

HFEA Compliance

Compliance and Enforcement Policy

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Purpose of this Policy

- 1.1 This document and appendices set out the Authority's policy on the approach to be adopted, and the measures taken, by the Authority's Compliance Department in order to promote and maintain compliance by licensed centres with :-
 - a) the provisions of the Human Fertilisation and Embryology Act 1990 ("the Act");
 - b) licence conditions;
 - c) directions issued by the Authority; and
 - d) the Code of Practice issued by the Authority under Section 25 of the Act.
- 1.2 This policy replaces all previous policies relating to these matters.

When to apply this procedure

- 2.1. The planned inspection process
- 2.2 The escalation and management of concerns regarding the compliance of a Centre

The enforcement policy

3. THE INSPECTION PROCESS

- 3.1 The purpose of an inspection is to:-
 - a) assess the extent to which centres comply with the Act; licence conditions; directions and the provisions of the Code of Practice;
 - b) provide an independent and professional perspective on the running of the centre;
 - c) promote good practice so that centres can improve the quality of service they provide to patients and donors;
 - d) provide centres with a positive learning experience;

- e) provide centres with the opportunity to feed back on their experience of the inspection process, in order to assist the Authority to continually improve its procedures;
- f) give patients reliable information about a centre's compliance with statutory and other obligations, and about the quality and safety of licensed activities undertaken at that centre.

3.2 All inspections will be:-

- a) evidence based, consistent, proportionate and open to scrutiny;
- b) undertaken in a professional and courteous manner;
- c) be focused on risk;
- d) aim to add value for centres and service users.

3.3 The core assumption will be that centres wish to demonstrate compliance with the Act; licence conditions; directions and the Code of Practice. The onus is on centres to demonstrate compliance, not on inspectors to find fault.

3.4 During the course of an inspection of a licensed centre, the inspection team may identify and require improvements to be made. The inspection team will explain to the Person Responsible for the centre why any improvement needs to be made and the legal basis for requiring it. The team will take account of the challenges a centre might face in meeting a requirement (but must always be mindful of the health, safety and well-being of people who use the service).

3.5 A report of every inspection will be drafted. The Persons Responsible for licensed centre will be shown the report in draft and will be provided with a reasonable opportunity to comment on the findings and recommendations of the draft report.

3.6 The final report will be sent to the Executive Licensing Panel or Licence Committee. The Executive Licensing Panel or Licence Committee make the final decision as to whether a licence should be granted, renewed, allowed to continue, varied, revoked or suspended. The Executive Licensing Panel or Licence Committee also make the final decision as to the actions a centre should take in relation to any area(s) of non-compliance identified as part of the inspection visit.

3.7 After consideration by the Executive Licensing Panel or Licence Committee, routine Inspection Reports will normally be published on the Authority's website. Reports will be produced and published in a style and format which is accessible to all our stakeholders, particularly patients.

4. THE ESCALATION AND MANAGEMENT OF CONCERNS REGARDING THE COMPLIANCE OF A CENTRE

- 4.1 Where the Authority becomes aware that a licensed centre has failed to comply with the provisions of the Act; the conditions attached to its licence; relevant directions issued by the Authority; or the Code of Practice issued by the Authority, it will normally first seek to encourage the centre to undertake any necessary remedial action and improvements. Where a centre persistently fails to comply, the Authority will seek to achieve compliance via an escalating scale of informal measures to formal enforcement action. The diagram at Appendix 1 demonstrates this approach.
- 3.2 Informal action may include any or all of the following actions:-
- a) contacting the Person Responsible to discuss area(s) of non-compliance and remedial action identified that that the Person Responsible must undertake and the timescales for doing so if formal enforcement is to be avoided;
 - b) informing the Person Responsible in writing of the minimum levels of remedial action identified that that the Person Responsible must undertake and the timescales for doing so if formal enforcement is to be avoided;
 - c) meeting with the Person Responsible to discuss requirements and improvement options (including formulating an improvement plan);
 - d) sending a warning letter to the Person Responsible, informing him that formal enforcement will be undertaken if the identified remedial actions are not completed within a given time scale;
 - e) an unannounced inspection visit to monitor compliance.
- 3.3 Formal action may include any or all of the following actions:-
- a) referring the case for consideration by the Executive Licensing Panel / Licence Committee with a recommendation that the licence should be varied (including by imposing additional conditions);
 - b) referring the case for consideration by the Executive Licensing Panel / Licence Committee with a recommendation that an additional inspection be scheduled in order to monitor compliance;
 - c) referring the case for consideration by the Executive Licensing Panel/Licence Committee with a recommendation for a shortened term licence should be granted;

- d) referring the case for consideration by the Licence Committee with a recommendation that the licence should be revoked (or suspended);
- e) exercising powers under Section 39 of the Act (taking possession of material from licensed centres during an inspection)
- f) applying for a warrant in accordance with 40 of the Act;
- g) where a criminal offence may have been committed, referring the matter to the police for criminal investigation; or
- h) where professional codes of conduct may have been breached, referring the professional concerned to the relevant professional body.

3.4 The Authority's compliance department may take formal action if:-

- a) there are concerns about the ability of the Person Responsible to discharge his duties under Section 17 of the Act;
- b) the centre has not completed or does not appear likely to complete any necessary remedial action within the stipulated time frame;
- c) the centre has a previous history of non-compliance or failure to undertake remedial actions promptly or within required timeframes;
- d) there is a risk to patients or service users, or to gametes and embryos; or
- e) there is evidence that a criminal offence may have been, or is being, committed.

3.5 In deciding whether to take formal or informal action, the Authority's compliance department will use professional judgement, may take legal advice; and will act proportionately. The compliance department will not make a recommendation for the revocation (or suspension) of the Licence unless one or more of the requirements of Section 18(1) or (2) of the Act are met.

3.6 The key mechanism in deciding what action (if any) to take, will be the Management Review. Where the compliance department becomes aware that a centre may not be complying with the Act; licence conditions; directions; or the Code of Practice, a management review meeting will be held in relation to that centre. Subsequent review meetings may be held to monitor the situation.

3.7 The conduct of the Management Review meeting will be in accordance with the department's protocol and the review meetings will be minuted to provide an audit trail of the consideration of the case and to demonstrate compliance with the principles set out in this policy.

- 3.8 The initial management review will include the centre inspector and at least one Head of Department and such other persons considered appropriate. Those conducting the review will at all times, seek to act in a way which is:
- Fair and non-discriminatory
 - Targeted
 - Efficient and effective
 - Transparent
 - Focused on patients
 - Proportionate
 - Risk focussed
 - Timely
 - Co-ordinated
 - Consistent
- 3.9 In taking action or making recommendations to the Licence Committee, the Authority's compliance department will take account of the **attitude** of the PR and the centre's compliance history, the **risk** to patients and the **impact** on people using the service.
- 3.10 Any recommendations made in respect of proposed conditions should be "SMART" (Specific, Measurable, Achievable, Realistic and Time-bound)
- 3.11 The Director of Compliance shall formulate any recommendations to be made at the conclusion of the Management Review. Where the recommendation is that the matter should be referred to the police or that a warrant should be obtained, the recommendation will be brought to the attention of the Chief Executive.
- 3.12 Where the Authority has reasonable grounds for suspecting that an offence under the 1990 Act is being or has been committed on any premises, it may apply to a Justice of the Peace for a warrant to enter, search and seize materials from those premises.
- 3.13 Where the Chief Executive has been informed that the recommendation of the Management Review is that a warrant should be applied for, he shall inform the Chair of the Authority of the recommendation and the reasons for it.
- 3.14 The Chair may consult the Deputy Chair and the Chair of the Audit and Governance Committee about the recommendation.
- 3.15 In the event of a disagreement amongst those consulted, the Chair may veto the recommendation. The decision to apply for the warrant shall otherwise be made by the Chief Executive.

Fig. 1: An illustration of the escalating scale of informal measures to formal enforcement action

