


2. Staff

This guidance note contains:

Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

 Refer to principles 2, 7 and 9

HFEA guidance

- Centre staff
- Medical staff
- Nursing staff ■
- Counselling staff
- Staff engaged in scientific services
- Competence and training of ICSI and embryo biopsy practitioners
- Staff involved in genetic testing

■ Section includes interpretation of mandatory requirements

Other legislation, professional guidelines and information



Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

17 The person responsible

- (1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure—
- (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,...

Schedule 3A Supplementary Licence Conditions: Human Application

Requirements for procurement of gametes and embryos

5. Licence conditions shall require all persons to whom a licence applies who are authorised to procure gametes or embryos, or both, to comply with the requirements (including as to staff training, written agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

Licence conditions

- T11 The centre must have an organisational chart which clearly defines accountability and reporting relationships.
- T12 Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals.
- T13 All personnel must have job descriptions that accurately reflect their tasks, and responsibilities.
- T14 Personnel carrying out licensed activities or other activities carried out for the purposes of providing treatment services that do not require a licence must, where appropriate, be registered in accordance with the appropriate professional and/or statutory bodies, (eg, General Medical Council, Health Professions Council, Nursing and Midwifery Council).



Mandatory requirements (cont)

- T15 Personnel must be provided with initial/basic training. Training must be updated as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development must be provided. The training programme must ensure and document that each individual:
- has demonstrated competence in the performance of their designated tasks
 - has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks
 - understands the organisational framework, quality system and Health & Safety rules of the centre in which they work, and
 - is adequately informed of the broader ethical, legal and regulatory context of their work.
- T16 The centre must have access to a nominated registered medical practitioner, within the UK, to advise on and oversee medical activities.



HFEA guidance

Centre staff

- 2.1** The centre should establish documented procedures for staff management that ensure all staff have:
- initial basic training and updated training as required
 - on-going competence assessment, with audits of this assessment
 - an annual joint review (with their line manager)
 - continuing education and professional development
 - staff records, and
 - appropriate access to meetings and communications.
- 2.2** Staff records should include:
- job description
 - terms and conditions of employment
 - a record of staff induction and orientation
 - a record of health and safety training
 - a record of education and training, including continuing professional development
 - relevant educational and professional qualifications
 - certificate of registration, if relevant
 - absence record
 - accident record
 - a record of annual joint reviews
 - occupational health record, and
 - a record of any disciplinary action.

The centre should ensure that confidentiality of staff records is in line with best practice and relevant legislation.



- 2.3** All staff should participate in an annual joint review that examines the needs of the centre and of the individual to improve the quality of the service to users and to encourage productive working relationships. Staff performing annual reviews must receive appropriate training.
- 2.4** The centre should have an effective way of communicating information to, and receiving suggestions from, staff. Centre management should also ensure that the accountabilities and reporting relationships shown in the centre's organisational chart are communicated within the centre.
- 2.5** Centre management should ensure that staff members who are in contact with patients and donors:
- are prepared to offer appropriate emotional support to people suffering distress at any stage of their investigation, counselling or treatment
 - understand and can explain the role of counselling, and
 - know when and how to refer people to the centre's qualified counsellor.
- 2.6** Centres should require all prospective and existing staff to report promptly all criminal convictions they have had to the person responsible. In deciding whether or not an individual shall take part in a licensed activity at the centre, the person responsible should take into account relevant previous convictions and breaches of regulations.

Medical staff

- 2.7** The person responsible should ensure that staff who must be registered with professional bodies are registered, their registration is up to date, and records of this are kept.
- 2.8** The individual with overall clinical responsibility for treatment services involving in vitro fertilisation should:
- have completed training recognised by the Royal College of Obstetricians and Gynaecologists (or an equivalent professional body)
 - be on the General Medical Council's Specialist Register, and
 - participate in a recognised programme of continuing medical education and professional development.
- 2.9** If the centre is licensed to provide insemination services only, the individual with overall clinical responsibility should:
- be a registered medical practitioner, and
 - have sufficient experience in an established fertility centre to be qualified to take full charge of the centre's treatment services.
- 2.10** Other medical staff who take part in providing treatment services should be registered medical practitioners with sufficient experience under supervision to qualify them to do so. Medical staff who do laparoscopies should be Fellows or Members of the Royal College of Obstetricians and Gynaecologists (or an equivalent professional body). Medical staff in training should follow relevant training programmes under appropriate supervision.

Nursing staff



Interpretation of mandatory requirements

2A

All nursing staff must be appropriately qualified and registered by the Nursing and Midwifery Council.

- 2.11** Nurses should be:
- working towards competencies set nationally, locally or both, to ensure appropriate standards of clinical competence, and



2.11 (cont)

- (b) able to provide evidence of competence in the duties performed (for example, a certificate for a recognised qualification or a written testimonial by another person who is suitably qualified and competent in that discipline or function).

Counselling staff

2.12 Treatment centres should ensure that at least one individual is appointed to fulfil the role of counsellor. All counsellors should have specialist competence in infertility counselling and:

- (a) hold a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to the level of diploma of higher education or above, and
- (b) be accredited under the scheme of the British Infertility Counselling Association (or an equivalent body), or show evidence of working towards such accreditation.

2.13 A member of staff appointed to the role of counsellor should be able to provide evidence of being an accredited member of, or working towards accredited membership of, a recognised professional counselling body. The body should have a complaints/disciplinary procedure, and the individual should have agreed to abide by an appropriate code of conduct or ethics.

See also guidance note:

- [3 – Counselling](#)

Staff engaged in scientific services

2.14 Centre management should ensure that the centre has access to a nominated registered scientist to advise on and oversee scientific activities.

2.15 All healthcare scientists working in licensed centres should be registered or show evidence of working towards registration with the Health Professions Council (HPC), or other equivalent body where applicable. It is expected that all staff should be registered with the HPC (or other equivalent body) within one year of their becoming eligible, including those eligible as international applicants after training overseas.

2.16 Healthcare scientists from overseas who are registered in their own country but working in a licensed centre as a visiting scientist, should seek temporary registration with the HPC (or other equivalent body).

2.17 Healthcare scientists employed in roles not yet requiring state registration (eg, aspirant groups, healthcare science assistants and healthcare science practitioners) should follow an appropriate induction and training programme for the tasks performed. Each individual should maintain proper records of this training.

2.18 The individual responsible for the seminology laboratory should:

- (a) possess a degree or higher national diploma in a relevant discipline
- (b) have acquired sufficient experience in such a laboratory to supervise and be responsible for one, and
- (c) be registered with the HPC as a clinical scientist or biomedical scientist, or be able to demonstrate equivalent training or expertise.

See also:

- [Guidelines for Good Practice – Association of Biomedical Andrologists](#)
www.aba.uk.net



- 2.19** The individual responsible for the clinical embryology laboratory should:
- possess an appropriate scientific or medical degree
 - have had sufficient experience in such a laboratory to be able to supervise and be responsible for one, and
 - be registered with the HPC (or other equivalent body) as a clinical scientist with specific expertise in clinical embryology.

See also:

- [Accreditation Standards and Guidelines for IVF Laboratories – Association of Clinical Embryologists](http://www.embryologists.org.uk)
www.embryologists.org.uk

Competence and training of ICSI and embryo biopsy practitioners

- 2.20** The person responsible should ensure that micromanipulation procedures such as ICSI and embryo biopsy are carried out only by practitioners who have the necessary competence.
- 2.21** Following training, the competence of each person performing micromanipulation procedures should be evaluated at intervals specified in the quality management system. Retraining should be given when required.

Staff involved in genetic testing

- 2.22** A senior clinical geneticist should be involved in the decision-making process when deciding whether a particular patient should receive treatment involving embryo testing.
- 2.23** The centre should ensure that a multidisciplinary team is involved in providing the embryo testing service. The team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticists and molecular geneticists. It should maintain close contact with the primary care physician or the referring clinician.
- 2.24** If the centre offers an embryo testing service, the individual responsible for this laboratory should:
- hold an appropriate scientific or medical degree
 - have acquired sufficient experience in an appropriately accredited medical genetics diagnostic laboratory to supervise and be responsible for one, and
 - be registered with the HPC (or other equivalent body) as a clinical scientist with specific expertise in clinical genetics.
- 2.25** If genetic testing of those seeking treatment or considering donation is offered, the centre should ensure that an individual is available who understands the:
- nature of the tests conducted
 - scope and limitations of the tests
 - accuracy and implications of the tests, and
 - meaning of the test results.



HFEA guidance (cont)

- 2.26** The centre should ensure that people seeking treatment have access to clinical geneticists and genetic counsellors.
- 2.27** The centre should work closely with the local genetics team of those seeking treatment.

See also guidance note:

- **10 – Embryo testing and sex selection**



Other legislation, professional guidelines and information

- The Nursing and Midwifery Order 2001
- BICA Guidelines for Good Practice in Infertility Counselling (2008) – www.bica.net
- Association of Biomedical Andrologists – Guidelines for Good Practice – www.aba.uk.net
- Association of Clinical Embryologists – Guidelines for IVF Laboratories Accreditation Standards – www.embryologists.org.uk
- Royal College of Nurses – www.rcn.org.uk