

# 26. Equipment and materials

## This guidance note contains:

 Refer to principles 7 and 8

### Mandatory requirements

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

### HFEA guidance

- Scope
- Protection and hygiene of staff
- Managing equipment and material
- Safety of equipment used to store cryopreserved gametes and embryos

### 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—

...

(b) that proper equipment is used,

...

### Licence conditions

T22 For every critical activity, identifying information about all of the materials and equipment must be documented.

T23 Activities must be carried out using equipment and materials designated for the purpose and maintained to suit their intended purpose and must minimise any hazard to patients and/or staff.

T24 All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer’s instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available.

T25 New, repaired and recommissioned equipment must be tested and validated before use. Test results must be documented.

T26 Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises must be performed regularly and recorded accordingly.

T27 Procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure.

T28 Sterile instruments and devices must be used for the procurement of gametes and embryos. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.

Human Fertilisation and Embryology Authority



## Mandatory requirements (cont)

- T29 When reusable instruments are used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.
- T30 Wherever possible only CE marked medical devices must be used.
- T31 The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and, when applicable, the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament under the Council of 27 October 1998 on In vitro Diagnostic Medical Devices.



## HFEA guidance

### Scope

- 26.1** For the purpose of this Code of Practice, 'equipment and materials' includes all equipment, disposables, reagents, and calibration and control materials used in the conduct of assisted conception processes.

### Protection and hygiene of staff

- 26.2** The centre should provide proper clothing and equipment for the personal protection and hygiene of staff carrying out licensed activities, together with written instructions for their use.

### Managing equipment and material

- 26.3** The centre should establish documented procedures for managing equipment and materials, including:
- selecting and procuring equipment and materials
  - ensuring the traceability of any products or materials that come into contact with gametes or embryos and that affect their quality and safety, and
  - maintaining inventory information and records for stock control.

See also guidance note:

- [19 – Traceability](#)
- [31 – Record keeping and document control](#)

### Safety of equipment used to store cryopreserved gametes and embryos

- 26.4** All centres storing gametes and embryos should have effective alarms and monitoring systems to ensure the safety of cryopreserved gametes and embryos. These systems should have:
- local alarms (ie, on individual dewars for either temperature or liquid nitrogen level)
  - an auto-dial facility or similar (eg, link to fire-alarm board) to contact staff outside normal working hours
  - adequate staffing and funding to implement formal emergency procedures, including having on-call arrangements, and
  - adequate spare storage space or vessels to enable transfer of samples if a vessel fails.



## HFEA guidance (cont)

See also guidance note:

- [17 – Storage and gametes of embryos](#)



## Other legislation, professional guidelines and information

- Directive 98/79/EC and Directive 93/42/EC can be found at [www.eur-lex.europa.eu/en/index.htm](http://www.eur-lex.europa.eu/en/index.htm)