

# 32. Obligations and reporting requirements of centres

This guidance note contains:


## Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

## HFEA guidance

- Legal obligations toward the HFEA ■
- Requests under the Freedom of Information Act 2000

## Other legislation, professional guidelines and information

 Refer to principle 10, 11 and 13

■ Section includes interpretation of mandatory requirements



## 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–

... (b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity)...

(g) that the Authority shall be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.

(3) It shall be a condition of every licence to which this subsection applies that–

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos, shall be recorded and provided to the Authority upon request.

#### 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–

... (g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

### Schedule 3B Inspection, Entry, Search and Seizure

#### Inspection of statutory records

1 (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.

(2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection–

(a) in a visible and legible form, or



## Mandatory requirements (cont)

(2) (cont)

(b) in a form from which they can be readily produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

### Arranging inspections

2 (1) Where a person—

(a) makes an enquiry to the Authority which concerns the making of a relevant application by that person, or

(b) has made a relevant application to the Authority which the Authority has not yet considered,

the Authority may arrange for a duly authorised person to inspect any of the premises mentioned in sub-paragraph (3).

(2) For the purposes of sub-paragraph (1) a “relevant application” means—

(a) an application for authorisation for a person to carry on an activity governed by this Act which the person is not then authorised to carry on, or

(b) an application for authorisation for a person to carry on any such activity on premises where the person is not then authorised to carry it on.

(3) The premises referred to in sub-paragraph (1) are—

(a) the premises where any activity referred to in sub-paragraph (2) is to be carried on;

(b) any premises that will be relevant third party premises for the purposes of any application.

(4) The power in sub-paragraph (1) is exercisable for purposes of the Authority’s functions in relation to licences and third party agreements.

### Entry and inspection of premises

3 (1) A duly authorised person may at any reasonable time enter and inspect any premises to which a licence relates or relevant third party premises.

(2) The power in sub-paragraph (1) is exercisable for purposes of the Authority’s functions in relation to licences and third party agreements.

4 (1) Subject to sub-paragraph (2), the Authority shall arrange for any premises to which a licence relates to be inspected under paragraph 3 by a duly authorised person at intervals not exceeding two years.

(2) The Authority need not comply with sub-paragraph (1) where the premises in question have been inspected in pursuance of paragraph 2 or 3 at any point within the previous two years.

### Entry and search in connection with suspected offence

5 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—

(a) that an offence under this Act is being, or has been committed on any premises, and

(b) that any of the conditions in sub-paragraph (2) is met in relation to the premises,

the justice of the peace may by signed warrant authorise a duly authorised person, together with any constables, to enter the premises, if need be by force, and search them.

(2) The conditions referred to are—

(a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;

(b) that the premises are unoccupied;



## Mandatory requirements (cont)

(2)(cont)

- (c) that the occupier is temporarily absent;
- (d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) In relation to Scotland–

- (a) any reference in sub-paragraph (1) to a justice of the peace includes any reference to a sheriff, and
- (b) the reference in that sub-paragraph to “on sworn information” is to be read as a reference to “by evidence on oath”.

### Execution of warrants

- 6
- (1) Entry and search under a warrant under paragraph 5 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.
  - (2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.
  - (3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall–
    - (a) produce the warrant to the occupier, and
    - (b) give the occupier–
      - (i) a copy of the warrant, and
      - (ii) an appropriate statement.
  - (4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall–
    - (a) produce the warrant to that other person,
    - (b) give that other person–
      - (i) a copy of the warrant, and
      - (ii) an appropriate statement, and
    - (c) leave a copy of the warrant in a prominent place on the premises.
  - (5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.
  - (6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.
  - (7) Where the premises in relation to which a warrant under paragraph 5 is executed are unoccupied or the occupier is temporarily absent, the person executing the warrant shall when leaving the premises, leave them as effectively secured as the person found them.



## Mandatory requirements (cont)

### Seizure in the course of inspection or search

- 7
- (1) A duly authorised person entering and inspecting premises under paragraph 3 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for –
    - (a) the purposes of the Authority’s functions relating to the grant, revocation, variation or suspension of licences, or
    - (b) the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction.
  - (2) A duly authorised person entering or searching premises under a warrant under paragraph 5 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Act.
  - (3) Where a person has power under sub-paragraph (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving that thing or preventing interference with it.
  - (4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.
  - (5) Where by virtue of sub-paragraph (1) or (2) a person (“P”) seizes anything, P shall leave on the premises from which the thing was seized a statement giving particulars of what P has seized and stating that P has seized it.

### Supplementary provision

- 8
- (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.
  - (2) Power under this Schedule to inspect or search any premises includes, in particular–
    - (a) power to inspect any equipment found on the premises,
    - (b) power to inspect and take copies of any records found on the premises, and
    - (c) in the case of premises to which a licence relates or premises which are relevant third party premises in relation to a licence, power to observe the carrying-on of the licensed activity on the premises.
  - (3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person’s control as are necessary to enable the power of entry, inspection or search to be exercised.
- 9
- (1) A person’s right to exercise a power under this Schedule is subject to production of evidence of the person’s entitlement to exercise it, if required.
  - (2) As soon as reasonably practicable after having inspected premises in pursuance of arrangements made under paragraph 2 or after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall–
    - (a) prepare a written report of the inspection, or as the case may be, the inspection and search, and
    - (b) if requested to do so by the appropriate person, give the appropriate person a copy of the report.
  - (3) In sub-paragraph (2), the “appropriate person” means–
    - (a) in relation to premises to which a licence relates, the person responsible, or
    - (b) in relation to any other premises, the occupier.



## Mandatory requirements (cont)

### Enforcement

- 10 A person who–
- (a) fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 8(3), or
  - (b) intentionally obstructs the exercise of any right under this Schedule,
- is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

### Interpretation

- 11 In this Schedule–
- (a) “duly authorised person”, in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision, and
  - (b) “licensed activity”, in relation to a licence, means the activity which the licence authorises to be carried on.

### 35B Fees

- (1) The Authority may charge a fee in respect of any of the following–
- (a) an application for a licence,
  - (b) the grant or renewal of a licence,
  - (c) an application for the revocation or variation of a licence,...

## Licence conditions

- T2 Suitable practices must be used in the course of activities authorised by this licence and in other activities carried out in the course of providing treatment services that do not require a licence.
- T3 Any member or employee of the Authority, on production of a document identifying the person as such, if so required, must at all reasonable times be permitted to enter those premises and inspect them (including inspecting any equipment or records and observing any activity).
- T4 In support of an inspection, the Authority must be provided, within 28 days of a request in writing being made, with such information as specified in the written requests or in Directions.
- T6 When carrying out licensable activities, the centre shall only use those processes which have been expressly authorised by the Authority and published on the HFEA website (as amended from time to time).

## Directions

- 0005** – Collecting and recording information for the HFEA
- 0008** – Information to be submitted to the HFEA as part of the licensing process
- 0011** – Reporting adverse incidents and near misses

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



### Legal obligations toward the HFEA



#### Interpretation of mandatory requirements

32A

Centres have various legal obligations toward the HFEA. The person responsible should familiarise themselves with these, which include:

- (a) allowing HFEA inspectors to enter centre premises or relevant third party premises at reasonable hours
- (b) allowing HFEA inspectors to inspect centre or relevant third party premises, including inspecting equipment and records, taking away copies of records and other required items, and observing any activity, and
- (c) notifying the HFEA of any new activities or treatment services, before those services or activities are carried out.

The law also requires centres to provide certain information to the HFEA, either on request or at intervals or by deadlines specified in Directions. This includes information relating to:

- (a) the quality or safety of gametes and embryos
- (b) the traceability of gametes and embryos
- (c) adverse incidents and near misses, and
- (d) register information, including:
  - (i) registration information for donors, patients and patients' partners
  - (ii) information on the intention to treat
  - (iii) IVF treatment and embryo creation information
  - (iv) donor insemination information
  - (v) treatment outcome information.

Directions also outline how and when information should be submitted. For example, licensed centres must report using the Electronic Data Interchange (EDI) system unless they are given prior written authority to use a different method.

### Requests under the Freedom of Information Act 2000

- 32.1** The Freedom of Information Act 2000 (FOIA) gives the public the right to access information held by central government, local government and other public organisations. The FOIA is intended to improve openness and accountability to the public. Therefore, any recorded information (eg, on paper, computer file, email, disk, tape or microfiche) submitted to the HFEA may be disclosed under the FOIA. This excludes information covered by the confidentiality provisions of the HFE Act 1990 (as amended). The HFEA will consider arguments from information providers for non-disclosure, but may decide that the information must be disclosed.



### Other legislation, professional guidelines and information

- Department of Health – Records Management: NHS Code of Practice, Parts 1 & 2 – [www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/Recordsmanagement/index.htm](http://www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/Recordsmanagement/index.htm)
- Freedom of Information Act 2000
- Environmental Information Regulations 2004, paragraph 5(6)

Copies of the relevant legislation can be found at [www.opsi.gov.uk](http://www.opsi.gov.uk)