

Authority Paper

Committee:	Authority Meeting
Meeting Date:	5 September 2007
Agenda Item:	7
Paper Number:	HFEA (05/09/07) 395
Paper Title:	HFEA Code of Practice Update – Decision Making Process
Author:	Rachel Hopkins, Policy Manager
For Information or Decision?	Decision
Resource Implications:	This work is being managed within existing resources within the Policy, Regulation, IT and Communications Teams. There will also be a need for some input from the Legal team.
Implementation:	The Code of Practice update will be published at the end of November 2007. Any amendments requiring new or changed practices will come into effect on 6 April 2008.
Communication:	The on-line version of the Code will be updated automatically on the publication date and a hard copy update will also be sent to PRs at all centres via the centre mailing. Quality Managers, other key stakeholders and any interested parties who requested an update via the website will also be sent a hard copy. The update will also be communicated internally prior to publication so that colleagues are aware of any changes that may impact on their work.
Organisational Risk:	High – There are reputational and operational risks if an effective updated Code of Practice is not produced on time.
Recommendation to the Committee:	Members are invited to: <ul style="list-style-type: none"> • approve the proposed decision making process for the Code of Practice update • grant delegated authority to the Regulation Committee to deal with updates which do not involve new policies and/or new versions of the Code
Evaluation:	The Code of Practice Update Project Group will review the process after this first update and suggest improvements, if required.

Purpose

1. This paper sets out the proposed decision making process for updates to the Code of Practice. It also seeks the Authority's agreement to delegate to Regulation Committee decision making powers for amendments to the Code which do not involve significant policy changes and/or new versions of the Code.
2. The proposed process will streamline decision-making, enabling publication of the first update to the 7th edition of the Code of Practice at the end of November 2007.

Background

3. The 7th Edition of the HFEA's Code of Practice came into force on 5th July 2007. Regular updates of the Code of Practice are planned so that it is kept up to date with any new policies and addresses any points of clarification or minor anomalies. The new format of the Code makes updating easier as users will be able to view updated sections of the Code on-line or replace pages of the hard copy of the Code, rather than trying to incorporate various additional communications such as Chair's letters.

Decision making process

4. An 'Update Protocol' is being developed to ensure that any updates to the Code are effectively managed, with a full audit trail of any changes made. The Policy Team is leading the development of the Update Protocol and a Code of Practice Project Group has been established (comprising colleagues from Policy, Regulation, IT and Communications) to handle proposed updates in accordance with the protocol.
5. The protocol will cover all types of required amendments covering new policies, policy changes, clarification of standard or guidance, updated external links and minor typographical errors. It will also set out the level of approval required for each type of amendment and how that should be obtained.
6. We propose a two tier approval system to streamline the approval process:
 - The Authority: signs off (i) new or amended standards/guidance that introduce new policy requirements (these will normally have been preceded by a policy review) and (ii) completely new editions of the Code (the next new edition - the 8th - will follow enactment of the Human Tissue and Embryos Bill).
 - Regulation Committee: signs off all amendments not involving a change in policy, for example points of clarification or correction of typographical errors.
7. The protocol also recognises the need to work with the professional bodies in the development of any new standards. This continues the partnership approach established when the standards were first developed. Professional bodies will be given early sight of any updates to enable comments to be made.
8. A summary of the proposed approval levels are set out in the table below:

Ministerial	New edition of Code of Practice
Department of Health	New edition of Code of Practice New policy = new standard/guidance
Authority	New edition of Code of Practice New policy = new standard/guidance

Regulation Committee	<p><i>(using delegated authority from Authority, may also act as 'pre-cursor' to Authority approval, as required)</i></p> <p>Clarifications (eg re-write paragraph)</p> <p>Additional paragraphs (to existing standards/guidance)</p> <p>Deleted paragraphs</p> <p>External links</p> <p>(Typos – to be informed)</p>
<i>Professional bodies group</i>	<p>New or amended standard – consult</p> <p><i>(Notify and keep informed of other changes)</i></p>

Timescale

9. Proposals for the first update to the Code of Practice will be put to the October meetings of Regulation Committee and the Authority, with publication at the end of November 2007. Any amendments requiring new or changed practices for centres will come into effect on 6 April 2008. This is in line with the Government's policy that domestic regulation which impacts on business should commence on one of two dates (6 April and 1 October) each year to enable them to plan for new measures and to implement them effectively).
10. The intention is to update the Code no more than two times year.

Communication

11. The on-line version of the Code will be updated automatically on the publication date and a hard copy update will be sent to PRs at all centres via the centre mailing. Quality Managers, other key stakeholders and any interested parties who request an update via the website will also be sent a hard copy.
12. The update will also be communicated internally prior to publication so that colleagues are aware of any changes that may impact on their work.

Recommendations

13. It is recommended that the Authority:
- approves the proposed decision making process for the Code of Practice update as set out in this paper;
 - grants delegated authority to Regulation Committee to deal with updates to the Code as set out in the table at paragraph 8 above.