

## **Title: EU Tissue/Cell Directive – A Catalyst for Quality Systems in Irish Fertility Units**

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**Objective: The EU Directives 2004/23/EC and 2006/17/EC for tissue and cells have focused previously unregulated Assisted Human Reproduction (AHR) Units in Ireland on the need for a structured Quality and Safety Management System.**

Abstract:

In 2005 the Report of the Commission on Assisted Human Reproduction identified that... *“Regulated quality assurance standards would also help to ensure that those accessing AHR services make decisions on the basis of the most thorough and reliable information available.”*

Reflective of this drive for quality and safety assurance the Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 and the supporting Directive 2006/17/EC of 8 Feb 2006, for the first time, laid down standards and technical requirements for the quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. These standards have very specific relevance to the previously unregulated area of Assisted Human Reproduction (AHR) and their application required the sector in many instances, to dramatically reassess and redesign their internal operations.

The Directives impact on every stage of the AHR process, from data protection requirements to reporting mechanisms, however, although the Directives “require a Quality Management System” the choice of that system is a decision for each AHR organisation (Article 16, 2004/23/EC). Many of the affected facilities, recognising the need for a proven QMS methodology, have followed the ISO9000 series, primarily that of ISO9001:2000, now ISO9001:2008. The ISO9001 QMS structure lends itself to incorporation of the Directives without comprising compliance of either the Directive or the standard, and of primary importance, it drives the focus for continuous improvement through the cycle of Plan, Do, Check, Act, a cycle which is critical to the continued compliance to the Directives.

Results:

With the introduction of the Directives, and in some cases the additional application of the ISO9001 QMS model, establishments have been faced with implementing a strategic re-organisation, now not only focusing on successful service application, but also developing, implementing and continually assessing its operations against regulations based on “international experience drawn upon through extensive consultation” (Regulation 6, 2006/17/EC). The Directives had provided establishment requirements based on international best practice and it was now the responsibility of the AHR facility to apply them to the satisfaction of their national Competent Authority and to be recognised as an authorised tissue establishment with licence to provide its fertility services. Auditing of facilities against the Directives, and the reflective national legislation, has also introduced another new facet to the AHR’s. Again, for the previously unregulated, the external audit experience can be daunting, however, the Competent Authorities have worked to assist tissue and cell establishments throughout the transition period, providing publications and guidelines to assist in the process. The Units themselves have also come together to communicate with each other regarding the licencing process and to share the operational tools that have proven successful in the application of the Directives.

Conclusions:

The EU Directives relating to Tissue and Cell establishments have had a profound effect on the previously unregulated AHR’s. These units have had to reassess their service provision to date, not only in line with the technical detail of the Directives, but they have also been required to incorporate a Quality Management System that will affect their operational methods and day to day activities. Though the incorporation and continual development of these requirements required significant resource support, their application will help to ensure an improved, consistent level of service throughout the AHR sector.