British Fertility Society

response to the

European Commission

public consultation on the

Draft Technical Requirements for Tissues and Cells

June 2005

About the British Fertility Society

The British Fertility Society (BFS) is a multi-disciplinary organization representing professionals with an interest in reproductive medicine. The objectives of the society are:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for and equity of access to fertility treatments.

The provision of assisted conception treatments to patients is a central part of the day-to-day work of BFS members and as such the society has an interest in policy developments in this area.

Background

In responding to this consultation, the BFS Executive Committee sent by e-mail to all 850 members of the society a request for comments on the draft directive. Members were invited to submit comments to the executive in any format and Professor Alison Murdoch, the current chair of the society, then collated these into this document. Briefly, BFS Members had comments on five issues raised by the directive as follows:

1. Quality Management

The main part of this document refers to Quality Management systems. This has already been discussed in detail and presented at several recent BFS meetings. There is a general acceptance within the United Kingdom that Assisted Conception Units should now be implementing a Quality Management system. Many Centres are already moving towards or have achieved a similar ISO standard. It will require changes in procedures and documentation for everyone, but is in line with the principals of clinical governance.

However, there are significant implications for implementation. One unit that has already achieved ISO accreditation has estimated their costs as follows.

Set up costs

Advisor	£25,000
Assigned Staff in first year	£25,000
Certification Visit	£4,600

Running costs per year thereafter

Quality Manager (part time)	£15,000
Quality Coordinator	£18,000
Surveillance audits	£2,000

Therefore, the cost to each Assisted Conception Unit will be in the order of £50,000 to set up a Quality Management system and £35,000 per annum to run it. It is expected that these costs will be similar no matter how big or small the unit.

Emphasis has also been placed on the demands on all team members of the accreditation process. Some have adapted to the strain well and others have found it more difficult. This must be taken into account when considering the process of implementing the new regulations.

BFS members request guidance in the process of Quality Management systems. Given the information above about the expected impact on clinics, central co-ordinated support and practical advice on the accreditation process is recommended.

The BFS will work with other professional groups to advise on appropriate minimum standards of professional practice, which will be evidence based where available.

2. Air Quality.

Section 2 D 3 of the document relates to air quality. In this context, the Directive appears to be designed primarily to protect the recipient, whereas in Assisted Conception Treatment the main concern is to the embryo. BFS members consider that the risks of air quality related disease transmission in Assisted Conception Treatment to the recipient is insignificant. Appropriate environmental control for the 'welfare of embryos' goes much further than just the air particle count. The BFS proposes that the minimum standards for environmental conditions for embryo growth as recommended by the Association of Clinical Embryologists[1] should be adopted. This should include the conditions necessary to protect against cross contamination.

The Directive recommends Grade A air quality for the open culture of cells. However, the document also allows exceptions.

> Section 2 D 4 (c) allows less stringent air quality requirement when the risk of transmission is significantly lower because of the method of application of cells. An example given is insemination. This relates to the extremely low risk of acquiring an endometrial infection from air borne particles of this quantity. We therefore support this recommendation. Furthermore, the risk to the recipient of intrauterine embryo transfer is equally low. We therefore recommend that, for the purpose of Assisted Conception Treatments, the requirement for Grade A is not appropriate (for the protection of the recipient).

[1] http://ace.ivf.net/ace/

> Section 2 D 4 (d) A further exception that might also apply to Assisted Conception as that a less stringent environment is acceptable if it is not technically possible to achieve Grade A. Current standard technology for performing Assisted Conception Procedures (such as Intra Cytoplasmic Sperm Injection) is not possible in Grade A conditions.

Despite these exclusions, there is still a requirement for an environment as close as possible to Grade A. However, this allows some flexibility for the professional societies to make appropriate recommendations for what they consider to be the minimum acceptable environmental requirements that are practically possible in Assisted Conception. We anticipate that this will be more rigorous than the current practice of many units but will not harm the clinical service or outcome.

3. The 'responsible person'.

This is currently defined in the parent Directive 2004/23 as a person who is qualified in "*medical or biological sciences*". Given the technical content of the Directive, it would seem essential to have a "responsible person" who is scientifically qualified to take responsibility for the laboratory procedures. The wording in the parent directive is ambiguous but BFS members consider that this should be at minimum level state registration and a PhD. In the UK there has been an inappropriate delegation of both scientific and clinical accountability to a single person with the current role of HFEA 'Person Responsible'. Any new regulations must take account of the shared and equal professional responsibilities of the clinical and scientific staff and allocate accountability accordingly.

4. Further specific points.

Section 2 A 5
There needs to be a clear definition of 'third party' in the context of ART.

Section 2 A 8
There needs to be a clearer definition of 'cell unit'. For example, one semen sample is a unit of cells and we cannot count each sperm as a cell unit.

Section 4
There needs to be a clearer definition of a 'serious adverse reaction' in relation to Assisted Conception. There may be some confusion here between reporting of incidents as part of a risk management system and the reporting required in this document which relates to clinical adverse reactions. This would only relate to, say, the use of donated sperm.

Section 5, 3
The requirement for the retention of serum in the context of Assisted Conception for cohabiting couples is not justified and should be removed. Serum retention in relation to donated sperm and eggs needs further justification and consideration of the implications.

5. General points

- There is potential for conflict in the confidentiality regulations of the HFE Act and the requirement for inter-institutional audit and recall of 'products'.

- The procedures proposed for recall of 'product' if, say, air quality standards fall, is not appropriate for Assisted Conception when an embryo cannot be 'returned'. Similar problems occur in the document because of the generality of its remit. It is recommended that a document be redrafted for circulation to ART centres for implementation to avoid concern and confusion.

- It will be important that those who are chosen to be inspectors under these new regulations have experience within Clinical Embryology and Andrology. They will need to be independent of the clinic but be experts in the field.