



THE HFEA RESPONSE TO PROFESSOR BRIAN TOFT'S REPORT:  
'INDEPENDENT REVIEW OF THE CIRCUMSTANCES SURROUNDING FOUR  
ADVERSE EVENTS THAT OCCURRED IN THE REPRODUCTIVE MEDICINE  
UNITS AT THE LEEDS TEACHING HOSPITALS NHS TRUST, WEST YORKSHIRE'

JUNE 2004

**HFEA RESPONSE TO THE TOFT  
REPORT: RECOMMENDATIONS JUNE  
2004**

<p><b>1. The HFEA should retain a panel of solicitors whose individual members can be called upon in rotation to sit with Licence Committees and advise where the activities of a centre have breached the HFE Act or Code of Practice. In these circumstances, the Licence Committee legal advisor should draft the terms of the condition or conditions to be applied to the Licence.</b></p> <ul style="list-style-type: none"> <li>• The HFEA's current structure meets this recommendation in full.</li> <li>• Full time legal adviser has been employed by the authority since 2003 and attends all Licence Committees.</li> <li>• Additional two solicitors advise on individual clinics, on particularly complex situations and provide an objective auditing and overview of licensing decisions on a quarterly or half year basis.</li> </ul>	<p>In place since 2003</p> <p>In place since November 2003</p> <p>In place since November 2003</p>
<p><b>2. The Government should amend the confidentiality provisions found in Section 33 of the HFE Act. The amendment must continue to secure the confidentiality of patients seeking ACSs and any children resulting from that treatment, but should permit information on ACSs to be shared by all those individuals and institutions that have a legitimate reason for requiring access to it.</b></p> <p><b>3. In the interim, the Authority should seek legal advice about the limits of the confidentiality requirements in the HFEA. On the basis of this advice they should then develop a policy on the sharing of information both within the Authority and more widely, that is consistent with their regulatory and advisory functions.</b></p> <ul style="list-style-type: none"> <li>• HFEA has provided the Secretary of State with its advice on any recommended revision to the Act.</li> <li>• In the interim advice sought from legal experts on the sharing of information and policy in place to meet the needs of advisory and regulatory responsibilities.</li> </ul> <p><b>4. All inspection reports, adverse event investigations and the minutes of LCs together with their conclusions suitably anonymised, should be published on the HFEA website.</b></p> <ul style="list-style-type: none"> <li>• Inspection reports and Licence committee decisions from September 2003 are publicly available on</li> </ul>	<p>Advice given to DH</p> <p>In place since April 2003</p> <p>In place May 2004</p> <p>In place since April 2003 Documents available on request for public since September 2003</p> <p>In place since</p>

request.	September 2003
<p><b>5. When making appointments to the Authority, the Secretary of State for Health should ensure that any advice he receives about the future requirements of the Authority takes fully into account all the expertise it requires across all its functions.</b></p> <ul style="list-style-type: none"> <li>• This recommendation is for the DH to implement. (We believe this to have been the case since 2002.)</li> </ul>	DH responsibility
<p><b>6. Within the limits of the HFE Act consideration should be given to the greater use of seeking expert advice externally, including co-opting individuals as necessary to provide the Authority with such advice on specific issues.</b></p> <ul style="list-style-type: none"> <li>• Individuals with specific expertise or experience are co-opted onto all standing committees of HFEA.</li> </ul>	In place since December 2002
<p><b>7. A formally structured induction training programme should be implemented as soon as possible to ensure that all new members of the Authority are appropriately briefed. The induction training programme should include not only the regulatory and legal aspects of the provision of ACSs but also an understanding of the structure and organisation of ACS centres with particular regard to skills mix, training, expertise and staffing.</b></p> <ul style="list-style-type: none"> <li>• There is a formal induction programme in place since 2003.</li> </ul>	In place since January 2003
<p><b>8. A formally structured CPD programme should be implemented as soon as possible to ensure that all members of the Authority are kept appropriately briefed.</b></p> <ul style="list-style-type: none"> <li>• An extended CPD programme has also been underway since spring 2003 (includes training on legal issues, freedom of information, corporate governance and inspection protocols.)</li> </ul>	In place since Spring 2003
<p><b>9. Working with the relevant professional bodies the HFEA should develop as a matter of urgency explicit objective formal protocols that cover all aspects of Assisted Conception Services that a Licence committee is required to consider when discharging its legal obligations.</b></p> <ul style="list-style-type: none"> <li>• Protocols being updated to be in place for inspections and for Licence Committee decision-making.</li> <li>• The HFEA is leading the work on detailed standards for all aspects of assisted reproduction in</li> </ul>	<p>Inspection protocols in place since 1998</p> <p>In place since Autumn 2004</p> <p>In place since</p>

preparation for EU Tissue Directive.	June 2003
<p><b>10. The minutes of Licence committee meetings should reflect in detail the discussions held when reviewing a centre's Licence.</b></p> <ul style="list-style-type: none"> <li>• Since early 2004 all Licence Committee minutes are kept to a standard format and include detail of discussion and reasons for decisions taken.</li> </ul>	In place since February 2004
<p><b>11. The use of recommendation by Licence Committees should cease immediately with licensing requirements and breaches of the HFE Act or Code of Practice being the subject of specific Licence conditions.</b></p> <ul style="list-style-type: none"> <li>• The HFEA accepts the importance of issuing licence conditions and issues these where a centre is failing to meet required standards.</li> <li>• Monitoring of conditions is carried out promptly. Recommendations are followed up separately.</li> </ul>	In place since January 2004
<p><b>12. Where it is believed that a centre is not engaging in best practice, a separate letter should be sent by the Licence committee concerned, advising the centre where improvements could be made. The advice in the letter should be discussed with the centre at the next inspection.</b></p> <ul style="list-style-type: none"> <li>• Advice on best practice is given separately through the appropriate use of recommendations and is also followed up.</li> </ul>	In place since January 2004
<p><b>13. The review panel recognises that Licence committees are not obliged to follow the recommendations of external inspectors. However, where such a decision is taken the rationale supporting it should be clearly stated in the minutes of the meeting.</b></p> <ul style="list-style-type: none"> <li>• The HFEA ensures that all Licence committee minutes make clear the reason for decisions.</li> </ul>	In place since December 2003
<p><b>14. The Authority should ensure that Licence committees are consistent in their approach to the evaluation of all Licence applications.</b></p> <ul style="list-style-type: none"> <li>• The HFEA meets this recommendation in full. Legal advice and standard criteria for assessing applications ensure consistent approach.</li> </ul>	In place since November 2003
<b>15. An explicit protocol outlining the action to monitor compliance with Licence Committee</b>	In place since

<p><b>instructions should be drawn up and all (Inspector Co-ordinators) regulation staff made aware of them.</b></p> <ul style="list-style-type: none"> <li>• A system is in place with legal advice as required to monitor compliance with Licence committee instructions.</li> </ul>	<p>June 2002</p>
<p><b>16.Licence committees should not make decisions regarding licences where they do not have members present with the expertise and experience to cover all the skill areas to be discussed.</b></p> <p><b>17.The area of expertise possessed by each member of a Licence Committee should be recorded on the minutes of a Licence Committee meeting for example clinician, embryologist, counsellor and so on.</b></p> <ul style="list-style-type: none"> <li>• Licence committees (organised in teams) are set up to ensure the necessary expertise for each agenda. Minutes record those present.</li> </ul>	<p>In place since June 2003</p> <p>In place since January 2003</p>
<p><b>18.The present Inspector Co-ordinator job description should be discarded and the role of Inspector Coordinators urgently reviewed. Following the review, a job description should be composed to reflect accurately the role that the Authority requires Inspector Co-ordinators to undertake. In the interim, the role of Inspector Co-ordinators should be limited to that in the Manual for Inspectors.</b></p> <ul style="list-style-type: none"> <li>• The HFEA abolished the role of Inspector Co-ordinators in January 2002 and replaced them with Regulatory Managers.</li> <li>• This role was replaced with two new roles; Senior Regulatory Managers and Regulatory Officers. Job descriptions for these roles are accurate to reflect their role.</li> </ul>	<p>In place since January 2002</p> <p>In place since July 2002</p> <p>In place since July 2002</p>
<p><b>19.The Authority should consider separating out the advisory and regulatory roles of Inspector Co-ordinators, or provide clear explicit guidance about the respective roles so as to avoid conflicts occurring.</b></p> <ul style="list-style-type: none"> <li>• The HFEA has met this recommendation since January 2002 with the establishment of the roles of senior regulatory managers and regulatory officers. (See recommendation 18.)</li> <li>• There is a new management structure in place to oversee the relationship between the advice-giving and regulatory control.</li> </ul>	<p>In place since January 2002</p> <p>In place since February 2004</p>

<p><b>20. While it is not essential for inspector coordinators to have prior experience of assisted conception services, the fact that many do not underlines the importance of formal induction training and continuing development programmes. These should be introduced as a matter of urgency to ensure that Inspector Co-ordinators have proper understanding of the law, of regulatory requirements and where appropriate, relevant scientific and medical issues.</b></p> <p><b>21. The Authority should consider arranging for Inspector Co-ordinators who have no experience of working in centres to undertake a brief secondment to gain awareness of the context in which the HFEA regulatory framework is applied.</b></p> <ul style="list-style-type: none"> <li>All staff go through standard induction programme. Regulation staff induction needs are assessed on an individual basis and a programme tailored accordingly including shadowing in centres.</li> </ul>	<p>In place since January 2002</p> <p>In place since Autumn 2003</p>
<p><b>22. Formal assessment should be introduced to ensure that all Inspector Co-ordinators meet the standard required by the Authority and continue to do so throughout their career.</b></p> <ul style="list-style-type: none"> <li>The HFEA has had a standard performance framework ensuring all staff meet the standard required since 2002.</li> <li>Training requirements each year are tailored to performance objectives. There is a full training plan for the regulatory staff.</li> </ul>	<p>In place since January 2002</p>
<p><b>23. The Authority should introduce, in consultation with the appropriate professional bodies, a formal appointment process for External Inspectors that reflects the needs of the job and enables selectors to make decisions on the basis of a broad range of data collected with a variety of methods. This should be a rigorous process, with assessment going beyond the scientific specialism of the individual to include an understanding of the relevance of issues relating to risk assessment and quality assurance techniques.</b></p> <ul style="list-style-type: none"> <li>The HFEA has met this recommendation since March 2003. External inspectors are formally appointed following a 2 day evaluation.</li> <li>Ongoing updating is provided.</li> <li>The HFEA is recruiting its own clinical inspector to carry out a proportion of inspections consistently and to monitor the performance of external inspectors.</li> </ul>	<p>In place since March 2003</p>

<p><b>24. The Authority should develop and introduce, following consultation with the appropriate professional bodies, a formal induction and CPD programme to ensure that External Inspectors are competent to carry out the role and are up to date with the latest developments in their respective fields. Attendance at these events should be mandatory to ensure that the inspectorate works as effectively as possible.</b></p> <ul style="list-style-type: none"> <li>• The HFEA meets this recommendation in full. (See above.)</li> </ul>	<p>In place since March 2003</p>
<p><b>25. The Authority should develop and introduce, following consultation with the appropriate professional bodies formal assessments of External Inspectors to ensure that they are proficient in their role and are up to date with the latest developments in their respective fields.</b></p> <ul style="list-style-type: none"> <li>• The HFEA is planning this recommendation in full. (See above).</li> </ul>	<p>In place from Autumn 2004</p>
<p><b>26. A complete review of the information required by an ESI should be undertaken with some urgency. Once the information requirements have been established all ESIs should be contacted to ascertain if they are in possession of that information.</b></p> <ul style="list-style-type: none"> <li>• The training of inspectors ensures all information needs are reviewed and met. In the future, further supervision from the HFEA's own clinical inspector will meet any additional development needs.</li> </ul>	<p>In place since March 2003</p>
<p><b>27. All inspectors should undertake the formal induction training recommended above and then be formally assessed as to their competence in the role. There should be periodic assessments to ensure that consistency is maintained.</b></p> <ul style="list-style-type: none"> <li>• Formal induction and assessment is in place for newly recruited inspectors.</li> <li>• Periodic assessments will be in place for all inspectors from Autumn 2004.</li> </ul>	<p>In place since March 2003</p> <p>In place from Autumn 2004</p>
<p><b>28. The Authority should undertake consultation with ESIs to determine the time they consider is required to familiarise themselves fully with the contents of papers for full and interim inspections.</b></p> <ul style="list-style-type: none"> <li>• The HFEA regularly meets with inspectors and reviews feedback on all inspection issues including time requirements.</li> </ul>	<p>In place since November 2002</p>
<p><b>29. It should be a requirement for Inspector Co-ordinators to ensure that the checklists have been properly completed after each inspection.</b></p>	<p>In place since January 2003</p>

<ul style="list-style-type: none"> <li>• Senior regulation staff take responsibility for documentation after inspections. Systems are in place to ensure that checklists are completed and that documentation is timely.</li> <li>• The HFEA sets a target of 4 weeks from inspection date to completion of draft report signed off by inspectors. Business re-engineering and use of IT is aimed at producing draft reports within 24 hours by end of 2004.</li> </ul>	
<p><b>30. The Authority should develop and introduce, following consultation with the appropriate professional bodies, checklists that contain as many objectively measurable standards as possible.</b></p> <ul style="list-style-type: none"> <li>• The HFEA utilises checklists and protocols that are measurable.</li> <li>• Professional bodies have worked in compiling standard operating processes for accreditation which will further contribute to measurable procedures.</li> </ul>	<p>In place since early 2003</p> <p>Ongoing</p>
<p><b>31. The Authority should ensure that the views of patients and their experiences are at the heart of the inspection regime. Therefore the practice of centres closing on inspection days should be stopped, and inspection teams should set aside time to discuss with patients or their representatives matters of importance to them.</b></p> <ul style="list-style-type: none"> <li>• Patient feedback process initiated to be implemented fully in June 2004.</li> </ul> <p><b>32. The discussion with patients or their representatives should be made an item on the inspection checklists</b></p> <ul style="list-style-type: none"> <li>• New methods for gathering patient views as part of inspection were piloted in 2003.</li> <li>• The method favoured by Patients consulted is now in place.</li> <li>• In addition, there is a patient representative on the Authority and joint working with patient organisations on a number of key areas including information provision.</li> <li>• Patient groups have been routinely consulted on key issues since 2003.</li> <li>• The Authority has also initiated a programme of random unannounced inspections since 2003, which</li> </ul>	<p>In place since November 2003</p>

<p>by their nature mean clinics are assessed while patients are being treated and the patient experience can therefore be observed.</p>	
<p><b>33. All centres should be subject to a full inspection each year until the HFEA has developed and validated a robust risk based assessment methodology, in order to determine those centres which are suitable for a more targeted inspection regime.</b></p> <ul style="list-style-type: none"> <li>• All centres receive an inspection each year which covers the essential core standards. In addition, centres are subject to unannounced inspections. Furthermore, information is gathered to inform those centres requiring a closer scrutiny. A risk matrix is under development and being piloted.</li> </ul> <p><b>34. The Authority should in consultation with External Specialist Inspectors review the time required to carry out comprehensive interim and full inspections.</b></p> <ul style="list-style-type: none"> <li>• The HFEA is working with inspectors on ongoing improvements in inspection and time requirements are reviewed regularly. The recruitment of a clinical inspector full-time in the HFEA to further assess needs of inspection in different settings/context.</li> </ul>	<p>In place since September 2003</p> <p>Ongoing</p>
<p><b>35. The review should take into account the best practice models that have become available since the setting up of the HFEA.</b></p> <ul style="list-style-type: none"> <li>• Other models of inspection are constantly reviewed. A learning set for regulators was established by the HFEA Chair and Chief Executive to inform this learning process and there are regular partnership meetings with other health regulators to allow ongoing sharing of best practice.</li> </ul>	<p>In place since March 2003</p>
<p><b>36. The Authority should ensure that the time allowed for all inspections is sufficient to allow ESIs to observe directly a centre's personnel performing their duties.</b></p> <ul style="list-style-type: none"> <li>• Time required is monitored through the ongoing feedback from ESIs.</li> <li>• Direct observation of duties is carried out at unannounced inspections and incident investigations.</li> </ul>	<p>In place since March 2003 and ongoing</p> <p>In place</p>
<p><b>37. The Authority should adopt the recommendations made in this report about formal training and development. This will help ensure that ESIs use a consistent approach in the application of the HFE Act and Code of Practice to ACSs.</b></p>	<p>In place since March 2003</p>

<ul style="list-style-type: none"> <li>Recommendation previously implemented through the HFEA's modernisation programme. See previous comments on training and development on Recommendation 23 and 24.</li> </ul>	
<p><b>38. The Authority should ensure that all centres are informed well in advance of the ESIs who will undertake the inspection at their centre and declare where they believe there is a conflict of interest.</b></p> <p><b>39. The Authority should ensure that all ESIs are informed well in advance of the names of the personnel at the centre they are to inspect and declare where they have an interest.</b></p> <ul style="list-style-type: none"> <li>Inspections are fixed on average four months in advance and both ESIs and centres are informed of the details of personnel in order to give adequate opportunity to note any potential or perceived conflict of interest.</li> <li>In addition, the recruitment of HFEA full time inspector will assist with independent inspection.</li> </ul>	<p>In place from 2003</p> <p>In place since April 2003</p>
<p><b>40. The Authority should reconsider the role of members on inspections and whether they should continue to have a formal role in the inspection of centres.</b></p> <ul style="list-style-type: none"> <li>Members of the Authority have not been part of inspections since October 2002 as a result of the modernisation programme.</li> </ul>	<p>In place since October 2002</p>
<p><b>41. The Authority should, in consultation with the relevant professional bodies, amend the Code of Practice so that it clearly articulates the relationship between the legal requirements of the HFE Act, guidance on compliance with the Act and advice on good practice.</b></p> <ul style="list-style-type: none"> <li>The 6<sup>th</sup> Code of Practice published in January 2004 states clearly the sections of the Act in relation to specific standards. It also spells out on each section the difference between recommended good practice and legal requirement.</li> <li>In addition, a full consultation enabled comments to be made on the level of clarity and any ambiguity to be addressed.</li> </ul>	<p>In place since January 2004</p>
<p><b>42. The Authority should consider seeking professional assistance with the rewriting of the code of Practice to make it clear to centres and to the public The Code of Practice should also make clear what the minimum requirements are where the Act uses words such as "suitable".</b></p> <ul style="list-style-type: none"> <li>Legal advice was sought to ensure accurate and clear language in the 6th Code of Practice. Public</li> </ul>	<p>In place since January 2004</p>

<p>consultation ensured clarity as perceived by the reader, including clinics, patient groups and professional bodies. It also ensured centres were clear about minimum requirements.</p>	
<p><b>43. The Code of Practice should make clear the criteria for those events that must be reported to the Authority without delay and those for which immediate reporting is not required</b></p> <p><b>44. The Authority should also ensure that all centres whether private or NHS, have protocols in place to deal with adverse events including a clear procedure for reporting within the organisation and to the HFEA where appropriate.</b></p> <ul style="list-style-type: none"> <li>• The Code of Practice, published in January 2004, makes clear the need for immediate reporting and ensures centres have their own protocol for managing adverse events. The HFEA has a policy in terms of reporting and investigation which is highlighted to all centres.</li> <li>• Centres own procedures are checked at inspection.</li> </ul>	<p>Policy in place November 2003</p> <p>Code confirmed policy January 2004</p>
<p><b>45. The Authority should ensure that only nominated members of the Executive, who have undertaken and are subject to formally structured programmes of training, such as those recommended for ICs, provide advice and information to centres and the public.</b></p> <ul style="list-style-type: none"> <li>• Formal training is provided to all regulation staff who communicate with centres or public.</li> <li>• In addition the HFEA's website has been updated and redesigned to enable consistent and timely response to queries from centres and public.</li> </ul>	<p>In place since June 2003</p>
<p><b>46. The Authority should immediately undertake a review of its adverse event procedures and systems. The review should produce clear guidance on how an adverse event is to be recorded and investigated and how the lessons learned are to be disseminated by the HFEA. The HFEA should also provide clear guidance as to how the implementation of such guidance is to be monitored.</b></p> <ul style="list-style-type: none"> <li>• The HFEA produced revised policies and procedures in October 2003. These ensure the reporting, investigation and recording of events to a standard protocol.</li> <li>• The HFEA also instituted an Alert system in 2003, whereby all adverse events are anonymously reported to all UK clinics with recommendations for actions to reduce the chance of a re-occurrence.</li> </ul>	<p>In place since October 2003</p>
<p><b>47. The Authority should in consultation with the relevant professional bodies seek to develop</b></p>	<p>In place since</p>

<p><b>comprehensive standardised protocols for all stages of ACSs treatments in conjunction with a training programme and a protocol monitoring system.</b></p> <ul style="list-style-type: none"> <li>• The HFEA supports the recommendation for standard procedures and have led their development in conjunction with ACE, BFS and BAS.</li> </ul> <p><b>48.The HFEA should introduce “active” witnessing to centres rather than “passive” system currently in use. i.e Each person involved should take an active role in identifying the patients and their gametes for each witness would take it in turn to read out the patient’s details and the other person would confirm or refute them.</b></p> <ul style="list-style-type: none"> <li>• Introduced double witnessing 2002.</li> <li>• The need for unique patient identifying at all stages of laboratory processes has been further highlighted to centres by Chair’s letter and this is monitored at inspections.</li> </ul> <p><b>49.The Authority should, in consultation with the relevant professional bodies, investigate the possible use of Patient Identification Bar code technology in ACS settings</b></p> <ul style="list-style-type: none"> <li>• Work on other risk reduction measures has been launched through a working party evaluating the principles of bar coding systems, other technologies and their application to laboratory safety, and of risk identification/human error systems.</li> </ul> <p><b>50.The Authority should, in consultation with the relevant professional bodies, investigate the possibility of using human reliability techniques to identify the potential for human errors to be made in ACS settings.</b></p> <p>(See above.)</p> <p><b>51.The Authority should seek to identify and form relationships with institutions that are concerned to investigate and learn from adverse events, such as the National Patient Safety Agency</b></p> <ul style="list-style-type: none"> <li>• Regular and ongoing work with the National Patient Safety Agency has been in place since 2003.</li> </ul>	<p>January 2003 and ongoing</p> <p>Recommendations 49 – 51: Working party in place to report by end 2004</p>
<p><b>52.The Authority should undertake a review of its document storage and retrieval policy and systems</b></p> <ul style="list-style-type: none"> <li>• The HFEA’s modernisation programme includes a review of document management and electronic</li> </ul>	<p>In place since 2003 and ongoing</p>

<p>document management is being implemented.</p> <ul style="list-style-type: none"> <li>• Systems have been in place since 2003 to ensure all incidents are recorded centrally.</li> <li>• A centres database was set up in 2003 which enables a computerised central framework for all relevant information.</li> </ul>	
<p><b>53.The Authority should in consultation with the appropriate professional bodies, develop minimum criteria against which an ICSI practitioner’s performance can be evaluated for licensing purposes.</b></p> <ul style="list-style-type: none"> <li>• HFEA inspectors with the necessary experience assess proposed ICSI practitioners against set standards and their findings are taken to formal Licence Committee.</li> <li>• Outcomes from clinic’s ICSI are routinely and regularly monitored.</li> </ul>	<p>In place 2003</p> <p>In place since 1997</p>
<p><b>54.The Authority should introduce a formal programme of consultation with all the appropriate professional bodies to discuss areas of mutual interest and concern.</b></p> <ul style="list-style-type: none"> <li>• Regular meetings and consultations take place with all major professional bodies including ACE, BFS, and BICA and joint work is undertaken on new policies, procedures and training.</li> </ul>	<p>In place since January 2003</p>
<p><b>55.The Authority should ensure a robust formal risk management system is developed and introduced as soon as possible The identification and reporting of potential risks to management should be a feature of every member of staff’s job description.</b></p> <ul style="list-style-type: none"> <li>• A risk register has been in place since March 2003, and there is an internal risk committee including members of staff at all levels. This ensures regular monitoring of the register and plans to mitigate risk, and awareness of all staff. In addition, the Risk Register is regularly monitored and reviewed in the Authority and its standing committees.</li> </ul>	<p>In place since March 2003</p>
<p><b>56. The Authority should seek to promote a risk aware culture throughout the HFEA</b></p> <ul style="list-style-type: none"> <li>• Risk awareness is developed (see above) through a variety of means including staff at all levels and in all functions of the Authority.</li> </ul>	<p>In place since March 2003</p>
<p><b>57.DH recommendation</b></p>	

<p><b>58. DH recommendation</b></p> <p><b>59. DH recommendation</b></p>	
<p><b>60. The Department and the Authority should review funding at least annually, based on the Authority's business and corporate plans, to ensure that the Authority's requirements are fully considered in the light of developments in assisted conception services themselves, as well as in risk management procedures.</b></p> <ul style="list-style-type: none"> <li>The issue of Annual Review Funding is particularly important and should take into account developments such as research regulation, NICE, accreditation and the European Tissue Directive. Arrangements are in place for Annual Review of funding with DH.</li> </ul>	<p>In place since January 2002</p>
<p><b>61. The Authority should develop and introduce, following consultation with the appropriate bodies, a formal induction and CPD programme to ensure that PRs are competent to carry out the role and are up to date with the latest developments in ACSs. Attendance at these events should be mandatory to ensure that centres work as effectively as possible.</b></p> <ul style="list-style-type: none"> <li>Since 2003 yearly training has been provided to PRs in conjunction with the professional bodies.</li> <li>From 2004, mandatory training is also to be provided for both PRs and Nominal Licensees to attend.</li> <li>Plans for formal induction for PRs and Nominal Licensees to be introduced in Autumn 2004.</li> </ul>	<p>In place since January 2003 and ongoing</p>
<p><b>62. The Authority should develop and introduce, following consultation with the appropriate professional bodies, a formal assessment of PRs to ensure that they are proficient in their role and are up to date with the latest developments in their respective fields.</b></p> <ul style="list-style-type: none"> <li>All PRs will from Autumn 2004 be assessed when they apply by CV and interview. In addition, yearly inspections include an evaluation of the PR.</li> </ul>	<p>In place from Autumn 2004</p>
<p><b>63. The Authority should make it a condition of granting a licence that a member of the senior management team of the organisation concerned be nominated as the Nominal Licensee or is otherwise closely engaged in the work or management of the centre.</b></p> <ul style="list-style-type: none"> <li>NHS centres are expected to appoint a member of senior management team as Nominal Licensee.</li> </ul>	<p>In place 2003</p>

<ul style="list-style-type: none"> <li>• The CMO letter of 2003 sent to all NHS organisations supported this.</li> <li>• Small single handed private organisations are encouraged to find alternative Nominal Licensees.</li> <li>• Since December 2003 122 licences out of 133 have a separate Nominal Licensee.</li> </ul>	
<p><b>64. The Authority should require all centres to have a robust risk management system in place. The identification and reporting of potential risks to PRs in centres should be a feature of every member of the staff's job description.</b></p> <ul style="list-style-type: none"> <li>• Job descriptions matter for professional bodies and employers.</li> </ul> <p><b>65. The Authority should seek to promote a risk aware culture throughout all centres.</b></p> <ul style="list-style-type: none"> <li>• The recommendation is accepted and actions in place to ensure it is met in full.</li> <li>• Training for PRs is now concentrating on risk awareness and management.</li> <li>• Annual conferences, site visits, the ALERT system, and inspections all contribute to and create a risk aware culture, focusing on knowledge of and mitigation of risk.</li> <li>• 2004 seminars planned to support all centres in implementing a risk register locally.</li> </ul>	<p>In place since January 2003 and ongoing</p>
<p><b>66. The Authority should require all embryologists who work unsupervised in either NHS or private practice to be state registered with the Health Professions Council as Clinical Scientists (Embryology). Embryologists who are not registered should be allowed to practise only when supervised by a state registered embryologist.</b></p> <ul style="list-style-type: none"> <li>• The 6<sup>th</sup> Code of Practice requires all centres to employ state registered embryologists or those working towards registration.</li> <li>• In addition work is underway to establish registration for other laboratory staff working in the field of IVF.</li> </ul>	<p>In place since January 2004</p>
<p><b><u>Chapter 9</u></b></p>	
<p>Recommendations relating to LGI and SJH</p>	

<p><b>67. The HFEA should inspect both centres to ascertain if the facilities at the two centres are in breach of the HFE Act and Code of Practice.</b></p> <ul style="list-style-type: none"> <li>This recommendation is accepted and met. All centres are inspected and compliance with the HFE Act and Code of Practice is assessed.</li> </ul>	<p>In place since January 2003</p>
<p><b>68 Recommendation for the Trust</b>  <b>70 Recommendation for the Trust</b>  <b>71 Recommendation for the Trust</b>  <b>72 Recommendation for to the Trust.</b></p>	
<p><b>69. The Authority should, following consultation with the appropriate professional bodies, provide clear guidance on how section 17(1), of the HFE Act should be interpreted with regard to the discharge of a PR's duties.</b></p> <ul style="list-style-type: none"> <li>The Authority has provided training since 2003 to support PRs with their interpretation, understanding and knowledge of the HFE Act and the Code of Practice and their duties/responsibilities. In addition, the CMO's letter (2003) drew this to the attention of all NHS organisations.</li> </ul>	<p>In place since January 2003</p>
<p><b>73. As set out in recommendation 64, the Authority should require all centres to have a robust risk management system in place. The identification and reporting of potential risks to Persons Responsible in centres should be a feature of every member of staff's job description.</b></p> <p>(See Recommendation 64.)</p> <p><b>74. As set out in recommendation 65, the Authority should seek to promote a risk aware culture throughout all centres.</b></p> <ul style="list-style-type: none"> <li>In place through inspection and ongoing working programme with clinics.</li> </ul>	
<p><b><u>Chapter 10 recommendations – LGI</u></b></p>	
<p><b>75 – 80, 83 Recommendations for the Trust</b></p> <p><b>81. As set out in recommendation 50, the Authority should investigate in consultation with the relevant professional bodies, the possibility of using human reliability techniques to identify the</b></p>	<p>See Recommendation</p>

potential for human errors to be made in assisted conception services settings.	50
<b>82. As set out in recommendation 49, the use of Patient Identification Bar Code technology should be explored.</b>	See Recommendation 49
<b><u>Chapter 11 recommendations - LGI</u></b>	
<p><b>84. The HFEA should inspect the centre to review the facilities and the volume of patients being treated to ascertain whether or not the centre's licences need to be varied.</b></p> <ul style="list-style-type: none"> <li>• This recommendation is met in full. All centres are inspected annually and the volume and complexity of patients being treated is considered as part of the evaluation process.</li> <li>• Where there are concerns over accommodation or staffing, for example, centres have their licences varied to reduce throughput.</li> </ul>	In place since 2003
<p><b>85-87 (3) Recommendation for Trust to carry out</b></p> <p><b>88. The use of Patient identification Bar Code technology should be explored as set out in Recommendation 49</b></p>	See Recommendation 51
<p><b>89. The HFEA should in consultation with the appropriate professional bodies, consider guidelines about embryologists' (and other staff's) workloads.</b></p> <ul style="list-style-type: none"> <li>• Work is underway with ACE to review the recommended workloads of embryologists.</li> <li>• In addition, workloads are considered when centres are inspected, and where the workload is considered a risk factor, licence conditions are imposed limiting the number of cycles the clinic can offer each year.</li> </ul>	Underway for report by end 2004
<p><b>90. The HFEA should, in consultation with the appropriate professional bodies, determine what the timescale should be for the replacement or recruitment of an embryologist before the patient number must be reduced to match the resources then available.</b></p> <ul style="list-style-type: none"> <li>• This Recommendation is met through the routine consideration of workload and manpower within the inspection and licensing process (see above).</li> <li>• Regular meetings with professional bodies discuss issues of reasonable timescales for recruitment</li> </ul>	In place for report by Spring 2005

and other actions for compliance.	
<p><b>91. The HFEA should undertake a robust but proportionate investigation of any serious adverse events as soon as it is reported.</b></p> <ul style="list-style-type: none"> <li>The HFEA has met this Recommendation since July 2003. The 6<sup>th</sup> Code of Practice states a clear requirement for centres to report adverse incidents within 12 hours. The HFEA's policy on adverse incidents states clear timely targets for investigation.</li> <li>In addition, the ALERT process ensures following investigation that reports are issued to all centres on the outcome and recommendations to minimise the chance of reoccurrence.</li> </ul>	In place since July 2003
<p><b>92. All centres should be subject to a full inspection each year.</b></p> <ul style="list-style-type: none"> <li>The HFEA inspects all centres each year. The interim inspection process has been revised and includes external inspectors and a thorough inspection of basic standards included in the Act and Code of Practice.</li> <li>The HFEA considers the use of risk indicators and varying levels of inspection to be appropriate and in line with best practice in Regulation as defined by Better Regulation Taskforce.</li> </ul>	In place since 2003
<b><u>Chapter 12 recommendations – SJH centre</u></b>	
<b>93 - 98 Recommendations relate to the Trust.</b>	
<p><b>99. The HFEA should implement the recommendation made in Chapter 8 regarding the COP making clear those adverse events that should be reported immediately and those where a later report is acceptable.</b></p> <ul style="list-style-type: none"> <li>This Recommendation is met in full. A clear policy is in place and the 6<sup>th</sup> Code of Practice states the criteria for immediate reporting of adverse events. (see Recommendation in Chapter 8)</li> </ul>	In place since October 2003 (policy) and since January 2004 within Code of Practice
<b><u>Chapter 13 recommendations – LGI centre</u></b>	
<b>100 - 102 (3) recommendations relate to Trust</b>	

<p><b>103. The Authority should require all centres to develop and introduce a formal induction training and assessment programme to ensure that embryologists recruited from one to another centre are familiar with all local working practices before they are allowed to work unsupervised.</b></p> <ul style="list-style-type: none"><li>• The Authority accepts the need for local induction and assessment of newly recruited staff. It believes all centres are responsible for ensuring this takes place and that staff are familiar with local working practices and standard operating procedures. Information required at inspection can monitor this process.</li></ul>	<p>In place through monitoring at inspections</p>
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