

## Authority Paper

<b>Committee:</b>	Authority Meeting
<b>Meeting Date:</b>	2 <sup>nd</sup> July 2008
<b>Agenda Item:</b>	10
<b>Paper Number:</b>	[HFEA (02/07/08) 451]
<b>Paper Title:</b>	Development of 8 <sup>th</sup> Code of Practice – Progress Report
<b>Author:</b>	Charles Lister & Jacky Moran
<b>For Information or Decision?</b>	Decision
<b>Resource Implications:</b>	There are resource implications in both developing and implementing this work. These are being addressed through Programme 2010.
<b>Implementation:</b>	Common commencement dates for new legislation are April & October. The 'go live' date for the 8 <sup>th</sup> Code of Practice, and the associated changes in inspection practice etc, is therefore assumed to be October 2009 subject to confirmation by Ministers.
<b>Communication:</b>	A communications strategy, including stakeholder involvement, is being developed through Programme 2010
<b>Organisational Risk:</b>	High – There is a reputational risk if the Authority does not review its approach to regulation in line with current best practice, and a corresponding gain from a clearer, better focussed Code of Practice. There are also risks associated with doing this work if we fail to communicate our intentions clearly enough (e.g. that this is about clarity of regulatory objectives and proportionality rather than 'light touch' regulation). These risks will be mitigated though the communications strategy.
<b>Recommendation to the Committee:</b>	Members comments are sought on the approach being taken to the development of the 8 <sup>th</sup> Code of Practice and, in particular, the draft principles at Annex C and the proposed structure of the new Code as illustrated at Annex D.
<b>Evaluation:</b>	Proposals will be developed for evaluating the impact of these changes will be developed along with other changes arising from Programme 2010

### 1 Introduction & Purpose

1.1 At the May Authority, Members agreed a new format for the 8th Code of Practice based around key principles. The broad aim of the revised Code is to:

- update guidance for centres in line with the HFE Bill when enacted;
- improve clarity for centres in understanding and meeting regulatory requirements.

1.2 The development work on the 8th Code is being done to a very tight timescale so that the consultation process can start as soon as possible after the HFE Bill receives Royal Assent. The key milestones are set out at Annex A. We are working on the assumption that Royal Assent will be later this month, although this is not yet certain.

1.3 The timetable means that the Authority will have only one opportunity to comment on the draft Code (on 17th September) prior to consultation. This paper updates Members on the progress made to date and invites comment on the draft principles and proposed format.

## **2 Code of Practice Working Group**

2.1 It was agreed at the last meeting that a Code of Practice Working Group should be established. This has been done, and the Terms of Reference and membership are at Annex B. The Working Group will provide additional scrutiny on the draft Code as it develops through meetings, teleconferences and email exchanges with the Executive.

## **3 Expert Adviser**

3.1 Expert advice on the use of principles in regulation is being provided by Professor Julia Black of the London School of Economics. Professor Black has written extensively on this topic and has advised policy makers, consumer bodies, think tanks and regulators in the UK and overseas on issues of institutional design, regulatory policy and implementation. She is also a research associate of the ESRC Centre for the Analysis of Risk and Regulation at the LSE.

## **4 Draft Regulatory Principles**

4.1 We have now produced a draft set of regulatory principles for your consideration and comment. These are set out at Annex C. We have also have provided an indication of the areas of the Code of Practice (the fact sheets) that would link to each principle.

4.2 The draft principles have been through a number of iterations following comment by HFEA staff and Professor Black. They were revised further in response to Member's feedback at the Code of Practice Working Group on 19 June.

4.3 Our criteria for the principles is that they should be:

- High-level and broadly stated;
- Derived from legislation;
- Contain terms which are qualitative not quantitative, as opposed to prescriptive 'bright line' rules;
- Short and concise – avoiding unnecessary words to convey basic concepts;

- Written in 'plain English' – avoiding misleading language, jargon, legal terminology and phrasing
- Self-contained – not referring to other principles or legislation.

4.4 The principles are not final, but we are satisfied that we have now reached a point where we can start to structure the Code around them. As the new Code develops, we are likely to return to the wording of the principles, and will agree any changes with the Working Group prior to the September Authority meeting. At this stage, it would be helpful if Members could focus on:

- Whether the principles strike the right tone;
- Whether the emphasis is right;
- Whether they sufficiently encapsulate the Authority's key regulatory objectives;
- Whether there are obvious gaps;
- Whether they go beyond our regulatory remit.

## **5 Example fact sheet – 'Staff Training and Qualifications'**

5.1 As members will recall, in the revised Code each principle will link to fact sheets covering different subject areas, e.g. on storage periods, quality management systems and so on. In practice some fact sheets will naturally relate to more than one principle. In drafting the Code, we will identify the primary principle for each issue and, where necessary, cross refer to the others.

5.2 Each fact sheet will include information arranged under the following headings:

- Mandatory requirements
- HFEA guidance
- Other relevant legislation and guidance (e.g. from professional bodies)

5.3 Grouping mandatory requirements and good practice guidance by subject should improve usability for centres by reducing the need to refer to different parts of the Code. This approach will also help us to identify and eliminate duplication (for instance, removing standards that duplicate or paraphrase licence conditions or the Act).

5.4 The fact sheet attached at Annex D (Staff Training and Qualifications) is intended to illustrate how fact sheets may be structured in the 8th Code. Please be aware that the layout and design will change, and the scope and content of the fact sheet has not yet been finalised.

5.5 We would welcome your thoughts, in particular, on whether the proposed new structure is likely to make it easier to distinguish mandatory requirements from good practice guidance and whether this format will improve the overall usability of the Code.

## **6 Stakeholder Consultation**

6.1 We are developing a stakeholder engagement plan for consultation on the 8th Code. This will include professional bodies, licensed centres and patient groups. On 25th June, we held a workshop session with members of the HFEA's Licensed Centres' Panel and other sector representatives to discuss our early thinking on the draft principles and the structure of the new Code. Feedback from this session will be presented to the Authority on 2nd July as part of the introduction to this paper.

## **7 Conclusion**

7.1 We would welcome Members comments on:

- the draft principles at Annex C focussing on the questions at paragraph 9 above
- the proposed new structure for the 8th Code of Practice as illustrated by the example fact sheet at Annex D.
- the general approach being taken to the development of the Code and whether this is on the right lines.

**8<sup>TH</sup> CODE OF PRACTICE – KEY MILESTONES**

<b>Milestone</b>	<b>Completion/ Delivery Date</b>
Working Group comments on first draft of principles	19 June 2008
Workshop with centres	25 June 2008
Authority agrees draft principles	2 July 2008
HFE Bill Royal Assent	By 21 July 2008?
Drafting of Code & consultation pack completed	By 29 August 2008
Draft Code/consultation package considered by Authority	17 September 2008
Consultation launched (14 weeks inc Christmas period)	6 October 2008
Public meetings held (for clinics, professional bodies, patients etc)	During consultation period
Consultation deadline	9 January 2009
Post-consultation Code agreed by Authority	18 March 2009
Code sent for Ministerial approval	Late March 2009
8 <sup>th</sup> Code published/ issued to centres	Late April/early May 2009
8 <sup>th</sup> Code comes into force	1 October 2009?
Updated online version goes live	1 October 2009?

## **Code of Practice Working Group Terms of Reference**

### **1. Constitution**

- 1.1 The Authority has established a Working Group to be known as the Code of Practice Working Group (The Working Group). The function of the Working Group is to support the Executive in developing and delivering the 8<sup>th</sup> HFEA Code of Practice.
- 1.2 The Working Group shall be dissolved once the 8<sup>th</sup> Code of Practice has been approved by the Secretary of State.

### **2. Membership**

- 2.1 The Working Group shall be chaired by the Deputy Chair of the Authority who shall appoint the members of the Working Group from the membership of the Authority.
- 2.2 Members are appointed for the life of the Working Group.

### **3. Duties**

- 3.1 To advise the Executive in the development of the 8th Code of Practice including commenting on draft sections of the Code and proposed format and structure.

### **4. Reporting to the Authority**

- 4.1 The Working Group will report its activities to the Authority either by verbal update from the Working Group Chair or through papers presented to the Authority.

### **5. Secretariat**

- 5.1 Secretariat functions will be provided by the Project Manager for the 8<sup>th</sup> Code of Practice.

### **6. Attendance**

- 6.1 Meetings of the Working Group will be attended by staff members engaged in the development of the 8th Code of Practice.
- 6.2 External advisers engaged by the Executive to help deliver the 8th Code of Practice may be invited to attend meetings at the discretion of the Chair.

### **7. Working Methods**

- 7.1 The Working Group will operate mostly through correspondence with the secretariat. Meetings will be held at the discretion of the Chair.

These Terms of Reference were agreed on 19<sup>th</sup> June 2008.

## Code of Practice Working Group

### Membership

HFEA Code of Practice Working Group		
<b>Ms Sharmila Nebhrajani</b> (Chair)		
<b>Mr Hossam Abdalla</b>	<b>Dr Maybeth Jamieson</b>	
<b>Mr Walter Merricks</b>	<b>Professor Emily Jackson</b>	
<b>Mrs Rebekah Dundas</b>	<b>Professor Neva Haites</b>	
<b><u>Observers:</u></b>		
<b>Professor Julia Black</b> London School of Economics	<b>Mr Ted Webb</b> Department of Health	
<b><u>HFEA Staff:</u></b>		
<b>Charles Lister</b> Programme 2010 Compliance Programme Manager	<b>Trish Davies</b> Deputy Chief Executive & Director of Regulation	<b>David Gomez</b> Legal Adviser
<b>Debra Bloor</b> Head of Inspection	<b>Juliet Tizzard</b> Head of Policy	<b>Jacky Moran</b> Project Manager – Code of Practice

**DRAFT HFEA REGULATORY PRINCIPLES**

<b>Draft principle</b>	<b>Indicative fact sheets (not exhaustive)</b>
1. Licensed centres should ensure that all licensed activities are conducted in a non-discriminatory manner and with proper respect for the privacy and confidentiality, dignity, comfort and well being of prospective and current patients and donors.	<ul style="list-style-type: none"> <li>• Human Rights and Equalities legislation</li> <li>• Counselling</li> </ul>
2. Licensed centres should ensure that licensed activities are conducted with proper respect for the special status of the embryo.	<ul style="list-style-type: none"> <li>• Termination and disposal</li> <li>• Research</li> </ul>
3. Licensed centres should take into account the welfare of any child who may be born as a result of treatment and any other child who may be affected by that birth.	<ul style="list-style-type: none"> <li>• Welfare of the child guidance, including supportive parenting</li> </ul>
4. Licensed centres should ensure that prospective and current patients and donors are given sufficient information in order to make informed decisions, and give their informed consents, before any licensed activity is undertaken.	<ul style="list-style-type: none"> <li>• Costed treatment plans</li> <li>• Donor information</li> <li>• Surrogacy</li> <li>• Storage periods</li> <li>• Information about research projects</li> <li>• [Egg sharing agreements]</li> <li>• 10 families limit</li> </ul>
5. Licensed centres should ensure that all licensed activities are conducted with proper skill and care and in an appropriate environment, in accordance with the conditions and principles of good clinical practice, to minimise risks to patients, donors and children born as a result of treatment, and ensure optimum outcomes.	<ul style="list-style-type: none"> <li>• Multiple births</li> <li>• PGD and tissue typing</li> <li>• Screening</li> <li>• Procurement/processing, storage and handling</li> <li>• Staff training</li> <li>• Premises and facilities</li> <li>• Witnessing</li> </ul>
6. Licensed centres should continually ensure that all processes and procedures used in the conduct of licensed activities are safe and of good quality	<ul style="list-style-type: none"> <li>• Quality management system</li> <li>• Laboratory processes</li> <li>• [Audit of outcomes]</li> <li>• Validation</li> <li>• Third party agreements</li> <li>• PGS</li> </ul>

	<ul style="list-style-type: none"> <li>• [Imports/Exports]</li> </ul>
7. Licensed centres should maintain proper and accurate records and information about licensed activities.	<ul style="list-style-type: none"> <li>• Traceability</li> </ul>
8. Licensed centres should ensure that all serious adverse reactions, all incidents (including serious adverse incidents) and near misses are reported to HFEA, and that complaints are properly investigated and lessons learned appropriately shared	
9. Licensed centres should ensure that all licensed research meets proper ethical standards and is only undertaken where there is a clear scientific justification and no viable alternative to the use of human embryos.	
10. Licensed centres should ensure that all licensed activities are conducted with proper regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK. This should include: <ul style="list-style-type: none"> <li>○ maintaining up to date awareness and understanding of legal obligations</li> <li>○ responding promptly to requests for information and documents from HFEA</li> <li>○ co-operating fully with inspections and investigations by HFEA or other agencies responsible for law enforcement or regulation of healthcare</li> </ul>	<ul style="list-style-type: none"> <li>• Reporting requirements</li> <li>• Register data/timely returns to HFEA etc</li> </ul>