

## EU TISSUES AND CELLS DIRECTIVE

### HFEA AIR QUALITY GUIDANCE NOTE

The EU Tissues and Cells Directive (EUTD) covers any service involving donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, for human application. It also extends the Human Fertilisation and Embryology Authority’s remit to include the licensing of services involving fresh gametes.

Under the EUTD, requirements relating to air quality are being introduced for all centres. This guidance note sets out these requirements and what they mean in practice. Please note that all previously issued guidance on air quality is superseded by this document.

#### 1. Purpose of the requirements

The purpose of the requirements is to minimise contamination between gametes and embryos, the general environment, and the practitioner. As gametes and embryos are non-sterile, it is important not to introduce any additional pathogens.

#### 2. Air Quality Requirements

Centres will be required to carry out procedures involving the manipulation of gametes/embryos in an environment where the air quality is of at least Grade C in the critical work area. A background environment of at least Grade D is also required.

It is not expected that micromanipulation procedures such as ICSI or embryo biopsy have to be carried out within a hood, where it is not practical to do so. However, as with all handling of gametes or embryos, documented procedures should be in place at all times to keep the risk of contamination minimal.

The air quality grades are defined as follows:

Grade	Max. permitted number of particles per m <sup>3</sup> equal to or above:			
	At rest		In operation	
	0.5µm	5 µm	0.5 µm	5 µm
A	3 500	1	3 500	1
B	3 500	1	350 000	2 000
C	350 000	2 000	3 500 000	20 000
D	3 500 000	20 000	Not defined	

(MHRA – Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2002)

Centres will be required to have documented procedures for achieving the air quality requirements and monitoring compliance.

The recommended limits for microbial contamination are:

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Grade	Air sample cfu/m <sup>3</sup>	Settle plates (diam. 90mm) cfu/4 hours	Contact plates (diam. 55mm) cfu/plate	Glove print 5 fingers cfu/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

(MHRA – Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2002)

### 3. Equipment and methods

There are no requirements on how the air quality grades are met; it is therefore for centres to decide what equipment/methods they use to achieve the required grades and what methods are used to monitor compliance.

One way to achieve grade C air quality is through a class II cabinet and microbial monitoring can be done using settle plates, keeping a record of any cultures observed. However, centres may use whatever equipment/methods they wish to meet the requirements.

### 4. If air quality falls below standard

Though centres must endeavour to maintain the air quality requirements, should validation systems indicate that air quality has fallen below the level required, there is no expectation that gametes or embryos should not be used or stored because of this.

### 5. Further reading

#### **The origin, effects and control of air pollution in laboratories used for human embryo culture.**

Hall J, Gilligan A, Schimmel T, Cecchi M, Cohen J. Human Reprod. 1998 Dec;13 Suppl 4:146-55

#### **Ambient air and its potential effects on conception in vitro.**

Cohen J, Gilligan A, Esposito W, Schimmel T, Dale B. Hum Reprod. 1997 Aug;12(8):1742-9

#### **Monitoring vocs in air – the development of ISO standards and a critical appraisal of the methods.**

Brown RH. J Environ Monit. 2002 Dec;4(6):112N-118N

#### **Control of air quality in an ART lab.**

Boone WR, Johnson JE, Locke AJ, Crane MM 4th, Price TM. Fertil Steril. 1999 Jan;71(1):150-4.

#### **Establishing quality control in the new IVF laboratory.**

Cutting R, Pritchard J, Clarke H, Martin K. Hum Fertil. 2004 Jun;7(2):119-25

#### **Culture and quality control of embryos.**

Cohen J, Gilligan A, Willadsen S. Hum Reprod. 1998 Jun;13 Suppl 3:137-44

#### **Optimisation of conditions for IBF and embryo culture**

Loumaye E, de Cooman S, Thomas K. Rev Med Brux. 1985 Nov;6(9):611-4.

