

25. Premises and facilities

This guidance note contains:

 Refer to principles 2, 7 and 8

Mandatory requirements

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

HFEA guidance

- Definition of premises ■
- Moving to new premises
- Changing existing premises
- Acquiring additional premises
- Centre facilities
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Staff facilities

■ Section includes interpretation of mandatory requirements

Other legislation, professional guidelines and information



Mandatory requirements

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

12 General conditions

(1) The following shall be conditions of every licence granted under this Act –

- (a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried out only on the premises to which the licence relates and under the supervision of the person responsible, (aa) that any activities to which section 3(1A)(b) or (1B) or 4(1A) applies shall be carried out only on the premises to which the licence relates or on relevant third party premises,...

16 Grant of licence

(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.

(2) The requirements mentioned in subsection (1) above are–

- ... (d) that the Authority is satisfied that the premises in respect of which the licence is to be granted and any premises which will be relevant third party premises are suitable for the activities...

(2) The Authority may revoke a licence otherwise than on application under subsection (1) if–

- ... (d) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,

- (e) it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are suitable for the activities entrusted to the third party by the person who holds the licence...



Mandatory requirements (cont)

Schedule 2 – Activities for which licences may be granted

- 4 (1) a licence under this Schedule can only authorise activities to be carried out on –
- (a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or 4(1A) applies, on relevant third party premises...
- (2) A licence cannot –
- ... (d) apply to premises of the person who holds the licence in different places.

Licence conditions

- T1 The activities authorised by the licence must be carried out only on the premises specified in this licence and under the supervision of the person responsible (PR). However, where authorised by a licence, procurement, testing, processing or distribution of gametes or embryos intended for human application can also be carried out on relevant third party premises, provided that such premises, and the activities undertaken there, are covered by the terms of a written third party agreement.
- T17 A centre must have suitable facilities to carry out licensed activities, or other activities carried out for the purposes of providing treatment services that do not require a licence.
- T20 In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP_ Annex 1 and Directive 2003/94/EC). It must be demonstrated and documented that the chosen environment achieves the quality and safety required.
- NOTE: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for processing tissue for use in transplantation are different than those listed above.
- T21 If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by CPA(UK) Ltd or another body accrediting to an equivalent standard. The pathology disciplines involved in diagnosis and investigation include andrology, clinical genetics, (cytogenetics and molecular genetics) haematology, bacteriology, virology and clinical biochemistry. Definition of premises



HFEA guidance

Definition of premises



Interpretation of mandatory requirements

25A

A licence can apply only to one premises; if a centre wishes to conduct licensed activities in a building different from the licensed premises, and not subject to a third party agreement, a separate licence will be required.

The HFEA must approve all new premises or changes to existing premises before use.

- 25.1** The HFEA defines premises as the specific area where a centre conducts its business, as identified on a floor plan submitted by the centre to the HFEA.
- 25.2** The centre should provide the HFEA with a floor plan that defines the premises to be licensed, including the purpose of each room.



Moving to new premises

- 25.3** Before moving to new premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of the intended move by submitting an application to vary the licence with information about the new premises. The HFEA will consider the application and information, and may need to inspect the premises.

Changing existing premises

- 25.4** Before planning any changes to the existing premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of any planned changes to the premises by submitting, in advance, an application for a variation of the licence with information on the planned changes.
- 25.5** The HFEA will consider the application and information, and may need to inspect the premises.

Acquiring additional premises

- 25.6** If a centre wishes to conduct licensed activities not subject to a third party agreement in premises other than those specified on the current licence (eg, in a different building), it should contact its inspector for advice and notify the HFEA in writing. The centre should also submit an application for a new licence with information about the additional premises.

Centre facilities

- 25.7** The centre should provide for the privacy, dignity and respect of all prospective and current patients and donors, as well as providing a safe working environment for all staff. Consultation and the exchange of personal information should be carried out in private (ie, cannot be overlooked or overheard by others).
- 25.8** The centre should have facilities for reception, clinical and counselling activity, laboratory work, storage of confidential records, storing gametes and embryos, and staff.
- 25.9** The centre should display a copy of its Certificate of Licence where it can easily be read by current and potential patients and donors.
- 25.10** The centre should have appropriate procedures to ensure premises comply with relevant requirements for safety and air quality, and these procedures should be validated.
- 25.11** The person responsible should assess how many treatment cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skill mix of staff members. Activity should be adjusted according to the findings of the assessment.

Clinical facilities

- 25.12** The centre should ensure that its clinical facilities:
- (a) provide privacy and comfort for those:
 - (i) considering donation and seeking treatment
 - (ii) undergoing examination and treatment, and
 - (iii) producing semen specimens.
 - (b) are equipped with backup and emergency clinical facilities that:
 - (i) are equivalent to those provided as standard practice in other medical facilities
 - (ii) are appropriate to the degree of risk involved in any planned procedure, and
 - (iii) can cope with emergencies known to occur in this clinical field.



Counselling facilities

25.13 The centre should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions.

See also guidance note:

- [3 – Counselling](#)

Laboratory facilities

25.14 The centre's laboratories should comply with current professional guidelines, legislation and regulations.

25.15 Procedures must be evaluated for hazards to laboratory staff, and precautions put in place to minimise potential hazards.

See also guidance note:

- [15 – Procuring, processing and transporting gametes and embryos](#)
- [24 – Third party agreements](#)

Staff facilities

25.16 The centre should have staff amenities that are easily accessible and include:

- (a) toilet facilities
- (b) a rest area with basic catering facilities and a supply of drinking water
- (c) a changing area and secure storage for personal belongings, and
- (d) storage for protective clothing.



Other legislation, professional guidelines and information

- Clinical Pathology Accreditation (CPA) UK Ltd – www.cpa-uk.co.uk