and GIFT centres

The HFEA will be holding workshops in September and October this year for IUI and GIFT centres to discuss issues such as how to apply for a licence, the HFEA Standards and appointing a Person Responsible and a Quality Manager.

The workshops will be held in London, Bristol and Manchester. Please contact Sandra da Silva, sandra.dasilva@HFEA.gov.uk, for further details and to register.

Further information

For archived editions of the EU Tissues and Cells Directive Newsletter, please see the "For Clinic Staff" section of the HFEA website: www.hfea.gov.uk

If you have any specific queries concerning the Directive please contact

Charles Lister, Head of Policy or Hannah Darby, Policy Manager
0207 291 8230 or 0207 291 8237
charles.lister@hfea.gov.uk or hannah.darby@hfea.gov.uk