Audit & Governance Committee meeting - agenda

9 December 2015

etc.venues, Tenter House, 45 Moorfields, London EC2Y 9AE

Agenda item		Time
1.	Welcome, apologies and declaration of interests	10:00am
2.	Minutes of 7 October 2015 **[AGC (09/12/2015) 475]**	
3.	Matters Arising **[AGC (09/12/2015) 476 SG]**	
4.	Register & Compliance Risks (Presentation)	
5.	Information for Quality (IfQ) Programme – Managing Risks **[AGC (09/12/2015) 477 NJ]**	
6.	Strategic Risks **[AGC (09/12/2015) 478 PR]**	
7.	Internal Audit a) 2015/16 plan and progress report **[AGC (09/12/2015) 479 DH Internal Audit]** b) Final Report – Incident handling **[AGC (09/12/2015) 480 DH Internal Audit]** c) Final Report – Requests for Information **[AGC (09/12/2015) 481 DH Internal Audit]**	
8.	External Audit – Update (Oral)	
9.	Implementation of Recommendations – Progress Report **[AGC (09/12/2015) 482 WEC]**	
10.	Resilience & Business Continuity Management (Presentation)	
11.	Review of AGC activities & effectiveness **[AGC (09/12/2015) 483 SK]**	

12.	Licensing Appeals: an evaluation **[AGC (09/12/2015) 484 PT]**	
13.	AGC Forward Plan **[AGC (09/12/2015) 485 SG]**	
14.	Any other business	
15.	Close (Refreshments & Lunch provided)	1:00pm
16.	Session for members and auditors only	1:00pm
17.	Next Meeting 10am Wednesday, 16 March 2016, London	

Minutes of Audit and Governance Committee meeting 7 October 2015

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☐ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	2		
Paper number	AGC (09/12/2015) 475		
Meeting date	9 December 2015		
Author	Dee Knoyle, Committee Secretary		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☐ Medium	☐ High
Annexes			

Minutes of Audit and Governance Committee meeting on 7 October 2015 held at etc.venues, Tenter House, 45 Moorfields, London EC2Y 9AE

Members present	Rebekah Dundas (Chair) Margaret Gilmore Jerry Page
Apologies	Gill Laver
External advisers	Internal Audit Lynn Yallop, Price Waterhouse Coopers (PWC) National Audit Office (NAO) George Smiles Sarah Edwards
Observers	Steve Pugh (Department of Health)
Staff in attendance	Sue Gallone, Director of Finance & Resources Juliet Tizzard, Director of Strategy & Corporate Affairs Nick Jones, Director of Compliance & Information Paula Robinson, Head of Business Planning David Moysen, Head of IT Wilhelmina Crown, Finance & Accounting Manager Sam Hartley, Head of Governance & Licensing Patrick Winters, Information for Quality Programme Support Officer Dee Knoyle, Committee Officer

Members

There were 3 members at the meeting.

1. Welcome, apologies and declarations of interests

1.1 The Chair welcomed attendees to the meeting.

1.2 There were apologies from Gill Laver.

1.3 There were no declarations of interest.

2. Minutes of the meeting held on 10 June 2015

2.1 The minutes of the meeting held on 10 June 2015 were agreed as a true record of the meeting and approved for signature by the Chair.

3. Matters arising

3.1 The committee noted the matters arising, in particular:

3.2 Plans to introduce a formal report on the Audit and Governance Committee's activities is on target for July 2016.

3.3 A report on the Appeals process will be submitted to the Audit and Governance Committee in December 2015.

3.4 The number of Audit and Governance Committee meetings per year will be reviewed in March 2016.

4. Strategy & Corporate Affairs Management

4.1 The committee received a presentation and briefing from the Director of Strategy & Corporate Affairs. The Strategy & Corporate Affairs directorate is made up of four departments: Governance and Licensing, Business Planning, Policy and Communications. The directorate has a £1.6 million budget, most of which is spent on the salaries of its 22 staff.

4.2 The director set out how the directorate is contributing to the delivery of the HFEA strategy.

4.3 Since the last time the director presented to the committee, the following risks have reduced:

- Stakeholder relations: The committee noted that the executive had received positive feedback from the Triennial Review for their implementation of the McCracken recommendations to improve stakeholder engagement.
- Licensing and governance: The capacity issues faced in 2014 have reduced, despite the recent appeal hearing. The processes in place minimise risk. There is a lower risk around Authority membership now members are in place.

4.4 Risks remain in:

- Handling PQs and FOI requests because the HFEA is a small organisation and they can be complex
- Communications as there are resource pressures caused by website redevelopment

4.5 The committee noted that staff are aware of the cost ceiling when responding to FOI requests, although there is a tendency to be overgenerous in providing information.

5. Regulatory Issues

5.1 The committee received an update from the Director of Compliance & Information about legal parenthood issues that have arisen, how the HFEA has dealt with these and the lessons learned.

5.2 The background was that the law was changed in 2009 to allow unmarried partners of women having treatment with donor sperm to become the legal parent at birth, where appropriate consent had been obtained together with the offer of counselling. Following an inspection in 2013 and further work undertaken by the Executive and clinics (including their audit of all cases) errors in legal parenthood consent forms were identified. The remedy in place is for the people involved to seek a declaration of parenthood from a court – without it they would not be the legal parent of their child, having a lifelong effect on the families involved e.g. parental responsibilities, financial responsibilities and inheritance.

5.3 Several cases were considered together by the the Family Division of the High Court, and in September 2015 the President of the Family Division, Sir James Munby, handed down a judgment (granting parenthood to seven of the affected families) which was highly critical of the clinics involved, and of the HFEA to some extent.

5.4 When the law changed, the HFEA provided guidance and the necessary consent forms to clinics, held workshops and made this a theme of inspections, to promote compliance with the requirements. When it was clear there were some issues, the HFEA required clinics to audit their records and reporting the results to the HFEA. The HFEA is monitoring the action clinics are taking on the issues identified, including ensuring that patients affected are contacted and offered the support and advice that they need.

5.5 A 'Clinic Focus' newsletter was recently sent to clinics conveying the message 'we all need to do more' referencing the judgment and the steps henceforth to be taken by the HFEA in responding to the issue. The HFEA is acting to protect the interests of affected couples in line with the HFEA strategy.

5.6 Where clinics have declared no anomalies, the HFEA is seeking assurance from each clinic's Person Responsible that their audit was robust; and that processes and procedures for gathering appropriate consents are in place such that cases will not arise in the future. Inspections are also checking that the consent processes in clinics are correct and that staff are properly trained.

5.7 The executive is reviewing the actions taken, including reviewing inspection methodology, consent forms and guidance, alongside the Judge's recommendations, to minimise future risks.

5.8 The committee welcomed this clear and open report which will ensure any opportunities for learning are taken. In particular members:

- Felt that the HFEA had responded well, balancing our concern for patients with appropriate regulatory action;
- discussed whether the HFEA has sufficient powers, concluding that is does;
- felt that appropriate action had been taken to date, and asked to be updated on developments, as appropriate.
- highlighted the hidden issues that may emerge as a result of patients using unregulated services, but recognised that patients using licensed services had a reasonable expectation of much higher standards of care.

6. Information for Quality (IfQ)

6.1 The committee received a progress report from the Director of Compliance & Information.

6.2 The programme is proceeding well with the suppliers Reading Room Ltd and Informed Solutions having been selected. Work has started on the HFEA website and Clinic Portal design, working towards 'Alpha' stage to be delivered by November 2015, ready for approval. The committee was reminded that the approvals process has previously resulted in delays, and the team has worked hard to streamline this area.

6.3 Internal systems developments are now being delivered using existing resource, supplemented by external resource where necessary.

6.4 The Register and IT teams are currently working on data migration cleansing. The committee noted that data migration is the biggest risk.

6.5 The programme's ambition for what it wants to deliver, and the budget available, means resources for the programme remain tight. More detailed planning has been undertaken to ensure an affordable costed plan.

6.6 The committee noted the timeline and that the HFEA website, Choose a fertility Clinic (CaFC) and the Clinic Portal are due to be completed by February 2016, with full data submission functionality available to clinics in October 2016, and for those clinics with third party patient record systems by April 2017. The timeline is dependent on data migration and, while there is an imperative to deliver as quickly as possible, there are no external time pressures.

6.7 The committee noted that IfQ is a transformation programme (more than an IT project) and that the budget will need to be managed carefully. They welcomed the planned launch of the Beta site at the HFEA conference in February 2016. The committee noted the IfQ programme will be subject to a further Gateway Review, probably in early 2016.

7. Cyber Security

7.1 The committee was provided with a paper and briefing by the Head of IT.

7.2 A map of current cyber attack sources and targets was displayed. The HFEA aims to prevent attack by using the Government's guidance ten steps to cyber security.

7.3 Current internal systems are assessed weekly for vulnerability to cyber attacks, and actions taken, as well as spot check penetration testing from time to time. The next penetration test is planned after the office move.

7.4 In moving towards more web-based products, the organisation is aware of threats to its data, in particular the Register. Web-based services will be subject to assessment by the Department of Health. The committee was satisfied that Government guidance is being adhered to when considering web-based systems and services.

7.5 Staff only have access to the information required for business use. Staff are trained and are very aware of information security. Encrypted devices are used to carry data and strict policies apply to homeworking.

7.6 The committee noted the threat of potential internal sabotage and cyber attacks from outside the organisation and were satisfied that good systems were in place to mitigate and control any possible attacks. The committee also noted the limitations in keeping information safe from internal sabotage and agreed that preventative measures should be taken to avoid such conduct. The committee noted the importance of removing access to information when staff leave.

8. Strategic risks

8.1 The committee was provided with a paper and briefing from the Head of Business Planning.

8.2 The Business Planning team maintains an operational risk log as well as a strategic risk register and risks are routinely reviewed by management.

8.3 Some internal work has started on risk assurance mapping and workshops are planned to focus on priority areas, led by the internal auditors, Price Waterhouse Coopers (PWC).

8.4 People management and resources was noted to have the highest number of operational risks across the organisation. This area will be prioritised for assurance mapping in quarter four, with performance and risk management being the next area for review.

8.5 There had been little change in severity of strategic risks. Another legal challenge has emerged since the papers were drafted for the committee. The committee acknowledged that the risk register is a live document and expect a number of changes to be made between meetings.

8.6 The committee welcomed the new format for presenting risk levels and their tolerance levels. Tolerance levels set were thought to be appropriate.

8.7 The IfQ programme is a thread that runs through other risks across the organisation, as the risk register is based on the HFEA strategy and the IfQ programme will deliver the strategy. The committee heard that IfQ risks feature in the IfQ programme risk register and a highlight report is presented with slides to the Corporate Management Group on a monthly basis.

8.8 The committee asked about financial pressures on the organisation. The HFEA has been excluded from the spending review requirements, but is expected to make further efficiencies where possible.

9. Internal Audit

9.1 The committee was provided with a progress report by the Head of Internal Audit.

9.2 The requests for information audit fieldwork has been completed and there were no major concerns. The draft recommendations will be reviewed to ensure they are proportionate.

9.3 The fieldwork has also been completed for incident handling and a report is being prepared.

9.4 A file note had been provided following audit activity on IfQ. Time is also planned in to review data migration.

9.5 Actions on all high priority recommendations had been reviewed and were now signed off.

9.6 The committee agreed the allocation of time to audits for the remainder of the year. The plan for next year will be considered when the arrangements for internal audit from April 2016 are known.

10. External audit

10.1 The committee was provided with the audit planning report (APR) by the NAO.

10.2 The timetable for the interim and final audits had been agreed by the executive.

10.3 While IfQ is a key business risk for the HFEA, accounting for IfQ programme expenditure will be a key part of the audit.

10.4 NAO hope to place more reliance on the HFEA's review of management accounts this year. The audit fee has been held at the same level - if any significant savings are made these will be passed on to the HFEA.

10.5 The HFEA should consider the guidance in the Annexes to the APR when presenting the financial reports.

10.6 The committee agreed the APR.

10.7 The committee noted that the final audit is taking place later than this year and therefore the planned date for the AGC meeting in June will need to be moved, possibly to the following week.

Action

10.8 Director of Finance & Resources to check the date of the final audit and agree a date for the AGC meeting in June 2016.

11. Implementations of recommendations progress report

11.1 The Finance Manager provided the committee with an update.

11.2 All outstanding recommendations have been completed. The committee thanked the executive for the good progress and noted the new improved format of the report.

12. Reserves policy

12.1 The committee received the draft Reserves Policy for approval and a briefing was given by the Director of Finance and Resources.

12.2 Minor changes had been made to the reserves policy, and the minimum reserves required had reduced slightly. The executive confirmed that this level of reserves was sufficient, unless a major legal case were to arise.

12.3 The committee approved the changes to the reserves policy and the revised minimum level of reserves will be agreed with the Department of Health.

13. Forward plan

13.1 The committee reviewed the Forward Plan of meetings.

13.2 Anita Bharucha, Authority Member, will become a member of the Audit and Governance Committee and will be attending the meeting in December. The committee will therefore have a total of 5 members, which will aid quoracy of three.

13.3 An update on the spending review and the office move will be provided at the next Audit and Governance Committee meeting.

14. Any other business

14.1 The Director of Finance & Resources confirmed the following:

- There were no whistleblowing or suspected fraud incidents reported since the last meeting.
- No other contracts had been awarded since the last meeting, other than those awarded to Reading Room Ltd and Informed Solutions for IfQ work, as reported earlier.

14.2 Members and auditors retired for their confidential session.

14.3 The next meeting will be held on Wednesday, 9 December 2015 at 10am.

15. Chair's signature

15.1 I confirm this is a true and accurate record of the meeting.

Signature

Name

Rebekah Dundas

Date

9 December 2015

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	**[AGC (09/10/2015) 476]**
Meeting Date:	9 December 2015
Agenda Item:	**3**
Author:	Sue Gallone
For information or decision?	Information
Recommendation to the Committee:	To note and comment on the updates shown for each item.
Evaluation	To be updated and reviewed at each AGC.

Numerically:

- 1 items added from October 2015 meeting, completed.
- 3 items carried over from earlier meetings, 0 completed.
- 4 items carried over from AGC self–assessment of performance,1completed.

Matters Arising from Audit and Governance Committee – actions from 11 June 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
3.2 HFEA to monitor Authority members' completion of online information governance training	Executive Assistant to Chair and Chief Executive	20 September 2014	**Ongoing** - being monitored by Executive Assistant. All Members completed the training and new Members are being reminded to undertake it.

Matters Arising from Audit and Governance Committee review of performance December 2014			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
e) Arrange for external members to attend Authority meeting as observers	Head of Governance & Licensing	September 2015	**Ongoing** – members invited to meetings, suitable dates to be agreed.
f) Arrange for external members to observe an inspection	Head of Governance & Licensing	September 2015	**Ongoing** – Inspectorate's business support team in contact with external members and attempting to find suitable dates.
i) Institute formal annual report to Authority board	Head of Governance & Licensing	July 2015	**Ongoing** – plan to formally report to July Authority meeting each year. Draft report to be agreed by Chair remotely. To be introduced for July 2016.
j) Give thought to improving communication from external appeals committees to AGC/Authority board, while maintaining independence of those committees.	Head of Governance & Licensing	October 2015	**Completed** – item 12 of agenda.

Matters Arising from Audit and Governance Committee – actions from 10 June 2015 meeting

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
9.6 Report progress on actions from the information governance group to AGC	Director of Finance and Resources	December 2015 March 2016	**Ongoing** – progress to be reported at meeting
12.7 Discuss number of AGC meetings at March 2016 meeting	AGC members	March 2016	**Ongoing**

Matters Arising from Audit and Governance Committee – actions from 7 October 2015 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
Check the date of the final audit and agree a date for the AGC meeting in June 2016	Director of Finance and Resources	December 2015	**Completed** – date agreed as 15 June 2016

Information for Quality Programme (IfQ) – Managing Risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	5		
Paper number	[AGC (09/12/2015) 477 NJ]		
Meeting date	9 December 2015		
Author	Nick Jones, Director of Compliance and Information		
Output:			
For information or decision?	For information		
Recommendation	The Committee is asked to note this update		
Resource implications	None as regards this update; Programme resource position set out in paper.		
Implementation date	In Progress		
Communication(s)	Extensive stakeholder communication		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	1. GDS 18 Standards 2. Website / CaFC Project – DH Assessment Recommendations 3. Clinic Portal Project – DH Assessment Recommendations		

1. Introduction

1.1. The Information for Quality (IfQ) Programme encompasses:

- The redesign of our website and Choose a Fertility Clinic (CaFC) function.
- The redesign of the 'Clinic Portal' (used for interacting with clinics) and combining it with data submission functionality that is currently provided in our separate EDI (Electronic Data Interchange) system (used by clinics to submit treatment data to the HFEA)
- A revised dataset and data dictionary which will be approved by the Standardisation Committee for Care Information (SCCI)
- A revised Register of treatments, which will include the migration of historical data contained within the existing Register
- The redesign of our main internal systems that comprise the Authority's Register and supporting IT processes.

1.2. This report updates the Audit & Governance Committee (AGC) on the progress of the Information for Quality (IfQ) programme, specifically in the areas covered by the AGC terms of reference.

2. Progress update

2.1. The IfQ Programme continues to make good progress since last update to AGC, achieving a significant milestone with the completion of the 'Alpha' phase. The IfQ Programme is now transitioning to Beta phase, in which the proof-of-concept work completed during Alpha will be iteratively built upon to produce a functioning 'beta' version of IfQ's 'minimum viable product.'

2.2. The Website and CaFC, and Clinic Portal projects have now concluded initial 'proof-of-concept' clickable wireframe and design prototypes for a range of key pages. These pages have been user tested, with the results currently being considered - within the context of the HFEA's strategic priorities - in order to refine the deliverables to be produced during the IfQ Programme's Beta phase.

2.3. Good progress continues to be made in the 'Internal Systems' work, the foundations or technical architecture. Additional specialist resources to our in-house team are in place as planned.

2.4. The work on register data cleansing continues, with the Register and IT teams making good progress on identifying and cleansing records. Test register data has now been successfully extracted from the current register database structure to the new database structure, an important proof of concept stage of the data migration strategy.

3. Approval to proceed and expenditure for Beta

3.1. As advised in the last IfQ update to AGC, the IfQ business case and associated digital expenditure controls for IfQ were conditionally approved by the Department of Health (DH) and the Cabinet Office's Government Digital Service (GDS) on 28 April 2015.

3.2. For digital expenditure (covering the front facing aspects of the Website, CaFC and Clinic Portal), DH and GDS granted conditional approval for £180,000 expenditure for the Alpha Programme phase only. As previously advised, expenditure beyond Alpha phase required a subsequent formal DH led approval process.

3.3. The first stage of this approval process has been met, with the IfQ Programme being granted approval to proceed by DH on the basis of a very positive assessment of the proof-of-concept deliverables from Alpha phase. This assessment comprised a thorough review of the IfQ's Alpha phase deliverables against the 18 Government Digital Service Standards, which can be found at Annex 1, for members' interest.

3.4. As with any assessment several recommendations have been made by DH, which we must consider during Beta phase. These can be found at Annex 2 and 3[1]. Receiving DH endorsement in this approval phase is a significant achievement that underscores the quality and viability of work produced during Alpha. The team put in considerable work and received management team's gratitude.

3.5. There is another approval stage. The Cabinet Office's Government Digital Service (GDS) must now approve Beta *expenditure* of c £290,000, in the light of DH's decision that IfQ has met their assessment criteria. This second stage approval from GDS is expected to follow within the next four weeks.

3.6. In view of the risk attached to delaying the commencement of Beta, the IfQ Programme Board has taken the decision to proceed 'at-risk' to Beta phase in advance of GDS final stage approval. With the alternative being to stop work, and having passed the rigorous DH assessment during the first phase of this approval, the IfQ Programme Board's view is that this is the appropriate approach.

[1] Please note in relation to Annex 2: HFEA are discussing with DH, regarding *user needs and assisted digital* recommendation 2 be amended to note the HFEA will be providing patient ratings and not actually free text or similar commenting feature.

4. Governance

4.1. The IfQ Programme Board has continued to meet and has reported progress on a monthly basis to the Corporate Management Group (CMG). An item regarding IfQ is presented at each meeting of the Authority, the latest on 7 October 2015.

4.1. The IfQ Programme is supported by a dedicated Programme Manager, appointed in October 2013 to set up the Programme and establish an effective framework for delivery of the Programme so that it could be taken in house at an appropriate time. The IfQ Programme is now making arrangements to effect a smooth transition to HFEA's in house programme management office, having developed a succession plan for a handover at end December 2015.

5. Risk and Issues update

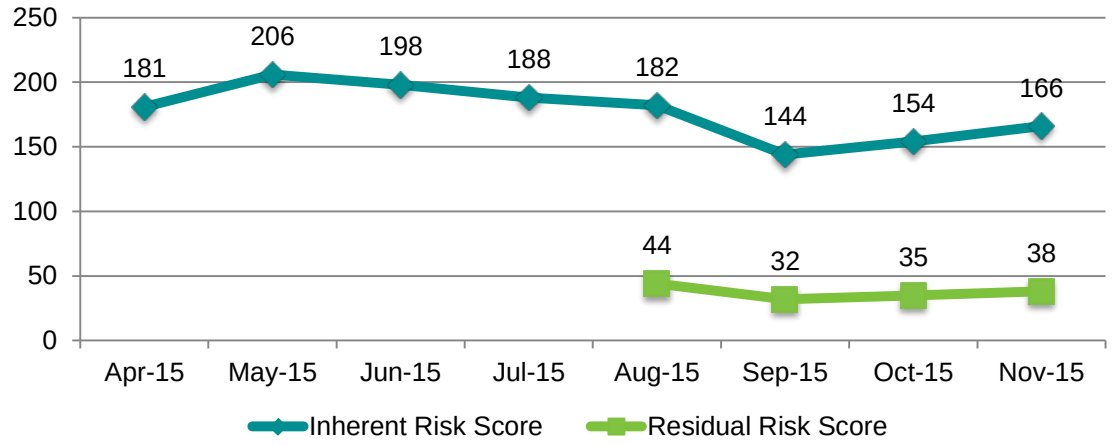
5.1. The IfQ Programme continues to manage risk and issues proactively, with Product Owners and the IfQ Programme Manager maintaining risk and issue logs. These are reported on at the IfQ Programme Board on a monthly basis, and are also reviewed in the context of IfQ Project and Programme highlight reports. IfQ risks are integral to the HFEA strategic risk register, covered under a separate item at this meeting.

5.2. As reported in the previous update to the AGC, key areas of risk for the IfQ Programme remain centred on data migration work, in particular regarding decisions about timing for cleansing and migrating 'must' and 'should' data, and striking an appropriate balance against key programme milestones and with achieving sufficient quality.

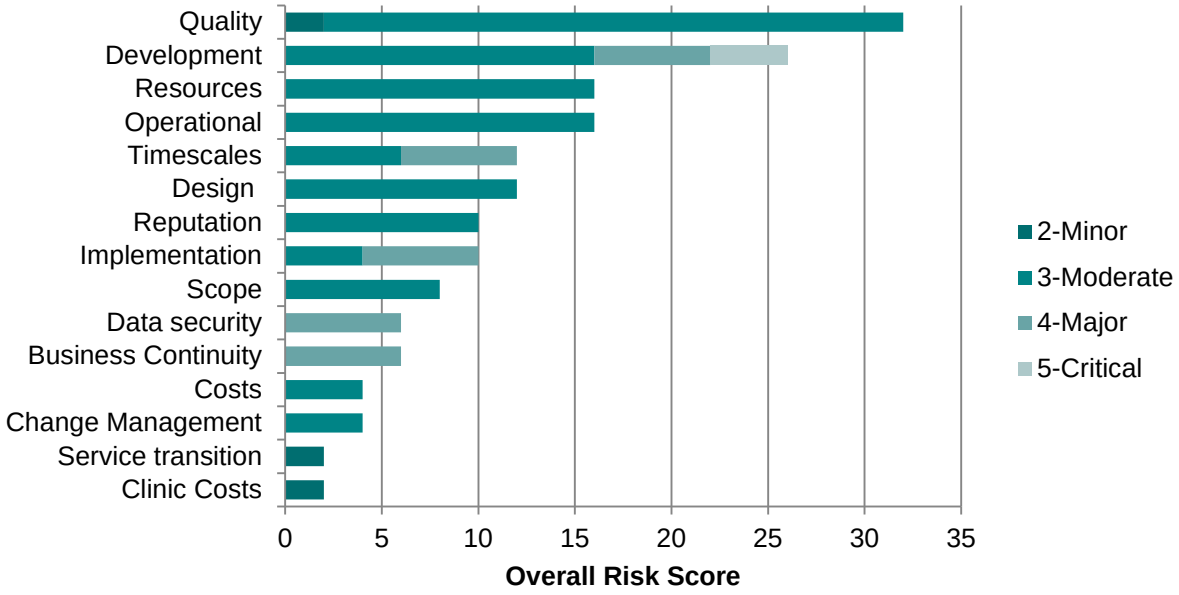
5.3. The graph below represents two different risk scores for the IfQ Programme. Risk scores are applied to each individual risk for different dimensions of that risk (e.g. probability and impact). The risk scores for the IfQ Programme have increased over recent months, relating primarily to the risk of delayed beta commencement having impacts on key milestones and programme budget.

5.4. The two summary risk scores represented are:

- The sum residual risk score for all risks currently active.
- The overall IfQ risk score, which combines impact and probability all active risks.



5.5. The bar graph below expands upon the current IfQ risk score for 166, showing those scores against IfQ Programme risk categories. This graph illustrates that the most significant areas of risk, considering perceived impact and likelihood, remain related to quality issues (with a focus on Data Migration work), and development related issues (as part of the Internal Systems work).



6. Internal Audit

6.1. As previously advised, the IfQ internal audit programme is to observe deliberations as regards the data migration strategy and implementation. A member of the internal audit team has now observed a March and September IfQ Programme Board. The IfQ Programme Board continues to manage the key risk areas identified by the IfQ internal audit programme, which relate primarily to data migration work.

7. Contract matters

7.1. As previously advised a (completed) contract awarded as part of the programme was subject to dispute. This minor (non-financial) dispute is closed, following confirmation from the supplier that it is taking no action.

8. Standing Instructions – Contracts Awarded

8.1. In accordance with Standing Financial Instructions the Committee is asked to note that no contracts have been awarded since the last meeting.

9. Recommendation

9.1. The Committee is asked to note this report

Nick Jones

Director of Compliance and Information

Digital Service Standard

1. Understand user needs. Research to develop a deep knowledge of who the service users are and what that means for the design of the service.

2. Put a plan in place for ongoing user research and usability testing to continuously seek feedback from users to improve the service.

3. Put in place a sustainable multidisciplinary team that can design, build and operate the service, led by a suitably skilled and senior service manager with decision-making responsibility.

4. Build the service using the agile, iterative and user-centred methods set out in the manual.

5. Build a service that can be iterated and improved on a frequent basis and make sure that you have the capacity, resources and technical flexibility to do so.

6. Evaluate what tools and systems will be used to build, host, operate and measure the service, and how to procure them.

7. Evaluate what user data and information the digital service will be providing or storing, and address the security level, legal responsibilities, privacy issues and risks associated with the service (consulting with experts where appropriate).

8. Make all new source code open and reusable, and publish it under appropriate licences (or provide a convincing explanation as to why this cannot be done for specific subsets of the source code).

9. Use open standards and common government platforms where available.

10. Be able to test the end-to-end service in an environment identical to that of the live version, including on all common browsers and devices, and using dummy accounts and a representative sample of users.

11. Make a plan for the event of the digital service being taken temporarily offline.

12. Create a service that is simple and intuitive enough that users succeed first time.

13. Build a service consistent with the user experience of the rest of GOV.UK including using the design patterns and style guide.

14. Encourage all users to use the digital service (with assisted digital support if required), alongside an appropriate plan to phase out non-digital channels/services.

15. Use tools for analysis that collect performance data. Use this data to analyse the success of the service and to translate this into features and tasks for the next phase of development.

16. Identify performance indicators for the service, including the 4 mandatory key performance indicators (KPIs) defined in the manual. Establish a benchmark for each metric and make a plan to enable improvements.

17. Report performance data on the Performance Platform.

18. Test the service from beginning to end with the minister responsible for it.

Health Digital Service Assessment

HFEA website and clinic finder tool

The HFEA website provides information for patients, donors, donor-conceived people, professionals working in clinics, researchers and the media. The redesign project aims to better meet user needs and upgrade an outdated infrastructure.

The clinic finder is a tool for patients and clinics to get impartial, unbiased information about clinics, the treatments they offer and how successful they are. The redesign project aims to give users a greater understanding of treatments and data.

Department / Agency:	Human Embryology and Fertility Authority (HFEA)
Date of Assessment:	12 November 2015
Date of Original Assessment:	N/A
Assessment Stage:	Alpha
Lead Assessor:	L. Scott
Result of Assessment:	Pass
Assessors:	D. Sheldon
Service Manager:	Trisram Dawahoo
Digital Leader:	Adam Bye

Assessment Report

The HFEA website and clinic finder has been reviewed against the 18 points of the Service Standard at the end of alpha development.

Outcome of service assessment

After careful consideration the assessment panel has concluded the HFEA website and Find a clinic tool is on track to meet the Digital by Default Service Standard at this early stage of development. We now expect the service team to address the recommendations made, course-correcting development where necessary, to ensure that the project remains on track and adheres to the Standard as it moves through beta.

We enjoyed meeting the service team and would like to extend thanks for the frank answers to our questions. We were impressed with the dedication, passion and hard work across the whole team, supported by their organisation, to change their working practices, embrace the Standard, and develop a product and service to meet user needs.

We were particularly struck by the quality of the user research, the user researcher's attitude and approach to identifying, validating and meeting user needs, and making user research a team sport.

Reasons

The service was assessed against all 18 points of the Digital by Default Service Standard. We asked questions from the prompts and evidence for assessors, supplied by GDS. This document has questions and the evidence sought for alpha, beta and live phases. We asked questions from the alpha section.

The service currently meets the requirements of the standard for an alpha service. Observations made below reflect some of the narrative about the service that we uncovered in the assessment. Recommendations are made later in this report.

User needs and assisted digital

The service team has carried out 28 1:1 interviews with current and prospective users of the service. We noted that the team had addressed feedback following their discovery phase about the suitability of previous research methodologies chosen. The panel is now confident that the service team has elicited a deep understanding of their range of users, and their top priority needs.

We were struck by the empathy the whole service team displayed towards their users, and their commitment to meeting those users' needs well. The team has ensured that this user insight is spread across the rest of the organisation, eg informing communications and content strategy.

The team identified no assisted digital users in their research, and demonstrated evidence that their user base has a higher level of digital capability than the national average. They plan to use an existing channel to provide assisted digital via phone, with a support team trained to take users through the service. They have also engaged with charities and support groups who may be able to provide a face to face channel.

The team have identified user needs they are unable to directly meet due to legislative remit, eg recommendations for best clinics, and cost. We had some concerns about other user needs that the team were aiming to meet via this product (eg general

information about problems conceiving), which could be better served by directing users to trusted sources of this information elsewhere.

User research plans and skills are comprehensive for the next phase with research built into the cycle. The user researcher will be upskilling the in-house service team, and expects to see them helping to run research in the next phase.

The team

The service works as one, co-located team with most of the recommended roles in place throughout alpha. Extra skills (eg policy, medical, clinical, stats) are accessed via in-house and stakeholder expert groups. Although the team has access to a content strategist, the content is produced by the Comms team. The in-house team are taking steps now to fill some of the deep technical skills gaps currently met by their supplier. They anticipate some ongoing support from interim contractors.

The team took a proactive approach to the move to use agile methodologies. They have invested time training themselves and others and also fostering the kind of organisational culture change that this shift necessitates.

The team has changed their working practices following retrospectives, eg a closer collaboration between developers and the product manager over story crafting.

The team showed some great examples of transforming governance. They use agile techniques to show rather than tell, via presentations to senior staff and weekly communications. They showed how this gives their executive team confidence in the project, meaning the service development team is freed up to continue delivering against user needs.

Security, privacy, tools and standards

The team have chosen their existing in-house technology suite, justified by their skillset and their confidence that it meets needs. They acknowledged their challenges around integrating their CMS with the clinic API, and the changing world of internal systems within the organisation. Story cycle time is standard at this stage of development and they are planning for more automation during the deploy cycle.

The service captures no user data as yet. They have researched potential threats to the service, and the risk is deemed low.

They plan to make the code open, and see a potential use for it by other governments. They are using open standards in development, and have made contact with other parts of government providing a similar offering, eg NHS Choices. We'd expect to see greater

ambition here to collaborate with other parts of government as the project develops. We understand that some uncertainty around future plans for the NHS.UK alpha project has delayed collaboration.

The team have identified where they need to explore to better meet needs via the clinic finder tool, eg users found the initial information too overwhelming. There are significant challenges in data presentation, and the team are exploring adding patient feedback to help users make an informed decision over clinic choice. The team have engaged with NHS Choices about this approach. The panel suggests this approach is rethought (see recommendations.)

Improving the service

The team had evidence that users were broadly successful in using the website unaided. They identified areas for improvement, eg navigation, and are exploring how to surface user support throughout the journey. The team explained how some users take a different route from what research had led them to anticipate, eg choice of clinic sometime precedes choice of treatment, and they are working to address this.

The clinic finder revealed more areas for improvement and evidence from research suggested the team needed to rethink the primary navigational approach (eg filter by treatment). We'd expect to see continued rigorous research to inform the development of the tool during beta.

Design

The team have not so far used the recommended best practice approach of sketching in code, testing and iterating (rather they are designing visuals first in mockups and wireframes).

The team are using their house style guide, developed alongside other style guides used in the health family. They are exempt from the visual branding of GOV.UK. However the GDS design patterns still stand as an accepted starting point for evidenced best practice in service design and user interaction standards. The team have not used these, and showed willingness to adopt them during the next phase of development.

Again, the GDS content style guide should be used as starting point for patterns (even if the service is exempt from technical style guide adherence) as to how users will successfully engage with a government service.

Analysis and benchmarking

The team are working with the Communications team who responsible for the offline channel – a booklet printed and distributed to clinics. They have identified where content is meeting needs that are best met on the digital product. They are engaging with clinics that disseminate the printed material to actively encourage users to go to the website. They are measuring channel shift and aim to reduce this printed channel, although they have no plans to cease it.

The team are using Google Analytics and will continue to do so as they build the beta. The team have a good understanding of how they will measure success, including a reduction in customer enquiries. They are already measuring performance on the performance platform.

Testing with the Minister

The team have engaged their most senior board member who has seen the service. They have no plans as yet with the current minister with portfolio for this area.

Recommendations

User needs and assisted digital

1. Continue to identify any users with assisted digital needs. Carry out research with users with assisted digital needs to test that journey.
2. Investigate alternatives to providing the facility to comment and feedback on clinics. This is a significant undertaking and we do not believe the service is equipped to run this facility at present.
3. Two possible options are a) provide the clinic data to NHS Choices who could then use their existing comment/feedback facility; b) provide the clinic data publicly and work with others (e.g. https://www.patientopinion.org.uk/) to provide the facility to patients via a third party.
4. Re-engage with NHS Choices to determine where the informational content for the public is best placed. As the team acknowledged, users seeking information about 'problems conceiving' are less likely to visit HFEA in the first instance, and more likely to turn to NHS and third parties.
5. There may be other types of user needs better addressed elsewhere. A key principle should be to not duplicate and instead signpost users to the best place to meet their needs. A re-think on this is required and the service team should not assume that its own website is the place for everything.

The team

1. We strongly recommend the addition of a content designer on the service team. They should also engage with the cross government content design community, adopt the GDS content style guide for patterns, and contribute back to that community with findings.
2. We expect to see a plan underway during beta to ensure the in-house team is capable of continuous iteration across the whole product to ensure this project does not stall after the 'design and build' phase.

Security, privacy, tools and standards

1. Look at using a content delivery network. This will help the website to scale when necessary and reduce load on the servers.
2. Develop the service to work regardless of browser capability. Follow the Service Manual guidance on progressive enhancement and ensure the menu and all other elements work with Javascript switched off.

Improving the service

1. Be considered with the amount of customisation and integration for the product in Umbraco and keep components loosely coupled. This will give you more flexibility and reduce any exit costs.

Data and open standards

1. Provide the list of clinics as a public register via an API and variety of different standard representations.
2. Engage with Paul Downey at GDS to discuss the cross-government registers work, and re-use the code or build their register to the standards GDS are setting.
3. Work closely with NHS Choices to provide the clinic data to their service finder.

Design

1. Ensure the design of the website is capable of iteration. The design should not be frozen once prototyping and transfer to Umbraco templates is complete.
2. Use the GDS design patterns and GDS style guide as starting point, even if you are exempt from adopting the visual style.
3. Test page length and sentence length with users to make sure the content density isn't detracting from comprehension.

4. The clinic finder makes use of icons which detracts from service design recommendations. These should be researched and thoroughly tested before making a decision to use them.
5. We discussed a simple search for the clinic finder based on the top things people want to filter the list by. As discussed in the assessment, the current treatment-based search is not working.
6. Stop printing specific URLs in the printed booklet - content may change.
7. Ensure that no link is left behind - we briefly discussed plans for URL redirection and we'd like to emphasise the importance of this.

Digital by Default Service Standard criteria

Criteria	Passed	Criteria	Passed
1	Yes	2	Yes
3	Yes	4	Yes
5	Yes	6	Yes
7	Yes	8	Yes
9	No	10	Yes
11	Yes	12	Yes
13	No	14	Yes
15	Yes	16	Yes
17	Yes	18	Yes

Health Digital Service Assessment

HFEA clinic portal

The clinic portal allows clinics to submit, obtain and manage clinic information and allows HFEA to give clinics performance data.

HFEA are redesigning the clinic portal to combine existing and enhanced functionality and make it easier to use by: improve the quality of data submitted to HFEA; reduce the "burden" associated with data submission; provide added utility; provide an improved user experience of accessing information and submitting data.

Department / Agency:□	Human Embryology and Fertility Authority (HFEA)
Date of Assessment:	12 November 2015
Date of Original Assessment:	N/A
Assessment Stage:□	Alpha
Lead Assessor:□	L. Scott
Result of Assessment:	Pass
Assessors:	A. Grimley
Service Manager:□	Chris Hall
Digital Leader:	Adam Bye

Assessment report

The HFEA clinic portal has been reviewed against the 18 points of the Service Standard at the end of the alpha development.

Outcome of service assessment

After consideration the assessment panel has concluded the clinic portal service is on track to meet the Digital by Default Service Standard at this early stage of development.

Reasons

The service was assessed against all 18 points of the Digital by Default Service Standard. We asked questions from the prompts and evidence for assessors, supplied

by GDS. This document has questions and the evidence sought for alpha, beta and live phases. We asked questions from the alpha section.

The service currently meets the requirements of the standard for an alpha service. The comment below reflect some of the observations we made during the discussion. Recommendations are listed later in this report. We now expect the service team to address the recommendations made, course-correcting development where necessary, to ensure that the project remains on track and adheres to the Standard as it moves through beta.

Thanks to the service team for answering questions frankly and contributing to the discussion. We were encouraged to see the appetite the team have to build a product according to the Standard and to meet user needs.

User needs and assisted digital

The service team used a blend of information gathering and observational research at 12 clinics, expert groups and analysis of customer feedback to establish the top user needs for the clinic portal. They have spoken to a range of staff as clinic size impacted who their main user would be, rather than role type. The team used personas developed during a discovery period of user research. We'd encourage the team to keep these updated as new finding about users are identified.

The team have identified needs which they have ambition to later meet, but are not in scope for this phase of development, eg giving users instant feedback re: compliance when they submit reports.

The alpha prototype has tested solutions to address 3 top user needs: a compliance task list, updating clinic details, and submitting a self-assessment risk questionnaire. the structure of the rest of the microsite has been wireframed.

The team have not found users with assisted digital needs. IT skills are higher than average.

There is a user researcher assigned to the service team and research and testing is planned into the sprint cycle. The team are considering a pilot with a private beta for more focussed research and testing. Clinics are all aware of the project and are actively encouraged to feedback and engage with the project team via the service manager.

The panel was encouraged to note the team's focus on user needs in designing the process rather than simply automating the current forms.

The team

The team is currently well resourced with the skills required to develop the service. They also seem to be managing the dependencies between user needs, front end development and underlying databases and infrastructure although this has led at times to refactoring effort.

The service team contains all the recommended roles at this stage of development. Gaps in the in-house team are infilled with support from the supplier. One important omission is a content designer working alongside the service team - copy is provided by HFEA staff.

There is a high dependence on external skills and expertise but no evidence of a structured and measurable plan to transition some of the skills in-house. We heard that interims are asked to transfer skills via pair programming and in-house code review. It's not yet clear how confidence and capability can be accurately measured. This will inevitably limit potential to continuously improve the service in future.

The team is using scrum and carries out agile ways of working. Alongside the dedicated delivery manager who joins the team from the supplier, the role of scrum master is rotated to upskill the in-house team. Although the team is not fully co-located, suppliers join the rest of the team for important sessions such as planning and design, and connect via remote working tools otherwise. The team use retrospectives to address ways of working, eg they now have pre-planning and sprint goals, and use agile techniques to prioritise the most valuable tasks.

Current technical capability and business processes have influenced how possible it is to meet some needs in a more bold way, eg allowing users to explore the data behind the reports, and having one licence application instead of many. The team have ambitious plans for the future. The current development is focussed on an MVP replica of the existing service, focusing on increased usability. This will allow the team to deliver an improved service at pace, incorporating a data cleanse and migration.

The team have used agile techniques to transform governance - eg programme board processes to approve budgets etc. A shared understanding of a prioritised list for the migration project is now in place, along with clarity.

Security, privacy, tools and standards

As an organisation, HFEA are well-versed in the IG implications of the services they maintain and address these diligently. They demonstrated their understanding of the nature of likely threats and appropriate responses. There is very low user impact of the service being unexpectedly offline.

The tool chain and technical stack they have adopted are widely used and understood although the choices made were largely influenced by the existing in-house skills. This is understandable but can limit detailed assessment of the trade-offs that are implied in a technology choice leading to a service outgrowing its stack. They have researched likely end-user configurations and are optimising the service in this regard. They have the considerable advantage of being able to mandate minimum requirements for the end users' technology.

Although they are aware of touch points with other services, such as the national directories of services, they have decided not to integrate with them.

Improving the service

The team can spin up identical environments for testing.

While they have not carried out specific research into browsers and device use, the team are aware of the IT setup of their users, and will be developing with this in mind. We learned that many clinics are running outdated systems with unsupported browsers.

The team are expecting desktop/laptop/tablet usage. Reports are printed out for dissemination to staff who are in the labs. The team have noted that printable content of reports is a currently unmet need that they will address.

The team learned through research that some of the navigation is not clear to users, including organisation of content and labelling. They are able to address this and test it in the next round of research.

Open source

Much of the technology stack is proprietary but the developed code is capable of being shared and will be, albeit in a limited way with third party commercial suppliers.

Design

The team are using their house style guide, developed alongside other style guides used in the health family. They are exempt from the visual branding of GOV.UK.

However the GDS design patterns still stand as an accepted starting point for evidenced best practice in service design and user interaction standards. The team have not used these, with the exception of form state and form layout, and showed willingness to adopt them during the next phase of development.

Again, the GDS content style guide should be used as starting point for patterns (even if the service is exempt from technical style guide adherence) as to how users will successfully engage with a government service.

Analysis and benchmarking

The team have relied almost exclusively on user research to gather evidence for user needs. They intend to connect with the business support team who manage the telephone enquiry line, though they have not used this feedback thus far.

The team have a target to reduce the time clinics take to complete certain tasks, and saving users 4hrs a week is a target, along with reducing error rates, reducing support calls, and increasing current satisfaction.

There was no evidence that the team had considered service metrics in any depth. We accept that some of the transactions can be complex and consist of multiple stages but looking at measurement can provide useful insights into actually reducing the complexity.

During the discussion we were able to identify a few areas which could be monitored, eg incomplete submissions, internal staff time taken, user support tickets which the team could put in place.

There is no offline competing channel, although most forms are paper only. The ambition is to digitise all paper channels.

The team cited evidence from research that their users expect and desire to use a fully digital service.

Testing with the Minister

The team have engaged their most senior board member who has seen the service. They have no plans as yet with the current minister with portfolio for this area.

Recommendations

User needs and assisted digital

1. Understand any potential users who would have needs met on the public facing website vs the clinic portal. Check the user journeys between the two are validated by research.
2. Continue to identify any users with assisted digital needs. Carry out research with users with assisted digital needs to test that journey.
3. Analyse other evidence, such as customer feedback and user support, to identify any unmet or emerging needs.

The team

1. We expect to see a plan underway during beta to ensure the in-house team is capable of continuous iteration across the whole product to ensure this project does not stall after the 'design and build' phase. This should include objective-based training plans addressing both the technical stack and agile working methods, eg junior-led programming or guided solo programming.
2. We strongly recommend the addition of a content designer on the service team. They should also engage with the cross government content design community, adopt the GDS content style guide for patterns, and contribute back to that community with findings.

Security, privacy, tools and standards

1. Recommend liaison with NHS 111 digital team to further investigate integration with other national services such as Directories of Service and Demographics/Patient identification.

Improving the service

1. Clarity on the primary aims and the minimum viable product to satisfy these - we heard great evidence that you are working to address the underlying needs identified by research rather than automating forms. This will discover new features and functions that you haven't yet envisaged - and you will need to know what 'done' looks like.

Design

1. Use the GDS design patterns and GDS style guide as starting point, even if you are exempt from adopting the visual style.
2. Ensure that no link is left behind - we briefly discussed plans for URL redirection and we'd like to emphasise the importance of this.

Analysis and benchmarking

1. Have a clear plan to work out how to measure whether your improvements have made things better or worse by establishing clear and meaningful KPIs for the service, as well as the 4 mandatory KPIs - that you can measure in the open on the performance platform.

Digital by Default Service Standard criteria

Criteria	Passed	Criteria	Passed
1	Yes	2	Yes
3	Yes	4	Yes
5	No	6	Yes
7	Yes	8	Yes
9	No	10	Yes
11	Yes	12	Yes
13	No	14	Yes
15	No	16	No
17	Yes	18	Yes

Strategic risks

Strategic delivery:	☒ Setting standards	☒ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	6		
Paper number	AGC (09/12/2015) 478		
Meeting date	9 December 2015		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is asked to note the latest edition of the risk register, set out in the annex.		
Resource implications	In budget.		
Implementation date	Strategic risk register and operational risk monitoring: ongoing. CMG reviews risk quarterly in advance of each AGC meeting. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Strategic risk register

Latest reviews

1.1. CMG reviewed the risk register on 18 November 2015. CMG discussed all risks, their controls, and scores. A new risk relating to the forthcoming office move has been added. Six of the 13 risks are currently above tolerance.

1.2. The strategic risk register is attached at Annex A, and includes an overview of CMG's general discussions about the risk register. The annex includes the graphical overview of residual risks plotted against risk tolerances, which was presented for the first time at the Committee's last meeting.

1.3. The Authority also received the risk register at its meeting on 11 November 2015. There were no comments on the details of the risks or the scores.

2. Risk assurance mapping

2.1. A risk assurance workshop (our first) has now been scheduled for 10 February 2016. The workshop will be run by DH Internal Audit.

2.2. As agreed previously, based on recent analyses of our operational risks, the workshop will focus on capacity and resilience. We believe this is the highest value area for us to start with. Current operational risks include turnover and recruitment, next year's office move, general resource and timescale pressures (eg, IfQ), team interdependencies and role-related bottlenecks.

3. Recommendation

3.1. AGC is asked to note the above, and to comment on the strategic risk register.

Annex A

HFEA strategic risk register 2015/16

Risk summary: high to low residual risks

Risk area	Risk title	Strategic linkage[1]	Residual risk	Current status	Trend
Office move	OM1: Office move	Efficiency, economy and value	**16 – High**	Above tolerance	⊙ (New)
Legal challenge	LC1: Resource diversion	Efficiency, economy and value	**15 – High**	Above tolerance	⇔⇔⇔⇔
Information for Quality	IfQ1: Improved information access	Increasing and informing choice: information	**12 – High**	Above tolerance	⇔⇔⇔⇔
Financial viability	FV1: Income and expenditure	Efficiency, economy and value	**12 – High**	Above tolerance	⇔⇔⇔⇔
Data	D1: Data loss or breach	Efficiency, economy and value	**10 – Medium**	At tolerance	⇔⇔⇔⇔
Data	D2: Incorrect data released	Efficiency, economy and value	**9 – Medium**	Above tolerance	⇔⇔⇔⇩
Information for Quality	IfQ3: Delivery of promised efficiencies	Efficiency, economy and value	**9 – Medium**	At tolerance	⇔⇔⇔⇔
Donor conception	DC2: Support for OTR applicants	Setting standards: donor conception	**9 – Medium**	At tolerance	⇔⇔⇔⇔
Capability	C1: Knowledge and capability	Efficiency, economy and value	**9 – Medium**	Above tolerance	⇔⇔⇔⇔
Regulatory model	RM1: Quality and safety of care	Setting standards: quality and safety	**8 – Medium**	At tolerance	⇔⇔⇔⇧
Regulatory model	RM2: Loss of regulatory authority	Setting standards: quality and safety	**8 – Medium**	At tolerance	⇔⇔⇔⇔
Information for Quality	IfQ2: Register data	Increasing and informing choice: Register data	**8 – Medium**	At tolerance	⇔⇔⇔⇔
Donor conception	DC1: OTR inaccuracy	Setting standards: donor conception	**4 – Low**	At tolerance	⇔⇔⇔⇔

[1] Strategic objectives 2014-2017:

Setting standards: improving the quality and safety of care through our regulatory activities. (Setting standards – quality and safety)

Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families. (Setting standards – donor conception)

Increasing and informing choice: using the data in the register of treatments to improve outcomes and research. (Increasing and informing choice – Register data)

Increasing and informing choice: ensuring that patients have access to high quality meaningful information. (Increasing and informing choice – information)

Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government. (Efficiency, economy and value)

The ‘trend’ column in the above table tracks the four most recent reviews by AGC, CMG, or the Authority (e.g. ⇧⇔⇩⇔).

Recent review points are:

AGC 10 June 2015 ⇨ CMG 2 September 2015 ⇨ AGC 7 October ⇨ CMG 18 November.

The Authority also recently received the risk register, at its 11 November meeting. No changes were proposed.

CMG overview

CMG reviewed the risk register and discussed each risk in detail at its meeting on 18 November.

CMG agreed that the office move, confirmed for April 2016, should now be added as a separate risk. The project plan and project risk log are being formulated now and the project was discussed at the monthly CMG meeting on 19 November. Since we are still in the early planning stages and no contract is yet in place, this comes in as our highest risk, but we expect this to decrease shortly (see the risk itself for details). The tolerance has been set quite low, at 6 (medium), since any major disruption as a result of the move could be costly to us in terms of strategic delivery.

CMG agreed that the recent judgment relating to legal parenthood, and the ensuing extensive work on consent issues, should be recognised in the two regulatory model risks. The judgment may have administrative consequences for the HFEA, and a range of additional work has already been needed. Further cases are expected over the coming months, although the HFEA is unlikely to participate in legal proceedings directly.

CMG also recognised that there are other factors which also affect the two regulatory model risks. Under the first regulatory model risk (RM1: adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the Act), the team Heads for both inspection and licensing are both leaving the HFEA in the next couple of months, and both are significant control owners for this risk. The controls will need to be assigned upwards pending recruitment, once they have left (in late November and January respectively). In light of this and legal parenthood considerations, we have raised the residual risk level for RM1 from 4 to 8 for the time being.

Under the second regulatory model risk (RM2: loss of regulatory authority), CMG discussed information provision risks. The HFEA’s current website is old, and based on a content management system that is error prone and difficult to manage. The IfQ work on the new website will completely mitigate this risk, but not until February 2016, when the beta phase of the project is reached. Meanwhile, we continue to tolerate the issue of regular website outages and frequent inability to publish data successfully at the first attempt, and a low risk that the old website could fail completely, preventing us from publishing any information for a period of time. This risk is informing our decisions about which content to move first to the new site, when we enter the beta phase of IfQ in February 2016. CMG did not however feel that any change in the residual risk score was merited at the moment, since good mitigations are in place.

CMG heard that indicative approval has now been received for the remaining IfQ work on the website, in that the recent Department of Health gateway review awarded excellent scores to the HFEA’s plans for delivering the remainder of the work. However, the approval decision still needs to be made formal by the GDS board, and so the final outcome will not be confirmed for a few more weeks (possibly around the time of the AGC meeting). Therefore, it is prudent to keep scores at the same level until at least that point.

The Authority also discussed the risk register, at its meeting on 11 November, and commented on issues including data security and staff turnover. No changes to scores were proposed.

Criteria for inclusion of risks:

- Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.
- Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank

Risks are arranged above in rank order according to the severity of the current residual risk score.

Risk trend

The risk trend shows whether the threat has increased or decreased recently. The direction of arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk scoring system

See last page.

Assessing inherent risk

Inherent risk is usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it'. This can be taken to mean 'if no controls at all are in place'. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes does introduce some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, in order for our estimation of inherent risk to be meaningful, the HFEA defines inherent risk as:

'the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.'

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇩ ⇔ ⇔ ⇧	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inspection/reporting failure.	Inspections are scheduled for the whole year, using licence information held on Epicentre, and items are also scheduled to committees well in advance.	In place – Debra Bloor/Nick Jones	At tolerance. The Head of Governance and Licensing and the Chief Inspector are both leaving the HFEA (in late November and mid January, respectively). While recruitment is pending, ownership of controls will move upwards to the relevant Director. This, together with the action plan being implemented in connection with legal parenthood consent issues, has raised the residual risk likelihood from 1 (very unlikely) to 2 (unlikely).
	Audit of Epicentre to reveal data errors. Queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Sam Hartley/Juliet Tizzard	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor/Nick Jones	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor/Nick Jones	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor/Nick Jones	
	Staffing model provides resilience in the inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	In place – Debra Bloor/Nick Jones	
Insufficient inspectors or licensing staff	Inspection team up to complement following earlier recruitment. (The Chief Inspector is leaving the HFEA in January, and will be replaced on a like-for-like basis.)	In place – Debra Bloor/Nick Jones	

	Licensing team up to complement following earlier recruitment. (The Head of Governance and Licensing is leaving the HFEA in November, but will be replaced on a like-for-like basis.)	In place – Sam Hartley/Juliet Tizzard
Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds for inspectors and support staff have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Debra Bloor/Nick Jones
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins
	Group induction sessions put in place where possible.	In place – Debra Bloor/Nick Jones
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation or rescheduling of work an option.	In place – Paula Robinson
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model amended in May 2015, to release an extra inspector post out of the previous establishment. This increased general resilience, enabling more flex when there is an especially high inspection/report writing/application processing workload.	In place – Debra Bloor/Nick Jones
	Greater sector insight into our PGD application handling processes and decision-making steps achieved in the past few years; coupled with our increased processing times from efficiency improvements made in 2013 (acknowledged by the sector).	In place – Debra Bloor/Nick Jones
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, legal parenthood consent issues, or several major Grade A incidents occur at once.	Resilient staffing model in place.	In place – Debra Bloor/Nick Jones
	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor/Nick Jones

	A detailed action plan in response to the legal parenthood judgement is being worked up. There has been correspondence with clinics, who are doing detailed audits. Through a detailed review of every clinic's responses, a summary list of all concerns is in progress. Management review meetings are taking place for all clinics at which there are handling concerns or anomalies. Plan of action being decided to address all of the concerns identified, with direct follow up with centres who have not responded at all. Where there are engagement concerns, we will do short-notice inspections, focused on parenthood consent.	In progress – Debra Bloor/Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 2: Loss of regulatory authority	There is a risk that the HFEA could lose authority as a regulator, jeopardising its regulatory effectiveness, owing to a loss of public / sector confidence.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Failures or weaknesses in decision making processes.	Keeping up to date the standard operating procedures (SOPs) for licensing, representations and appeals.	In place – Sam Hartley/Juliet Tizzard	At tolerance. Although two additional risk sources have been identified (website outages until the new beta website is live and the plan of work to address legal parenthood consent issues), these are being well managed and/or tolerated, and the overall risk score has not increased.
	Learning from past representations and Appeal Committee hearings incorporated into processes.	In place – Sam Hartley/Juliet Tizzard	
	Appeals Committee membership maintained. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – Sam Hartley/Juliet Tizzard	
	Staffing structure for sufficient committee support.	In place – Sam Hartley/Juliet Tizzard	
	Decision trees; legal advisers familiar.	In place – Sam Hartley/Juliet Tizzard	
	Proactive management of quoracy for meetings.	In place – Sam Hartley/Juliet Tizzard	
	New (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – implementation due end of 2015.	To be put in place – Sam Hartley/Juliet Tizzard Licensing Officer role – December 2015 (postponed from June 2015) Delegations in SOs – April 2016	
Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy (and application of existing policy, meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor/Nick Jones	
	Inspector training, competency-based recruitment, induction process, SOPs, quality management	In place – Debra Bloor/Nick Jones	

	system (QMS) and quality assurance all robust.	
Effect of publicised grade A incidents.	Staffing model provide resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Debra Bloor/Nick Jones
	SOPs and protocols with Communications team.	In place – Debra Bloor/Nick Jones
	Fairness and transparency in licensing committee information.	In place – Debra Bloor/Nick Jones
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor/Nick Jones
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place. Head level 6 month contract recruited to manage the office move and review records management.	In place – SMT
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Sam Hartley/Juliet Tizzard
	Further work planned on records management in parallel with IT strategy.	Linked to IT strategy work – in progress – Jamie Munro/David Moysen
Until the IfQ website project has been completed, there is a continued risk of HFEA website outages, as well as difficulties in uploading updates to web pages.	Alternative mechanisms are in place for clinics to get information about materials such as the Code of Practice (eg, direct communications with inspectors, Clinic Focus).	In place – Debra Bloor/Nick Jones
	The IfQ work on the new website will completely mitigate this risk (the new content management system will remove the current instability we are experiencing from using Red-Dot). This risk is informing our decisions about which content to move first to the beta version of the new site.	In progress – beta phase February 2016 – Juliet Tizzard
Negative media or criticism from the	HFEA approach is only to go into cases on the basis	In place - Peter Thompson

sector in connection with legally disputed issues or major adverse events at clinics.	of clarifying legal principles or upholding the standards of care by challenging poor practice. This is more likely to be perceived as proportionate, rational and necessary (and impersonal), and is in keeping with our strategic vision.	
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound, or which generate additional regulatory sanctions activity (eg, legal parenthood consent).	Licensing SOPs, committee decision trees in place. Mitochondria donation application tools completed.	In place – Sam Hartley/Juliet Tizzard
	Update of compliance and enforcement policy (and application of existing policy meanwhile).	Significant progress – revision discussed at September 2015 Authority – revised policy Spring 2016 - Debra Bloor/Nick Jones
	Seeking the most robust possible assurance from the sector with respect to legal parenthood consent issues, and detailed plan in operation to address identified cases and anomalies.	In progress – Debra Bloor/Nick Jones
	QMS and quality assurance in place in inspection team.	In place – Debra Bloor/Nick Jones

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 1: Improved information access	If the information for Quality (IfQ) programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	Increasing and informing choice: ensuring that patients have access to high quality meaningful information.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**4**	**12 High**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Inability to extract reliable data from the Register.	Detailed planning and programme management in place to ensure this will be possible after migration. Migration strategy developed, and significant work being done to identify all of the data that will require correction before migration can be done. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones	Above tolerance. Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering, throughout. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015. The digital side of the programme received only partial approval; full delivery still requires additional gateway approvals at this stage (ie, prior to beta). The Department of Health gateway review has taken place and awarded a high score to the
Unable to work out how best to improve CaFC, and/or failure to find out what data/information patients really need.	Stakeholder engagement and extensive user research completed as intrinsic part of programme approach. This is being elaborated further during subsequent sprints.	In place and ongoing – Juliet Tizzard	
Stakeholders not on board with the changes.	In-depth stakeholder engagement done, to inform the programme's intended outcomes, products and benefits – including user research consultation, expert groups and Advisory Board.	In place and ongoing – Juliet Tizzard/ Nick Jones	
Cost of delivering better information becomes too prohibitive.	Costs were taken into account as an important factor in consideration of contract tenders and negotiations.	In place – Nick Jones	

Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations.	In progress – delivery by end Mar 2016 – Juliet Tizzard	HFEA, but we still need to await the formal decision on this by the Government Digital Service board (expected mid December). At this stage, therefore, there remains a risk of negative impact, although this risk now feels much lower.
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted.	In place – Juliet Tizzard In place – Nick Jones (decision received April 2015)	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling where possible/affordable to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	
Delivery quality is very supplier dependent. Contractor management could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and required close joint working and communication among all involved contractors during the Sprint Zero start-up phase and beyond. Sound project management practices in place to monitor. Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management. Ability to consider deprioritising other work, through CMG, if necessary.	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options were scrutinised carefully as part of project. Appropriate new CMS now chosen, and all involved teams happy with the selection.	In progress – implemented in beta phase, February 2016 – Juliet Tizzard	
Communications infrastructure incapable	Needs to be updated as part of IfQ in order to	In place – set out in business case –	

of supporting the planned changes.	support the changes.	Juliet Tizzard (Dec 2014)
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.	In place – Nick Jones
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	Being considered – Nick Jones/Sue Gallone/Jamie Munro

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 2: Register data	HFEA Register data becomes lost, corrupted, or is otherwise adversely affected during IfQ programme delivery.	Increasing and informing choice: using the data in the Register of Treatments to improve outcomes and research.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			2	5	10 Medium		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**4**	**8 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Risks associated with data migration to new structure, together with records accuracy and data integrity issues.	IfQ programme groundwork focusing on current state of Register. Extensive planning in progress, including detailed research and migration strategy.	In place – Nick Jones/Dave Moysen	At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.
Historic data cleansing is needed prior to migration.	A detailed migration strategy is in place, and a data cleansing step forms part of this.	In place – Nick Jones/Dave Moysen	
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporates consideration of fields and reporting needs are agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones	
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen	
System interdependencies change / are not recognised	Strong interdependency mapping being done between IfQ and business as usual.	Done – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place – Nick Jones	
Potential risks associated with the HFEA's likely office move in April 2016, in	Early awareness of the potential for disruption means that this can be managed through careful	Being considered – Nick Jones/Sue Gallone/Jamie Munro	

that this will coincide with the delivery period for some IfQ milestones.	planning.		

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor user acceptance of changes, or expectations not managed.	Stakeholder involvement strategy in place and user testing being incorporated into implementation phase of projects.	In place – Nick Jones/Juliet Tizzard	At tolerance.
Clinics not consulted/involved enough.	Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups have ended, but a stakeholder group for the implementation phase is in place.	In place – Nick Jones/Juliet Tizzard	
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.	Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery were a critical part of the decision in awarding the contract.	In place and contracts awarded (July 2015) – Nick Jones	
Efficiencies cannot, in the end, be delivered.	Detailed scoping phase included stakeholder input to identify clinic users' needs accurately. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In place – Nick Jones	
Cost of improvements becomes too prohibitive.	Contracts only awarded to bidders who made an affordable proposal.	In place (July 2015) – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedded into new ways of working.	In place (June 2015) – Nick Jones	

Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	Being considered – Nick Jones/Sue Gallone/Jamie Munro	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**5**	**15 High**		
			Tolerance threshold:		12 High		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Complex and controversial area.	Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson	Above tolerance. One case decided in the HFEA's favour at summary judgement, but is now to be appealed (in February 2016). A recent judgement on consents for parenthood may have administrative consequences for the HFEA. Further court cases are also likely, although the HFEA is unlikely to participate in legal proceedings directly. The 'M' case regarding the export of gametes for treatment abroad will also go to a final appeal in the next few months.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin/Sam Hartley/Juliet Tizzard	
Lack of clarity in HFE Act and regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.	Panel in place, as above, to get the best possible advice.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested.	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. Standard licensing pack completely refreshed and distributed to members/advisers (April 2015).	In place – Sam Hartley/Juliet Tizzard	
Subjectivity of judgments means the	Scenario planning is undertaken at the initiation of	In place – Peter Thompson	

HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case.	any likely action.		
HFEA could face unexpected high legal costs or damages which it could not fund.	Discussion with the Department of Health would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency.	In place – Peter Thompson	
Legal proceedings can be lengthy and resource draining.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson	
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.	In place – Peter Thompson	
Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.	Licensing SOPs, committee decision trees in place.	In place – Sam Hartley/Juliet Tizzard.	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Data D 1: Data loss or breach	There is a risk that HFEA data is lost, becomes inaccessible, is inadvertently released or is inappropriately accessed.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			2	**5**	**10 Medium**		
			Tolerance threshold:		10 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen	At tolerance.
Loss of Register or other data.	As above.	In place – Dave Moysen	
	Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen	
Cyber-attack and similar external risks.	Secure system in place as above, with regular penetration testing.	In place – Dave Moysen	
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen	
	Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones	
Business continuity issue.	BCP in place and staff communication procedure	In place – Sue Gallone	

	tested. A period of embedding the policies is in progress. Awareness of the importance of maintaining business continuity will be built into our office move planning.		
Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen	
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇩	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			5	4	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		8 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice. Head level 6 month contract to be recruited to manage the office move and review records management.	In place – SMT Head post recruitment in progress September 2015 - SMT	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which in January 2015 (for example) were among the highest we have ever experienced. Volumes have decreased recently. However, at the same time, the number of FOI requests (on other subjects) has increased. FOIs, however, are less impactful owing to the longer timeframes available for responding, so we have lowered the impact score from 4 (major) to 3 (moderate) to reflect this change.
	TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Sam Hartley/Juliet Tizzard	
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Completed October 2015 – Sam Hartley/Juliet Tizzard	
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, attempts are made to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones	
	PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific Policy Manager.	In place - Sam Hartley/Juliet Tizzard	

Answers in Hansard may not always reflect advice from HFEA.	The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.	In place – Sam Hartley/Juliet Tizzard / Peter Thompson	
Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.	As above – expert staff with the appropriate knowledge and understanding in place.	In place – Juliet Tizzard / Nick Jones	
Servicing data requests for researchers - poor quality of consents obtained by clinics for disclosure of data to researchers.	There is a recognised risk of centres reporting research consents inaccurately. Work to address consent reporting issues is being planned.	Actions to be confirmed – end of November 2015 – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 1: OTR inaccuracy	There is a risk that an OTR applicant is given incorrect data.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			1	**4**	**4 Low**		
			Tolerance threshold:		4 Low		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Data accuracy in Register submissions.	Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones	At tolerance (which is very low for this risk).
	Audit programme to check information provision and accuracy.	In place – Nick Jones	
	IfQ work will identify data accuracy requirements for different fields as part of the migration process, and will establish more efficient processes.	In place – Nick Jones	
	If subsequent work or data submissions reveal an unpreventable earlier inaccuracy (or an error), we explain this transparently to the recipient of the information, so it is clear to them what the position is and why this differs from the earlier provided data.	In place – Nick Jones	
Issuing of wrong person's data.	OTR process has an SOP that includes specific steps to check the information given and that it relates to the right person.	In place – Nick Jones	
Process error or human error.	As above.	In place – Nick Jones	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Donor conception DC 2: Support for OTR applicants	There is a risk that inadequate support is provided for donor-conceived people or donors at the point of making an OTR request.	Setting standards: improving the lifelong experience for donors, donor-conceived people, patients using donor conception, and their wider families.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			3	**3**	**9 Medium**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Lack of counselling availability for applicants.	Counselling service pilot established with external contractor in place.	In place (June 2015) – Nick Jones	At tolerance. The pilot counselling service has been in place since 1 June, and we will make further assessments based on early uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period.
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries. However, there is currently also one member of staff on long term sick leave, and this together with work pressures from IfQ delivery means there is still some pressure on team capacity (being discussed by managers).	In place, with current team capacity issue under discussion – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	
	SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – In June the ongoing management of the Pilot transferred to Rosetta Wotton.	

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Financial viability FV 1: Income and expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k)	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			⇔ ⇔ ⇔ ⇔	Sue Gallone
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			4	**3**	**12 High**		
			Tolerance threshold:		9 Medium		

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	Above tolerance, but 2014/15 overspend was able to be met from reserves. 2015/16 on course for small under-spend but risk of legal costs remains. In November 2015, the Authority approved a proposal to increase per-cycle fees by £5 (to £80) and to end the small 'eSET discount' for elective single embryo transfer, which has been in place for a few years to assist with the introduction of the Authority's multiple births policy (now firmly established and in place). This should help secure sufficient funds going forward.
	Fees Group created enabling dialogue with sector about fee levels. Fee increase agreed (November 2015), and eSET discount to end, subject to Treasury agreement.	In place. Fees Group meetings in April and October, ongoing – Sue Gallone	
GIA funding could be reduced due to changes in Government/policy	A good relationship with DH Sponsors, who are well informed about our work and our funding model.	Quarterly meetings (on-going) – Sue Gallone	
	Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone	
	Budget discussions with DH finance to set out needs in context of spending review.	November and December 2015 – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any short-fall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required. IfQ Programme Board regularly reviews the budget and costs.	Monthly – Sue Gallone Monthly – IfQ Programme Board	
Upwards scope creep during projects, or emerging during early development of	Periodic review of actual and budgeted spend by IfQ project board and monthly budget meetings with	Ongoing – Wilhelmina Crown	

projects eg, IfQ.	finance.		
	Cash flow forecast updated.	Monthly (on-going) – Morounke Akingbola	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 4 / Impact: 4 / Inherent risk: 16 High Residual risk level: Likelihood: **3** / Impact: **3** / Residual risk: **9 Medium** Tolerance threshold: 6 Medium	⇩ ⇔ ⇔ ⇔	Peter Thompson

Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. When the period of highest turnover appeared to be ending (May 2015), CMG slightly reduced the likelihood of this risk, but still decided to retain it, given that high turnover could recur. Indeed this may now be starting to happen. Since the HFEA is a small organisation, with little intrinsic resilience, it seems prudent to have a low tolerance level for this risk.
	A programme of development work is planned to ensure staff have the skills needed, so as to ensure they and the organisation are equipped under any future model, maximising our resilience and flexibility as much as possible. Staff can access civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA has been proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also already been reviewed extensively (including the McCracken review). Turnover is variable, and so this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson	

Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson
	Staff survey and implementation of outcomes, following up on Oct 2014 all staff conference.	Survey done (Jan 2015) – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones
	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	In place – Peter Thompson
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG.	In place – Paula Robinson
	Early emphasis given to team-level service delivery planning for 2015, with active involvement of team members. Delivery (and resources) in Q1 to date were also considered at monthly CMG in May, and delivery is currently on track. CMG will continue to review this.	In place (Jan 2015) – Paula Robinson
	Moratorium on new project work under consideration in planning for remainder of 2015/16 and for 2016/17, so as to prioritise IfQ delivery and therefore strategy delivery) within our limited resources.	Ongoing dialogue about this in place as part of business planning (August 2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of Civil Service Learning.	In place – Peter Thompson

Regarding the recent work on licensing mitochondrial replacement techniques, there is a possible future risk that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	New issue for consideration – Juliet Tizzard	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner
Office move OM 1: Office move	There is a risk that the office move could compromise our capability and capacity to deliver our strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level: Likelihood: 5 / Impact: 4 / Inherent risk: 20 Very high Residual risk level: Likelihood: **4** / Impact: **4** / Residual risk: **16 High** Tolerance threshold: 6 Medium	New ⊙	Sue Gallone

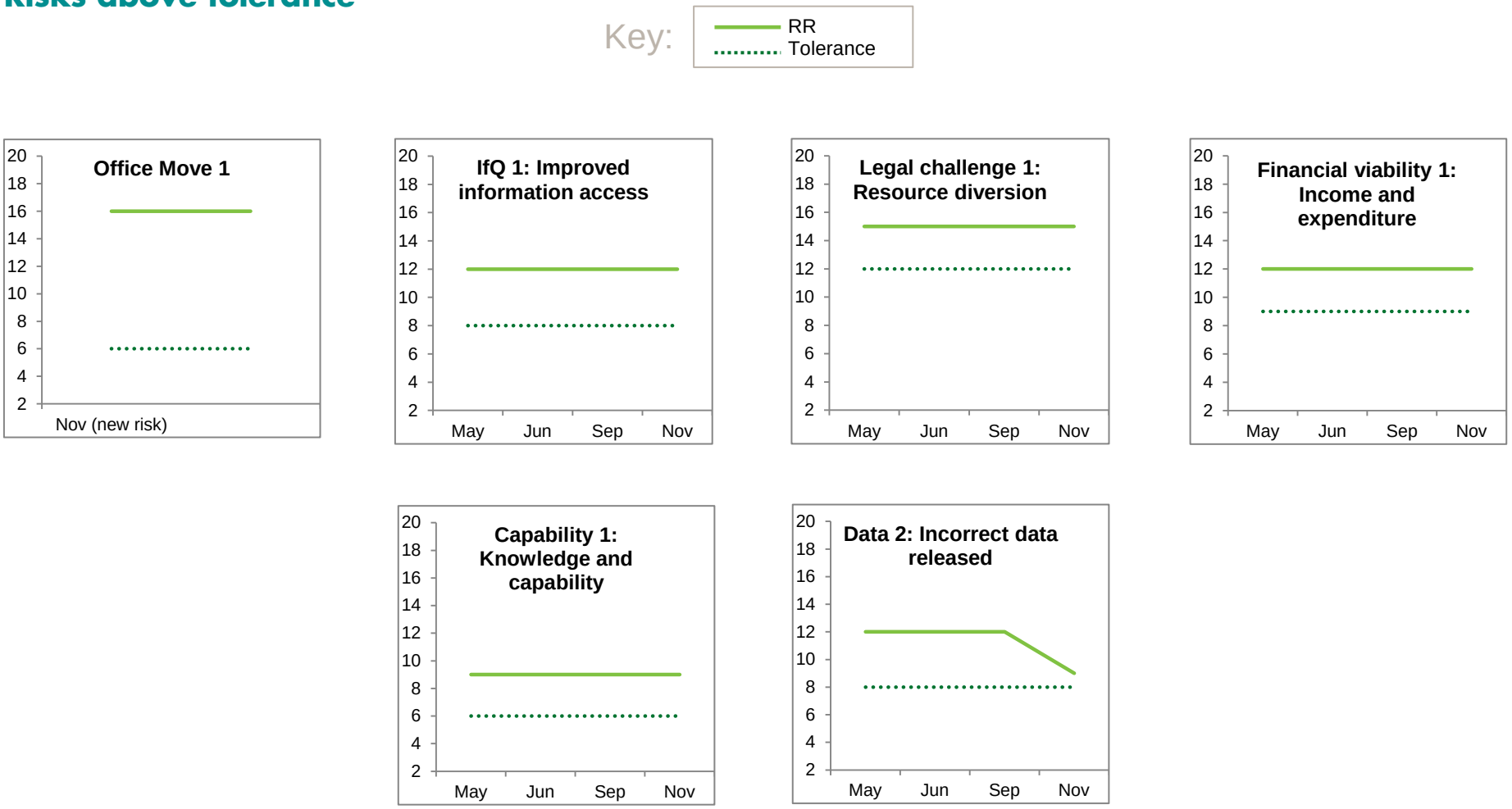
Causes / sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Contractual risks.	Contract being drafted by NICE. Signing should follow shortly.	By early December 2015 - Sue Gallone	Above tolerance for now, until more detailed planning and assurance work has been done. This is underway. We feel that the likelihood should be able to be reduced as soon as certain things have been resolved, eg, contract signed, staff engagement group fully started up, Office 365 implications and timing of any data migration clearer. All these things are being actively worked on now.
Preparation and space planning risks, including establishing clarity about the facilities available in the building (eg, lockers).	Project manager in place. Staff engagement group being established. Detailed information becoming available about the new office space. Visits started, building relationship with NICE facilities team.	From now until the move – Jamie Munro	
Storage availability will be limited. The HFEA has some unavoidable paper records in Register team, Legal, Finance.	Planning work being done to identify unavoidable paper records, and to determine whether any of these can be scanned to reduce storage needs.	For resolution by end of January 2016 – Jamie Munro	
The office will be shared, and there will be generally less space, and limited meeting room availability.	The meeting room risk mainly applies to smaller meetings such as one to ones. Larger meeting room availability in the building is manageable. Meeting rooms are being secured in advance from April/May onwards (on a like-for-like basis). Staff engagement group to consider cultural and ways of working impact of having less ‘free space’ in which to have impromptu or small meetings. Trips to the new office will be planned so that staff can see the space. Our IT kit will be replaced with laptops/tablets before the move, so that smaller desks will not be an issue. There will be preparation planned in before the move, to deal with the reality of reduced storage (eg, ‘Tidy Fridays’ etc. - but staff capacity for this will be very limited owing to IfQ and other high workloads).	From now until the move and slightly beyond – Jamie Munro	

The actual move – practical risks.	We will be moving minimal kit and no desks, reducing both risk and cost. Detailed planning and communications will take place with all involved, including contractors, NICE and HFEA staff. Following procurement framework to select contractors, and selecting carefully.	From now until the move – Jamie Munro
Cabling risks – ensuring communications lines are available to HFEA in new office.	Establish needs and place orders as necessary.	From now until the move – David Moysen
IT risks (information security, business continuity, introduction of new equipment and Office 365 upgrade in advance of move).	Office 365 upgrade project in place to include issuing of new laptops. Register safeguards will be put in place; security of new Comms Room will be considered with NICE. Business continuity plan already in place, and arrangements will continue for now – to be reviewed after move. Planned timing of surrounding tasks (eg, IfQ milestone delivery) will need to allow for some down-time. Back-ups will continue and will be stored off site as now.	From now until the move and slightly beyond – David Moysen
People risks: resources to participate in planning, packing etc., turnover and/or extra management work resulting from change of location, engagement on ways of working, willingness to adapt etc.	Staff engagement, communications and HR contractual considerations built into project plan. Staff engagement group being established and first meeting being planned. Staff being issued with new, smarter IT kit, including tablets/laptops replacing PCs, a better access method for secure HFEA login, and Office 365 available.	In place and ongoing – Jo Triggs
Diversion from business. Coincides with the delivery period for some IfQ milestones, which are key to delivering	Early awareness of the potential for disruption means that this can be managed through careful	Detailed planning and awareness raising beginning in November – Paula Robinson (and all managers)

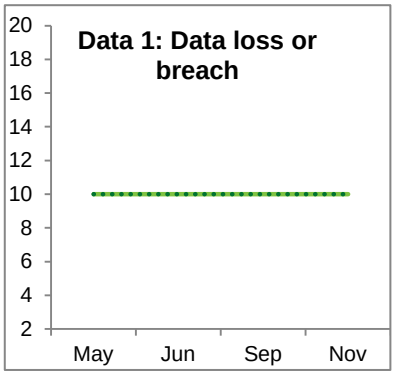
our strategy to publicly announced timescales. Some other work will also coincide because of year-end considerations.	planning and prioritisation.		
Cost increase compared to current rent.	Unavoidable, but in keeping with DH requirements which will reduce costs overall for the health ALBs as a whole group. Costs factored into to funding required from 2016/17. Business case includes ensuring the HFEA is in line with Government Estates Strategy.	In place – Sue Gallone	
Project failure - The move could fail to take place if unforeseen issues arise, or the timetable could be jeopardised by factors outside the HFEA's control.	Contract will shortly be secured and planning is in place. Should the new building become unavailable for some reason, at any point, (eg, fire, flood), business continuity arrangements would apply while a new plan was put in place. (There is no option to stay on in Finsbury Tower beyond April.)	Detailed risk-based planning in place – Jamie Munro	

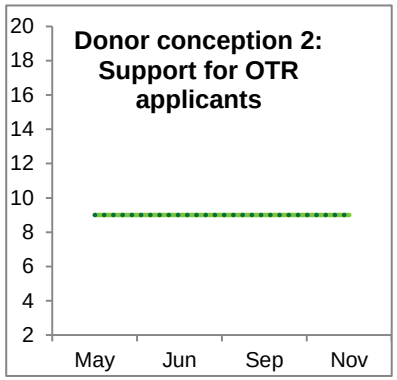
Tolerance vs Residual Risk:

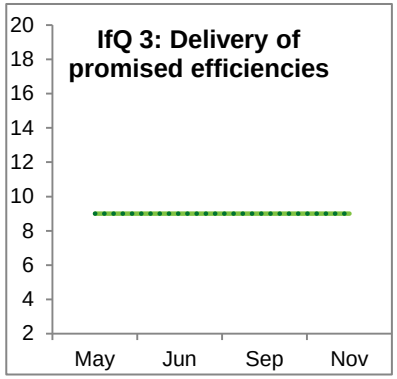
Risks above tolerance

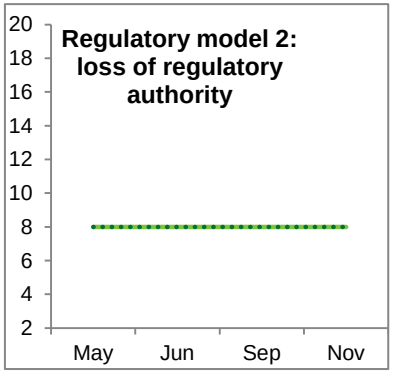


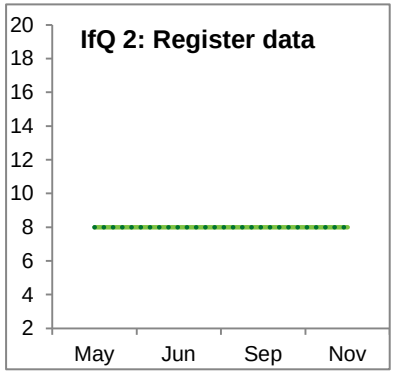
Risks at tolerance

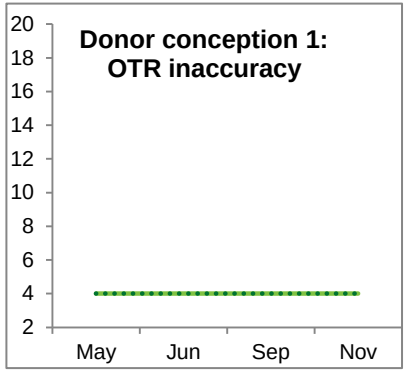












Risk below tolerance

None.

Scoring system

The HFEA uses the five-point rating system when assigning a rating to both the likelihood and impact of individual risks:

Likelihood:	1=Very unlikely	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Insignificant	2=Minor	3=Moderate	4=Major	5=Catastrophic

Risk scoring matrix

Impact	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
5.Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
4. High	4 Low	8 Medium	12 High	16 High	20 Very High
3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium

Risk Score = Impact x Likelihood

Likelihood

HFEA Internal Audit Progress Report

1) Purpose of paper

This paper sets out the progress to against the 2015/16 Audit Plan since the last Audit and Governance Committee in October 2015.

2) Progress against 2015/16 Internal Audit Plan

2.1 Status of agreed plan:

The table below summarises the progress against each of the review areas in the 2015/16 Audit Plan.

Reviews per 2015/16 IA plan	Audit scope per 2015/16 plan	Status	Findings			Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			High	Medium	Low				
Requests for Information	The HFEA may be required to release information as a result of: • Parliamentary Questions (PQs); • Freedom of Information (FOI) requests; and • Data Protection (DP) requests. We will examine current policies and procedures for the release of information under these circumstances and consider whether: • Current policies and procedures cover all relevant information held by the HFEA to which PQs, FOI and DP requests might relate; • Authorisation for the release of information is restricted to the appropriate committees and/or individuals; and • Risks in relation to the release of sensitive information have been identified, are regularly monitored, and are aligned to mitigating	Final report issued 26/10/15	0	2	2	**Moderate**	15	10.5	10.5

Reviews per 2015/16 IA plan	Audit scope per 2015/16 plan	Status	Findings			Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			High	Medium	Low				
	controls.								
Incident Handling	It is a requirement of licensed centres to report adverse incidents to the HFEA, where adverse incidents are described as 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre.' NOTE: there are circa 500 incidents raised in each year in relation to circa 50,000 activities undertaken by the clinics. These incidents must be notified to the HFEA within 24 hours of their taking place. Once these reports are received, the HFEA must investigate the incident and respond in line with its Compliance and Enforcement Policy. In addition, HFEA has a responsibility to review and respond to complaints made against clinics. Circa 10 complaints are received each year. We will review current policies and procedures relating to incident and complaints reporting and responses and consider whether: • The HFEA's responses to reported incidents and complaints in the 12 months to the date of fieldwork have been conducted in line with agreed procedures; • The HFEA produces and retains sufficient documentation to support its response to incident and complaint reports; • Clear and sufficient information is available to all licensed centres to encourage the timely and	Final report issued 24/11/15	0	0	6	**Moderate**	12	10	10

Reviews per 2015/16 IA plan	Audit scope per 2015/16 plan	Status	Findings			Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			High	Medium	Low				
	appropriate reporting of adverse incidents and complaints; • HFEA has appropriate performance reporting of all incidents and complaints in order to make appropriate management decisions on their relationships with the clinics.								
Data Migration – Register of Treatments	Building on the 2014/15 'Register of Treatments' review, we will: • Provide 'critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database; • Test a sample of data between the old and new Registers to verify the accuracy and completeness of data.	First update memo issued September 2015	N/A – No ratings provided			N/A	12	10.5	3
Assurance mapping	The focus of assurance mapping of 'capacity and resilience' has been agreed with the Director of Finance and Resources and the Head of Business Planning.	Final ToR issued 27/11/15. Workshop agreed for 10/02/15	N/A – No ratings provided			N/A	0	3	1
Audit Management	All aspects of audit management to include: • Attendance at liaison meetings and HFEA Audit and Governance committees; • Drafting committee papers/progress reports; • Follow-up work; • Drafting 2016/17 audit plan; • Resourcing and risk management; and • Contingency.	Ongoing	N/A – No ratings provided			N/A	8.4 (inc. 2.4 days c/f from 14/15)	8.9	7
		Total Findings:	**0**	**2**	**8**				
						Total days	**47.4**	**42.9**	**31.5**

2.2 Summary of reports issued since the last Audit and Governance Committee:

Since the last Audit and Governance Committee in October 2015 we have issued:

- The final Request for Information report; and
- The final Incident Handling report.

A summary of the findings from these reports are set out overleaf.

Requests for information (*Overall report rating: MODERATE*):

- **Policies and Procedures are overdue for review (*No rating)***
  It was noted that the Information Access Policy (last updated October 2010) and Information Access SOP (last updated in June 2012) were overdue for review at the date of the audit, and the PQ SOP was under review at the audit date (previously reviewed in October 2011). However, given that an overall finding around outdated policies was raised as part of the Internal Policies review in 2014/15 (Ref: HFEA201415003, Finding #2), we have not raised this as a detailed finding in Section 2 of the report.

- **Formal written authorisation is currently not required prior to submission of responses to PQs and FOI requests *(Medium)***
  The PQ SOP states that the Chief Executive is required to sign-off all PQs prior to submission of responses. However, formal written authorisation is currently not required and therefore it was not possible to see evidence of this authorisation taking place during our audit testing. In addition, whilst responses to FOI requests are signed off by the Information Access and Policy Manager, again no formal written authorisation was available to demonstrate this.

- **Failure to meet the 48 hour deadline for PQs in two cases since 1st January 2015 was at least in part due to staff availability *(Medium)***
  HFEA have missed the 48 hour deadline for PQs in two out of 75 cases since the start of the calendar year. In both cases, the reason was in part staff availability, where the staff members required to respond to the request were not available to prepare the response. This suggests that there may be a business resilience risk that requires addressing, to ensure that KPIs are not breached, and prevent damage to HFEA's reputation.

- **The audit trail held on TRIM (the Authority's Information Management system) for PQs is not currently sufficient to show how policies and procedures have been adhered to *(Low)***
  Currently the only information held on TRIM to show the PQ response process for each request is the draft response prepared to send back to parliament. Information on the date the initial request was received, and the date that the initial response was sent back to the Department of

Health, however, is not stored on TRIM. Whilst this information was made available from staff members' email inboxes for the purposes of the audit testing, there is a risk that key audit trail evidence is lost if not held on TRIM.

- **There is scope to improve the PQ log to allow for easier access to groups of similar requests, and access rights to the PQ log are not currently restricted *(Low)***
  As noted above, a new PQ log was introduced prior to the 2015 summer parliamentary recess, with the aim of ensuring accessibility to previous similar PQs and therefore the consistency of responses provided. Whilst the log is not yet fully operational, the aim going forward is that it will list all PQs received, and responses given. It was noted that currently any staff member at HFEA can access and edit the PQ log. Access to edit the log should be restricted to the appropriate individuals.

Incident Handling (*Overall report rating: MODERATE*):

- **The Risk Matrix in the policy is not entirely reflective of the incident severity grading in practice *(Low)***
  There is a Risk Matrix that has been developed which is designed to show how incidents will be assessed according to the severity of incidents and near misses, and the likelihood of recurrence. However, as drawn it is not entirely reflective of incident severity grades in practice and therefore should be reviewed.

- **Policies and Procedures are overdue for review *(Low)***
  At the time of our review a number of policies and procedures were under review. The SOP for managing patient complaints and SOP for management of Grade A adverse incidents were both last updated in August 2012, the SOP for management of the Grade B and C adverse incidents was last updated in November 2011, and the Compliance and Enforcement Policy in October 2011. Management need to complete the process of updating the policies and procedures.

- **Rationale for closure of a complaint is not documented within the Epicentre system *(Low)***
  We identified one complaint from our sample of five where the complainant had indicated that they were not satisfied with the response to the complaint. In such circumstances the SOP indicates that there would be further follow up. In this particular instance we understand that it was felt that further correspondence would not change the outcome and might be unhelpful, so no further actions were taken but this rationale was not formally documented.

- **Performance reporting of incidents and complaints is not formalised *(Low)***
  We understand that the number of incidents and complaints are reported to, and discussed within, management and trends monitored. However, there are no formal reports or evidence of discussion in meetings to demonstrate that this is taking place.

- **Some documents on the Epicentre system cannot be opened *(Low)***
  We noted that some Word documents (six that we found) cannot be opened from Epicentre due to IT issues. The documents can, if required, be found and opened on TRIM.

2.3 Follow-up work:

The HFEA performs its own follow-up work where it reviews the status of agreed audit actions prior to each Audit and Governance Committee.

As such, Internal Audit has been asked to provide independent assurance only over those agreed actions which relate to high priority recommendations. This approach was agreed with the Director of Finance and Resources.

No high risk issues have been raised as part of the 2015/16 plan. However, two high risk issues from the 2014/15 Internal Policies review were outstanding at date of our last IA progress report in October 2015, and are therefore reviewed below.

Below is the current status for both of the two high risk issues:

	Complete
	In progress (within agreed timescale)
	In progress (original timescale elapsed)
	No action yet taken

Name of Audit	Issue	Management Action	Responsible Officer and Timescale	Current Status
Internal Policies Review	Completeness of register and allocation of ownership of register and policies. The register is not complete, with policies currently available to staff not being included within the register. We understand that a staff member from the Governance and Licensing team has been allocated from January 2015 with responsibility for keeping the register up to date going forward and liaising with individual departments to ensure that policies are current and reflect best practice.	Complete list to be compiled, to specification outlined in recommendation. Proposals for priority of update/ streamlining of policies to be considered by SMT.	Complete list to be in place by end April 2015. Priorities/streamlining of policies to be considered by SMT by end August 2015 Both actions owned by Head of Governance and Licensing (HoGL)	SMT have reviewed and approved the proposed SOP for the maintenance of policies, including the register and timetable for completion of the outstanding policies.
Internal Policies Review	The majority of policies evidenced on the register are past their revision date and are not subject to version control. From review of 46 HFEA policies on the Register, we found that only two were up to date as at the date of this review.	SMT to give consideration to process to be used to introduce/	Set process for introduction/revision/ monitoring of policies to be in place by end	As above.

Name of Audit	Issue	Management Action	Responsible Officer and Timescale	Current Status
	There are also no set procedures for documentation standards for policy creation or the subsequent monitoring of policies. We note from discussion with Heads of departments that the organisation had gone through a period of uncertainty in previous years insofar as its main responsibilities were considered for transfer to the Care Quality Commission, and that this may have delayed the proactive update of policies. Subsequent to the decision by Government to not progress this transfer further in January 2013, and also to not pursue a further proposal to merge the Human Tissue Authority and HFEA, as announced by the Department of Health in July 2013, Heads of departments have begun to re-engage with the process of ensuring that policies are reviewed and up to date. We note the uniform and positive view from all Heads of departments to ensure that this is now addressed as a matter of urgency.	revise/monitor policies, proportionate to size of HFEA and number of functions	June 2015 Owner: HoGL	

2.4 Impact on Annual Governance Statement:

All reports issued with a high risk rating or report findings that are individually rated high risk will have an impact on the Authority's Annual Governance Statement (AGS). To date, no high risk issues have been raised as a result of work undertaken during 2015/16. However, if the high risk issues remain outstanding by the end of 2015/16, they should again be referenced in the AGS.

Internal Audit coverage 2013/14 - 15/16:

Review area	High-level scope	2013/14	2014/15	2015/16
Strategy/Compliance				
Francis and McCracken	Robust arrangements are in place to respond to the recommendations of the Francis and McCracken reports.	4		
Corporate Governance	An assessment of the efficacy of key HFEA committees	4		
Risk Management	Review and testing of the arrangements in place for managing risk at all levels across HFEA, including monitoring, filtering and escalation processes.	4		
Internal Policies	Review of the HFEA's arrangements to monitor, review and refresh key policies, procedures and terms of reference.		4	
Operational				
Requests for information	Review of policies and procedures in relation to Parliamentary Questions (PQs), Freedom of Information (FOI) requests and Data Protection (DP) requests.			4
Incident Handling	Review of current policies and procedures relating to incident and complaints reporting and responses			4
Financial				
Payroll and expenses	Accuracy and completeness of payments payroll and expense payments. Compliance with HMRC rules of payments for expenses and emoluments made to committee members	4		
Standing Financial Instructions	Assurance over current standing financial instructions, including a comparison with HFEA's existing arrangement versus good/best practice.		4	
Information Technology				
Information for Quality	Assurance over the IfQ programme using PwC's 'Twelve Elements Top Down Project Assurance Model'.		4	
Register of treatments	'Critical friend' input into key project meetings in relation to the migration of data to the new register of treatments.		4	
Data migration – Register of treatments	'Critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database. Testing a sample of data between the old and new Registers to verify the accuracy and completeness of data.			4

Appendix A – Report Rating Definitions

Substantial	In my opinion, the framework of governance, risk management and control is adequate and effective.
Moderate	In my opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In my opinion, there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	In my opinion, there are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

Appendix B - Limitations and responsibilities

Internal control

Internal control systems, no matter how well designed and operated, are affected by inherent limitations. These include the possibility of poor judgment in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Future periods

Historic evaluation of effectiveness is not relevant to future periods due to the risk that:

- the design of controls may become inadequate because of changes in operating environment, law, regulation or other; or
- the degree of compliance with policies and procedures may deteriorate.

Responsibilities of management and internal auditors

It is management's responsibility to develop and maintain sound systems of risk management, internal control and governance and for the prevention and detection of irregularities and fraud. Internal audit work should not be seen as a substitute for management's responsibilities for the design and operation of these systems.

We endeavour to plan our work so that we have a reasonable expectation of detecting significant control weaknesses and, if detected, we shall carry out additional work directed towards identification of consequent fraud or other irregularities. However, internal audit procedures alone, even when carried out with due professional care, do not guarantee that fraud will be detected.

Accordingly, our examinations as internal auditors should not be relied upon solely to disclose fraud, defalcations or other irregularities which may exist.

This report has been prepared solely for the Human Fertilisation & Embryology Authority in accordance with the terms and conditions set out in our engagement letter with the Department of Health. We do not accept or assume any liability or duty of care for any other purpose or to any other party. This report should not be disclosed to any third party, quoted or referred to without our prior written consent.

Our Internal audit work has been performed in accordance with Public Sector Internal Auditing Standards (PSIAS). As a result, our work and deliverables are not designed or intended to comply with the International Auditing and Assurance Standards Board (IAASB) and International Framework for Assurance Engagements (IFAE).

Health Group Internal Audit

REFERENCE NUMBER: DHX215008002
FINAL REPORT
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY
NOVEMBER 2015

Health Group Internal Audit provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arms length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

Health Group Internal Audit focuses on business priorities and key risks, delivering its service through three core approaches across all corporate and programme activity:

- Review and evaluation of internal controls and processes;
- Advice to support management in making improvements in risk management, control and governance; and
- Analysis of policies, procedures and operations against good practice.

Health Group Internal Audit findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and its arms length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

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INCIDENT HANDLING

Overall report rating: Moderate

CONTENTS **PAGE**

Date fieldwork completed:	**05 October 2015**
Staff survey results available	**22 October 2015**
Staff survey results assessed	**28 October 2015**
1st draft report issued:	**28 October 2015**
Management responses received:	**19 November 2015**
Final report issued	**24 November 2015**

Report Author:	Umair Khan
Version №:	2
Date:	24/11/2015

Health Group
Internal Audit

Distribution List – Draft Report

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Distribution List – Final Report

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1. Introduction

1.1 This review has been undertaken as part of the 2015/16 Internal Audit Plan which was approved by the Audit and Governance Committee.

1.2 It is a requirement for licensed centres to report adverse incidents to the HFEA, with adverse incidents defined as 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre'. There are approximately 500 incidents reported each year from around 50,000 activities undertaken by clinics.

1.3 All incidents must be notified to the HFEA within 24 hours of them taking place. Once reports are received, the HFEA must consider the issue, investigate (if appropriate) and respond in line with its adverse incident management protocols. Incidents reported to HFEA are graded A, B and C according to their severity and likelihood of recurrence, with A being the most severe. Category A and more severe Category B incidents would lead to an investigation. In the 12 months to September 2015, there were 434 incidents reported which included one Grade A, 185 Grade B and 251 Grade C.

1.4 We have reviewed procedures relating to incident handling and complaints management. This included whether:

- The HFEA's responses to reported incidents and complaints in the 12 months to the date of fieldwork has been in line with agreed procedures;
- The HFEA produces and retains sufficient documentation to support its response to incident and complaints received;
- Clear and sufficient information is available to all licensed centres to encourage the timely and appropriate reporting of adverse incidents and complaints; and
- HFEA has appropriate performance reporting of all incidents and complaints in order to make appropriate management decisions on their relationships with the clinics.

1.5 In addition, within this review we have considered HFEA's management of complaints. HFEA has a limited responsibility to review and respond to complaints made against clinics where the matter indicates that a clinic may not have complied with the terms of its licence, including if a clinic has not followed its own complaints process in dealing with a complaint. We understand that approximately 60 patient "queries" are received annually, of which perhaps 10 might represent formal complaints that warrant further investigation. Queries will typically relate to matters that centres should respond to under their own complaints process, but will be deemed formal complaints if it is established that the matter concerns either non-compliance with the licence or if a

centre has failed to follow its complaints process. In the year from 1 October 2014, HFEA had received 73 queries, of which 13 had been deemed formal complaints.

1.6 As part of our work we tested a sample of 25 incidents, including the Grade A, 10 Grade B and 14 Grade C incidents. We also reviewed a sample of five formal complaints from the total of 13 in the last 12 months to ensure that matters have been handled by HFEA in line with the Standard Operating Procedures ('SOPs').

1.7 In addition, as a further part of our review we worked with management to develop a survey to clinics to assess the level of awareness of their responsibility for raising incidents with the HFEA and to collate views on the effectiveness of the process. The survey was issued with the Clinic Focus paper in September 2015 which is sent to all clinics (approximately 130) and has a total of around 500 subscribers. The results of the survey have been included in the appendix to this report, although unfortunately there were only eight responses which means the results must be treated with caution.

2. Review conclusion

2.1 The overall rating for the report is **Moderate** - some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.

3. Summary of Findings

3.1 **The Risk Matrix in the policy is not entirely reflective of the incident severity grading in practice**
There is a Risk Matrix that has been developed which is designed to show how incidents will be assessed according to the severity of incidents and near misses, and the likelihood of recurrence. However, as drawn it is not entirely reflective of incident severity grades in practice and therefore should be reviewed.

3.2 **Policies and Procedures are overdue for review**
At the time of our review a number of policies and procedures were under review. The SOP for managing patient complaints and SOP for management of Grade A adverse incidents were both last updated in August 2012, the SOP for management of the Grade B and C adverse incidents was last updated in November 2011, and the Compliance and Enforcement Policy in October 2011. Management need to complete the process of updating the policies and procedures.

3.3 **Rationale for closure of a complaint is not documented within the Epicentre system**
We identified one complaint from our sample of five where the complainant had indicated that they were not satisfied with the response to the complaint. In such circumstances the SOP indicates that there would be further follow up. In this particular instance we understand that it was felt that further correspondence

would not change the outcome and might be unhelpful, so no further actions were taken but this rationale was not formally documented.

3.4 **Performance reporting of incidents and complaints is not formalised.**
We understand that the number of incidents and complaints are reported to, and discussed within, management and trends monitored. However, there are no formal reports or evidence of discussion in meetings to demonstrate that this is taking place.

3.5 **Some documents on the Epicentre system cannot be opened.**
We noted that some Word documents (six that we found) cannot be opened from Epicentre due to IT issues. The documents can, if required, be found and opened on TRIM.

Survey results

3.6 As explained, the number of responses to the Survey means that results need to be treated with caution. However, it is positive that respondents had read the Annual Complaints Report, regularly read Clinic Focus and had used articles and the report on incidents to review local practices. One outcome of note is that two of the respondents stated that they did feel inhibited in reporting incidents, citing the culture at a clinic and job safety, that a report would be scrutinised at a subsequent inspection and HFEA's focus on seeing a reduction in the level of B and C rated incidents as factors This tension will exist as a result of the nature of regulation, but the comments should be taken to highlight the need to continually monitor the balance of communications.

Summary of Findings

3.7 The table below summaries the number of findings by rating:

	High	Medium	Low
Policies and Procedures	0	0	1
Risk Management	0	0	1
Incidents and complaints handling	0	0	2
Documentation	0	0	1
Survey	0	0	1
Total	**0**	**0**	**6**

3.8 Section 2 of this report includes specific and detailed recommendations against observations and findings.

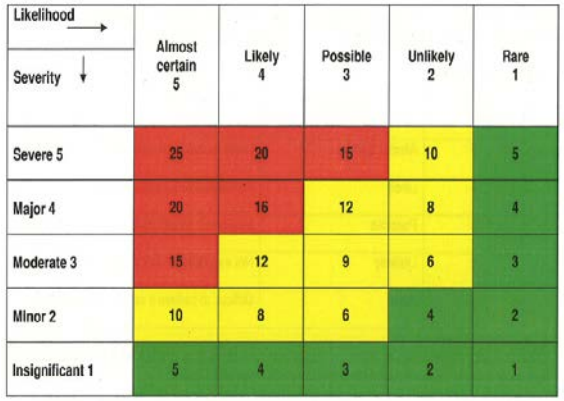
4. Action Required

4.1 Public Sector Internal Audit Standards require you to consider the recommendations made in Section 2; and complete section 3 (Agreed Action Plan) detailing what

action you are intending to take to address the individual recommendations, the owner of the planned actions and the planned implementation date. The agreed action plan will then form the basis of subsequent audit activity to verify that the recommendations have been implemented effectively.

4.2 Finally, we would like to thank management for their help and assistance during this review.

Detailed Findings

<table>
<tr><th>IMPORTANCE</th><th>NO</th><th>FINDING/OBSERVATION</th><th>RISK/IMPLICATION</th><th>RECOMMENDATION</th></tr>
<tr><td>Low</td><td>1</td><td colspan="3"><u>Risk Management</u>
The Risk Matrix in the policy is not entirely reflective of the incident grading in practice</td></tr>
<tr><td></td><td></td><td>Incidents reported to HFEA are graded A (red), B (yellow) and C (green) according to their severity and likelihood of recurrence. This is depicted in the policy by way of the following Risk Matrix:
 
<table>
<tr><th>Likelihood →
Severity ↓</th><th>Almost certain 5</th><th>Likely 4</th><th>Possible 3</th><th>Unlikely 2</th><th>Rare 1</th></tr>
<tr><td>Severe 5</td><td>25</td><td>20</td><td>15</td><td>10</td><td>5</td></tr>
<tr><td>Major 4</td><td>20</td><td>16</td><td>12</td><td>8</td><td>4</td></tr>
<tr><td>Moderate 3</td><td>15</td><td>12</td><td>9</td><td>6</td><td>3</td></tr>
<tr><td>Minor 2</td><td>10</td><td>8</td><td>6</td><td>4</td><td>2</td></tr>
<tr><td>Insignificant 1</td><td>5</td><td>4</td><td>3</td><td>2</td><td>1</td></tr>
</table>
When we reviewed the grading of our sample of 25 incidents, the gradings applied appeared reasonable to us under the framework but in some cases did not fully align with the matrix. For instance, a severe incident is usually rare and might rightly be graded A, but per the matrix rare incidents are all coloured green regardless of their severity. Similarly, mild to moderate OHSS (Ovarian Hyper stimulation Syndrome) is a known and fairly common side effect of fertility treatment and is graded C in practice, but per the matrix it might be</td><td>There may be uncertainty as to the grading of incidents, which could lead to an inconsistent response and potential for challenge.

In practice, the limited number of staff involved in the process means coding is likely to be consistent, but could be open to question by someone referring to the matrix.</td><td>The risk matrix should be reviewed to see whether it can be updated to better reflect the balance between severity and likelihood of recurrence.</td></tr>
</table>

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		argued to be Grade B as whilst the severity is minor the likelihood is likely or possible.		
Low	**2**	**<u>Policies and Procedures</u>** **Key Policies and Procedures are overdue for review**		
		We noted that a number of key policies and procedures are under review having not been updated for some time: • The SOP for Managing Patient Complaints and that for Managing A grade Adverse Incidents have not been updated since August 2012; • The SOP for Managing B and C grade Incidents has not been updated since November 2011; and • The Compliance and Enforcement Policy has not been updated since October 2011. The version published on the HFEA website states that it is due for review in April 2013. We noted that within the existing policies there are some references to certain systems and processes that are no longer applicable or relevant. However, we recognise that this has been identified by management and that these policies and procedures are already undergoing review. We also noted that the narrative for the Grade A category states that an inspection is required for these	Staff may not be fully aware of the required process for managing incidents and complaints. This could lead to HFEA's response being inappropriate or ineffective. Lapses in process may be more likely to arise if there is staff turnover or if roles have to be reassigned during a period of absence of a key individual. There could be uncertainty as to whether investigation by the HFEA is required in circumstances where there is a severe incident but other bodies are undertaking their own investigations.	Management should ensure that the ongoing review of policies and procedures is completed and revised versions formalised and issued. The updates should take account of the findings from this review. The wording around when an investigation should be undertaken should be reviewed to better describe when HFEA would undertake its own investigation and when it might rely on the results of investigations by others.

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		incidents but we understand that HFEA does not always need to undertake an investigation itself, for instance if it can obtain assurance from external investigations.		
Low	3	**Closure of formal complaints** **Rationale for closure of one complaint in our sample was not formally documented.**		
		We reviewed a sample of five formal complaints and in one instance there was evidence that the complainant was not wholly satisfied with the final correspondence. The SOP indicates that where the complainant is not satisfied, HFEA should advise them that they may request a review by the Head of Clinical Governance within 10 working days of notification of the outcome of the initial consideration. However, in this instance the complaint was closed on the system without any further follow up. The final correspondence from the complainant noted that they did understand that there was nothing further the HFEA could do, but that they remained dissatisfied with their treatment and the service at the particular clinic. The Clinical Governance Lead/Inspector stated that HFEA could have written another letter re-iterating that there is nothing further they could do, but in this case it was felt that it would have only induced further unnecessary correspondence. This rationale for closing the complaint, however, was not documented.	There is a risk of inconsistency, which could lead to challenge and reputational harm if complaints are not fully dealt with in line with the SOP. HFEA may find it harder to demonstrate full compliance with the SOP if the rationale for decisions is not formally recorded on the system.	As best practice, when closing complaints on the system, a rationale should to be documented for closure if it is noted that the complainant is fully satisfied with the response.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
Low	4	**Performance reporting** **Performance reporting of incidents and complaints to management is not documented.**		
		It was confirmed by the Clinical Governance Lead/Inspector that the number of incidents and complaints are reported to, and discussed within, management. This is usually done within her monthly one to one meetings with the Chief Inspector. The numbers and trends are also discussed with Director of Compliance from time to time. However, these meetings are not documented and there are no formal reports so there is limited evidence that management has considered the number and type of incidents and complaints and assessed whether any particular response may be required. In due course, the numbers are summarised within the Annual Report, which states the number and trends of the reported incidents and details any Grade A incidents along with the key learning outcomes are published on the HFEA website.	If the numbers and the resulting trends of incidents and complaints are not appropriately analysed and monitored on a timely basis management may fail to identify potential issues that may have warranted action. If action is not taken where required, then there is increased risk of issues recurring or of policies and procedures not being developed to improve services.	Some formalisation of brief reporting of the number of incidents and complaints and of any relevant trends or other matters should be considered. formalised. This could perhaps be done on a quarterly basis.
Low	5	**Documents accessibility due to IT issue** **Certain documents are not accessible from the Epicentre System**		
		Epicentre is the core system used by HFEA for the management of the incidents and complaints. The incidents are reported via the dedicated outlook mailbox which is accessible to all Clinics' on the HFEA website and these reports along with any	Speed of accessing information may be reduced if staff attempt to find information in Epicentre and then have to go to other systems.	IT Services should identify and seek to remedy the issue causing certain documents not to be openable from Epicentre.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		documentation are then uploaded onto TRIM (Record Management System) and Epicentre. We noted that due to an IT issue certain documents uploaded onto Epicentre cannot be opened. In our testing we identified six attachments in a specific version of Microsoft Word that we could not open. In all cases the documents were also available on TRIM and within the outlook mailbox, and were accessible.		
	6	**Survey Results**		
Low		While the response rate to the survey was low there are some comments that HFEA management may wish to reflect on in terms of enhancements to incident reporting. Please refer to Section 5 of this report for the full survey results. As mentioned in section 1.7 above, the survey was issued with the Clinic Focus paper in September 2015 which is sent to all clinics (approximately 130) and has a total of around 500 subscribers. Unfortunately there were only eight responses which means the results must be treated with caution	Where stakeholders do not see any change a as a result of comments made from such surveys, engagement levels may fall. Not acknowledging appreciation to those who responded to the wider population of subscribers might miss an opportunity to encourage more people to respond to any future surveys.	Send out a thank you communication regarding the survey to the full population and a brief summary of any changes that are planned to be taken as a result of the comments made.

3 Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
1	The risk matrix should be reviewed to see whether it can be updated to better reflect the balance between severity and likelihood of recurrence.	**Low**	Review risk matrix	Accepted by the Clinical Governance Lead who has reviewed the Risk Matrix. It has been revised to reflect the balance between severity and likelihood of recurrence. Waiting for sign off by the Chief Inspector to be completed by 31 December 2015.		
2	Management should ensure that the ongoing review of policies and procedures is completed and revised versions formalised and issued. The updates should take account of the findings from this review. The wording around when an investigation should be undertaken should be reviewed	**Low**	SOP review	Accepted by the Clinical Governance Lead. In process for completion 31 December 2015.		

3 Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
4	to better describe when HFEA would undertake its own investigation and when it might rely on the results of investigations by others.					
3	As best practice, when closing complaints on the system, a rationale should to be documented for closure if it is not that the complainant is fully satisfied with the response.	**Low**	Further information on how to handle an unhappy complainant now added to the complaint handling SOP.	Accepted by the Clinical Governance Lead. Rolled into the SOP update to be completed by the end of December 2015.		
4	Some formalisation of brief reporting of the number of incidents and complaints and of any relevant trends or other matters should be considered. formalised. This could perhaps be done on a quarterly basis.	**Low**	Quarterly meetings now in calendrer	Accepted by the Clinical Governance Lead. The Clinical Governance Lead and the Chief Inspector will meet in December to set the standing agenda and use this first meeting as a “look back” over 2014.		

3 Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
5	IT Services should identify and seek to remedy the issue causing certain documents not to be openable from Epicentre.	**Low**	Liaised with IT regarding this issue	Accepted by the Clinical Governance Lead. There was an issue on our document management server (HP Trim) It seems the service that enables this functionality was offline and after some troubleshooting we have resolved this issue.The Clinical Governance Lead checked the six items that could not be opened via Epicentre at the time of the audit. All six items can now be opened via Epicentre.		
6	Send out a thank you communication regarding the survey to the full population and a brief summary of any changes that are planned to be taken as a result of the comments made.	**Low**	A brief thank you will be sent out in the December edition of Clinic Focus	Accepted by the Clinical Governance Lead. Clinic Focus is sent to over 120 clinics and 500 individual subscribers. Due to the very low volume of responses (8) – no meaningful information was gleaned to make any changes to the current system. Therefore a brief thank you to those that		

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
				participated will be mentioned in Clinic Focus.		

Report Rating - Definitions

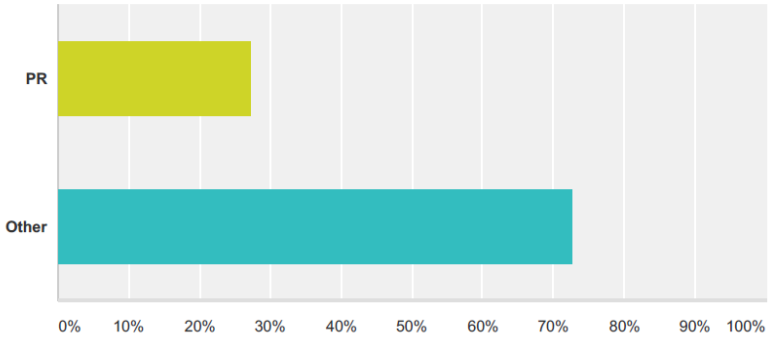
Substantial	In my opinion, the framework of governance, risk management and control is adequate and effective.
Moderate	In my opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In my opinion, there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	In my opinion, there are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

5 Appendix

Appendix – Survey Results

Q1 Please indicate whether you are a PR (Person Responsible) or other clinic staff member.

Answered: 11 Skipped: 0



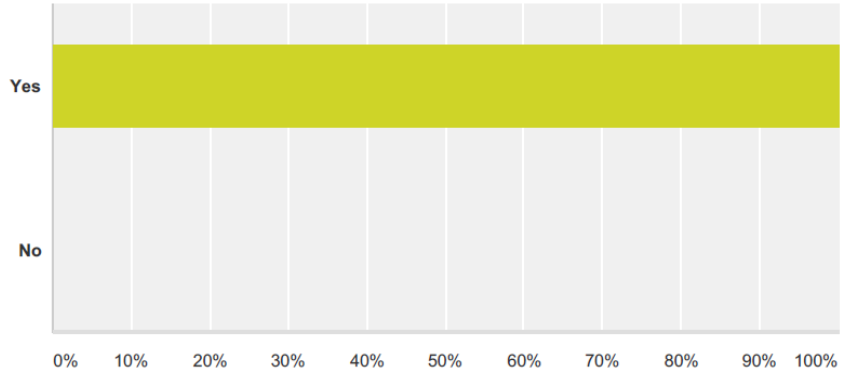
Answer Choices	Responses	
PR	27.27%	3
Other	72.73%	8
Total		11

5 Appendix

Appendix – Survey Results

Q2 Did you read the annual incident report ('Adverse incidents in fertility clinics: lessons to learn')?

Answered: 8 Skipped: 3



Answer Choices	Responses	
Yes	100.00%	8
No	0.00%	0
Total		8

Comments were added by respondents as follows;

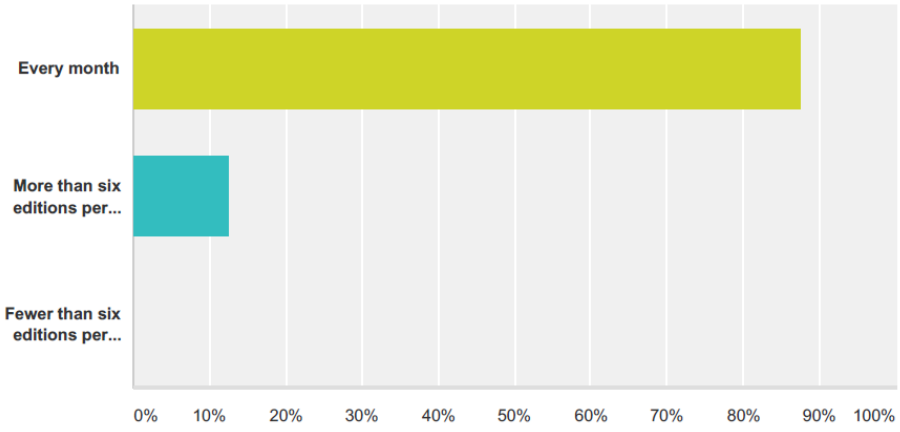
- Yes, admin services have been reviewed.
- Clinic practices have not been changed so far, but we will discuss key learning points at upcoming management meeting to ensure we are following best practice.
- Yes we now produce quarterly incident reports and also an annual report.

5 Appendix

Appendix – Survey Results

Q3 How often do you read the Clinic Focus newsletter?

Answered: 8 Skipped: 3



Answer Choices	Responses	
Every month	87.50%	7
More than six editions per year	12.50%	1
Fewer than six editions per year	0.00%	0
Total		8

Appendix – Survey Results

Q4 Have you reviewed any of your clinic's practices as a result of the articles in Clinic Focus?

Answered: 8 Skipped: 3

7 of 8 respondents who answered this question said that they had reviewed clinic practices in response to articles.

Appendix – Survey Results

Q5 Is there anything you would change about the annual report or Clinic Focus to make them more helpful to your work?

Answered: 7 Skipped: 4

6 of 8 respondents said that there would not change anything. Other comments were:

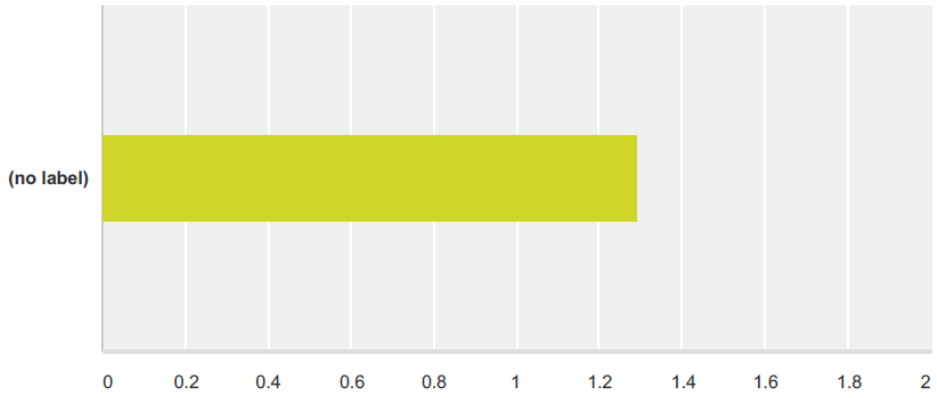
- Annual report could look at trends in lower grade incidents and recommendations from those, and include shared learning from RCAs carried out by clinics.
- In the annual report list more the minor incidents i.e. a brief title for each such as 'wrong sticker put on patient notes'. Some clinics report things that others don't.

5 Appendix

Appendix – Survey Results

Q6 Do you understand your incident reporting responsibilities? Please rate on a scale of 1 (understand completely) to 5 (no understanding).

Answered: 7 Skipped: 4



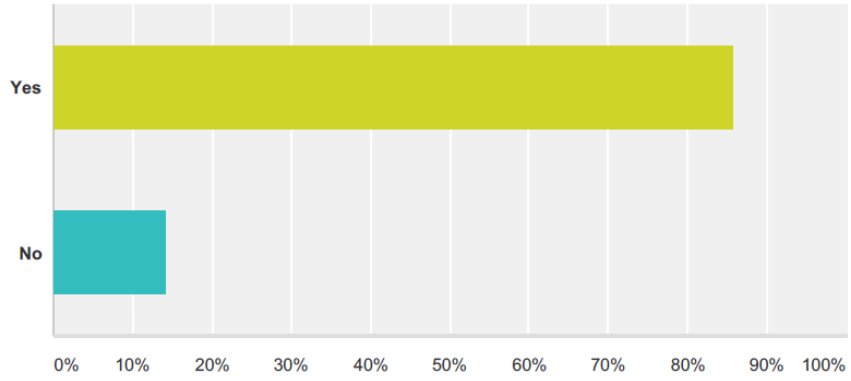
	1	2	3	4	5	Total	Weighted Average
(no label)	85.71% 6	0.00% 0	14.29% 1	0.00% 0	0.00% 0	7	1.29

5 Appendix

Appendix – Survey Results

Q7 Do you think that incident reporting helps you improve the safety and quality of services offered to your patients? If 'No', what could we do to help you achieve this?

Answered: 7 Skipped: 4



Answer Choices	Responses	
Yes	85.71%	6
No	14.29%	1
Total		7

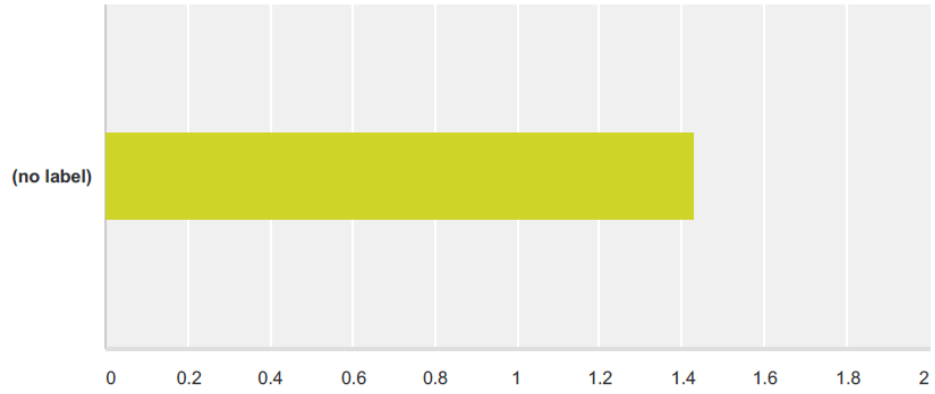
One comment was made explaining the no response: “If we didn’t report incidents we would still do a root cause analysis.

5 Appendix

Appendix – Survey Results

Q8 Is the incident reporting system straightforward to use? If you find it difficult to use, what improvements could you suggest? Please answer on a scale of 1 (very straightforward) to 5 (difficult to use.

Answered: 7 Skipped: 4



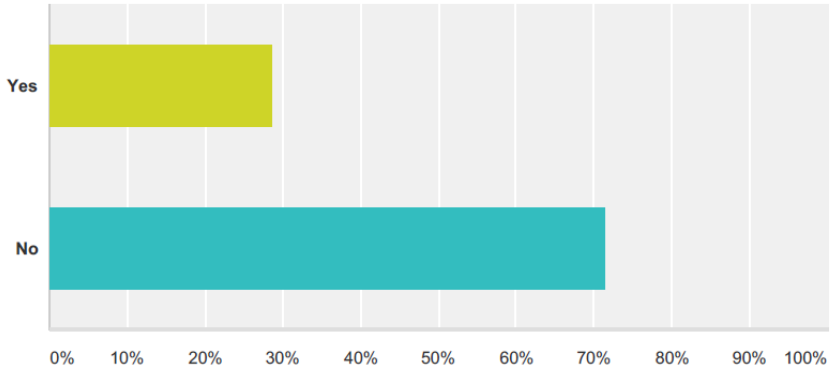
	1	2	3	4	5	Total	Weighted Average
(no label)	71.43% 5	14.29% 1	14.29% 1	0.00% 0	0.00% 0	7	1.43

5 Appendix

Appendix – Survey Results

Q9 Have you ever felt inhibited from reporting an incident?

Answered: 7 Skipped: 4



Answer Choices	Responses	
Yes	28.57%	2
No	71.43%	5
Total		7

The two respondents who commented yes to this question provided further explanation as follows:

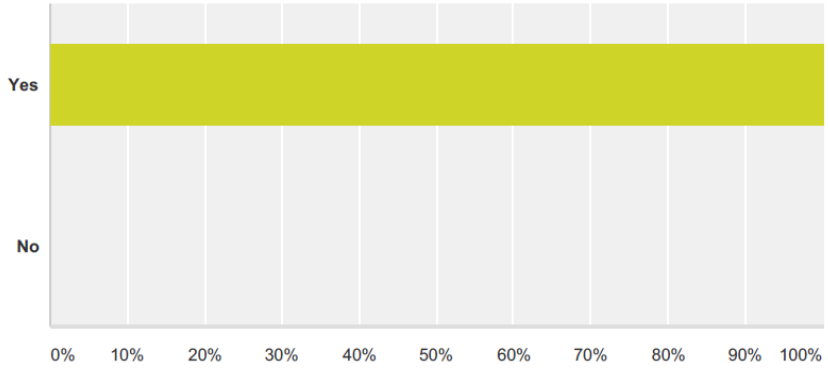
- By culture of clinic, and safety of job. Whistleblowing versus incident reporting can be a very difficult dilemma.
- As a PR any report is expected to be scrutinized at a subsequent inspection as a result consideration for reporting an event can be seen as giving ammunition to the inspection team / making a noose for your own neck.

5 Appendix

Appendix – Survey Results

Q10 Do you think the root cause analyses completed by your clinic are useful in helping you identify how to stop incidents recurring?

Answered: 7 Skipped: 4



Answer Choices	Responses	
Yes	100.00%	7
No	0.00%	0
Total		7

Appendix – Survey Results

Q11 Please provide any other comments you have that will help the HFEA improve your experience of the incident management process.

Answered: 3 Skipped: 8

Clarity from the HFEA, particularly around clinical incident reporting as is currently very vague, would improve meaningful reporting and create a level playing field for clinics.

I feel it is important to encourage an open culture surrounding incidents and the 'no blame' culture is extremely important to encourage openness. I also feel it is important that learning is shared with the entire clinic to prevent re-occurrence and enable learning. I feel the reporting of incidents to the HFEA is simple and straightforward.

HFEA commentary such as "...reducing their grade B and C incidents. Such mistakes are often distressing to patients, largely avoidable and frankly shouldn’t happen..." are frankly not particularly helpful since they themselves can create underreporting. IVF clinics have comparable incident rates to other clinical fields around the world (published evidence!) and as such grade B and C incidents while frustrating are going to happen while humans are involved in the processes. The HFEA ask us to reduce B and C's but in the same breath to ensure we are reporting all incidents. If you want us to report everything then don’t expect the B's and C's to reduce significantly. I can only conclude from the statement above that the HFEA is an error free authority? I've personally seen evidence to the contrary. We are all in this together surely?

Health Group Internal Audit

REFERENCE NUMBER: DHX215010001
FINAL REPORT
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY
OCTOBER 2015

Health Group Internal Audit provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arms length bodies, bringing a disciplined approach to evaluating and improving the effectiveness of risk management, control and governance processes.

Health Group Internal Audit focuses on business priorities and key risks, delivering its service through three core approaches across all corporate and programme activity:

- Review and evaluation of internal controls and processes;
- Advice to support management in making improvements in risk management, control and governance; and
- Analysis of policies, procedures and operations against good practice.

Health Group Internal Audit findings and recommendations:

- Form the basis of an independent opinion to the Accounting Officers and Audit Committees of the Department of Health and its arms length bodies on the degree to which risk management, control and governance support the achievement of objectives; and
- Add value to management by providing a basis and catalyst for improving operations.

For further information please contact:

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REQUESTS FOR INFORMATION

Overall report rating: MODERATE

CONTENTS **PAGE**

Date fieldwork completed:	**11 September 2015**
1st draft report issued:	**22 September 2015**
Management responses received:	**19 October 2015**
Final report issued	**26 October 2015**

Report Author:	Aimee Gibson
Version №:	3
Date:	26/10/2015

Health Group
Internal Audit

Distribution List – Draft Report

Main recipient

Sue Gallone
Juliette Tizzard
Sam Hartley
Charlotte Keen

Cc:

Lynn Yallop (Head of Audit)

Distribution List – Final Report

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Juliette Tizzard
Sam Hartley
Charlotte Keen

Cc:

Lynn Yallop (Head of Audit)

1. Introduction

1.1 This review has been undertaken as part of the 2015/16 Internal Audit Plan which was approved by the Audit and Governance Committee.

The HFEA may be required to release information as a result of:

- Parliamentary Questions (PQs);
- Freedom of Information (FOI) requests; and
- Data Protection (DP) requests.

This review has focussed on the policies and procedures in place to respond to the above types of request, and processes in place to mitigate key risks associated with information access. To put the report findings into context please note the following statistics in terms of requests HFEA have had since January 2015:

- PQs – 75;
- FOIs – 73; and
- DPAs – none within the last two years.

Following discussion with management we have also reviewed, and provided advice where appropriate, on the following areas:

- The introduction, by HFEA, of a new log which has been designed to improve the accessibility of previous responses to PQs. It is clear that this log will serve as a very useful tool for ensuring consistency of responses to PQs, and recommendations for further improvement of this log are provided in Finding #4 below
- The process to review those responses which relate to small numbers of individuals, to ensure that the confidentiality of these individuals is protected. The Authority now have a policy of substituting the number of individuals for '<5' if a response involves less than five individuals, and we have confirmed through our sample testing that this is being consistently applied. Another key element of this new process, due to be rolled out in the months following the audit, is the introduction of a panel of HFEA management who will meet to consider the response to requests that involve small numbers of individuals. This will further decrease the risk of disclosure of identities; and
- We have also reviewed whether the current Key Performance Indicators (KPIs) regime effectively promotes the quality of services in relation to requests for information, beyond meeting minimum statutory requirements.

2. Review conclusion

2.1 The overall rating for the report is **Moderate** - some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.

3. Summary of Key Findings

3.1 **Policies and Procedures are overdue for review**

It was noted that the Information Access Policy (last updated October 2010) and Information Access SOP (last updated in June 2012) were overdue for review at the date of the audit, and the PQ SOP was under review at the audit date (previously reviewed in October 2011). However, given that an overall finding around outdated policies was raised as part of the Internal Policies review in 2014/15 (Ref: HFEA201415003, Finding #2), we have not raised this as a detailed finding in Section 2 of the report.

3.2 **Formal written authorisation is currently not required prior to submission of responses to PQs and FOI requests**

The PQ SOP states that the Chief Executive is required to sign-off all PQs prior to submission of responses. However, formal written authorisation is currently not required and therefore it was not possible to see evidence of this authorisation taking place during our audit testing.

In addition, whilst responses to FOI requests are signed off by the Information Access and Policy Manager, again no formal written authorisation was available to demonstrate this.

3.3 **Failure to meet the 48 hour deadline for PQs in two cases since 1st January 2015 was at least in part due to staff availability**

HFEA have missed the 48 hour deadline for PQs in two out of 75 cases since the start of the calendar year. In both cases, the reason was in part staff availability, where the staff members required to respond to the request were not available to prepare the response. This suggests that there may be a business resilience risk that requires addressing, to ensure that KPIs are not breached, and prevent damage to HFEA's reputation.

3.4 **The audit trail held on TRIM (the Authority's Information Management system) for PQs is not currently sufficient to show how policies and procedures have been adhered to**

Currently the only information held on TRIM to show the PQ response process for each request is the draft response prepared to send back to parliament. Information on the date the initial request was received, and the date that the initial response was sent back to the Department of Health, however, is

not stored on TRIM. Whilst this information was made available from staff members' email inboxes for the purposes of the audit testing, there is a risk that key audit trail evidence is lost if not held on TRIM.

3.5 **There is scope to improve the PQ log to allow for easier access to groups of similar requests, and access rights to the PQ log are not currently restricted**

As noted above, a new PQ log was introduced prior to the 2015 summer parliamentary recess, with the aim of ensuring accessibility to previous similar PQs and therefore the consistency of responses provided. Whilst the log is not yet fully operational, the aim going forward is that it will list all PQs received, and responses given. It was noted that currently any staff member at HFEA can access and edit the PQ log. Access to edit the log should be restricted to the appropriate individuals.

Summary of Findings

3.6 The table below summaries the number of findings by rating:

	Total recs	High	Medium	Low
Policies and Procedures	3	0	2	1
PQ response log	1	0	0	1
Requests involving small numbers	0	0	0	0
KPIs	0	0	0	0

3.7 Section 2 of this report includes specific and detailed recommendations against observations and findings.

4. Action Required

4.1 Public Sector Internal Audit Standards require you to consider the recommendations made in Section 2; and complete section 3 (Agreed Action Plan) detailing what action you are intending to take to address the individual recommendations, the owner of the planned actions and the planned implementation date. The agreed action plan will then form the basis of subsequent audit activity to verify that the recommendations have been implemented effectively.

4.2 Finally, we would like to thank management for their help and assistance during this review.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
Medium	**1**	**Policies and Procedures** **Formal written authorisation is currently not required prior to submission of responses to PQs and FOI requests**		
		All PQs are required to be signed off by HFEA's Chief Executive, as outlined in the PQ SOP. However, discussion with management, and detailed testing of 20 PQs confirmed that a written record of this authorisation is currently not required. On the morning that the response must be submitted, a meeting will be held with the Chief Executive, Information Access and Policy Manager and other relevant staff and the Chief Executive will sign off the response. However minutes are not taken in these meetings and there is no formal written record of sign-off, due to the quick turnaround time for PQs. In addition, responses to FOI requests are reviewed by the Information Access and Policy Manager prior to submission. Again, this is currently done via a verbal meeting held between the Information Access and Policy Manager and the staff member(s) who have prepared the response. However there is no formal requirement for written authorisation to be obtained and held on file prior to the response being submitted. Whilst the Information Access SOP does	Without formal written authorisation of final responses to PQs or FOI requests before they are sent out, there is not a sufficient audit trail on file to show that the requests have been responded to in line with HFEA's policies and procedures. Were HFEA to receive a complaint or enquiry on a particular request, it may be important for HFEA to be able to demonstrate that it has followed its own internal procedures, and that the response was prepared and authorised appropriately.	A written record of authorisation of PQ and FOI responses should be required in all cases, and held on TRIM. This written record could be in the form of minutes taken during meetings held with the authoriser or via an email or other form of written authorisation.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		not explicitly state that the Information Access and Policy Manager must sign off all FOI responses, as best practice a written record of sign-off should be available on file.		
Medium	**2**	**Policies and Procedures** **Failure to meet the 48 hour deadline for PQs in two out of 75 cases since 1st January 2015 was at least in part due to staff availability**		
		As part of the audit testing for this review, 20 PQs were sampled, and supporting evidence viewed, in order to validate that the 48 hour deadline had been met. In two out of these 20 cases, the 48 hour deadline was missed. In one instance (PQ ref HL5228) the response was late because the staff member required to deal with the request was not available. In the second instance (PQ ref HL4885), the late response was in part due to the complexity of the question and data, but again in part due to staff availability. Given that both of these instances were at least in part due to staff availability, this suggests that there may be a business resilience risk that requires addressing.	HFEA fail to meet their KPIs due to staff availability issues. This could cause significant reputational damage and affect the timing of parliamentary decisions.	Whilst it is understood that the nature of having a small team means staff availability will often be a key constraint, HFEA should ensure, where possible, that there are always at least two staff members at the Authority who can respond to each type of request. HFEA should carry out an analysis into the types of requests received, and staff members who are able to respond to these requests, in order to identify request types where responses are currently reliant on one individual.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
Low	3	**Policies and Procedures** **The audit trail held on TRIM for PQs is not currently sufficient to show how policies and procedures have been adhered to**		
		HFEA is notified of PQs via a daily email from the Department of Health (DoH), and upon receipt of this email HFEA have 48 working hours to respond to the request. Compliance with the 48 hour timeframe is measured by when HFEA sends its initial response back to DoH. Following this, there will often be a number of email exchanges between DoH and HFEA in order to ensure DoH are also happy with the response. Information on the date the initial request was received, and evidence to show that the request was responded to within the 48 hour deadline, is not stored on TRIM. Currently, only a copy of the draft response is held on TRIM (Note: As part of our testing of 20 PQs, the above information was made available, as whilst not on TRIM it is currently stored in staff email inboxes). Discussion with management confirmed that due to the volume of email exchanges that can occur between the DoH and HFEA before the final response is sent, it is not deemed efficient to store all of this	Without a clear audit trail on TRIM, there is a risk that key audit trail information relating to PQs may be lost, as it is currently stored in email inboxes. As a result, HFEA may be unable to demonstrate how it followed its policies and procedures as well as compliance with the 48 hour response deadline.	Sufficient information should be stored on TRIM for HFEA to be able to demonstrate that it has followed its internal policies and procedures, as well as meeting the 48 hour deadline for PQ responses. Information held on TRIM should therefore include as a minimum: • Details of the date that the request was initially received from DoH. • Written evidence of authorisation of the initial response (as noted in Finding #1) sent to DoH. • Email evidence showing the initial response sent out to DoH request was responded to within the 48 hour deadline, to show that the KPI has been met. • Details of the final response agreed between the DoH and HFEA (in the form of email exchanges), once email

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		information on TRIM. Going forward, HFEA plan to include information relating to PQ responses on the new PQ log that is now in place which will list all PQs that are received, and the responses provided to these PQs. However, there is still scope to include key information on TRIM. It is noted that for FOI requests, the information currently included on TRIM includes details of the initial request received and the date received, as well as the final response sent out to the requestor, allowing HFEA to show that they complied with the 20 working day response timeframe for FOI requests.		exchanges have taken place.
Low	**4**	**PQ Response log** **There is scope to improve the PQ log to allow for easier access to groups of similar requests, and access rights to the PQ log are not currently restricted**		
		Shortly prior to the summer parliamentary recess, a PQ response log was introduced. Whilst the log is not yet fully operational, going forward the PQ log will list all PQs received, and responses given, and the log is designed to allow for easy searching of similar requests, so that HFEA ensures its responses are consistent with that of previous requests. It was noted that the log can currently be	If access to the PQ log is not sufficiently restricted, there is a risk that edits may be made to the log that are inaccurate, and that the log therefore does not accurately reflect PQs that HFEA have received and responded to.	Access to edit the PQ log should be restricted to those staff members who are responsible for keeping the log updated.

Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		viewed and edited by any staff member in HFEA. The log is currently held in the Security and Access Policy folder on TRIM. Whilst it may be appropriate for the majority of staff to be able to view this log, editing of this log should be restricted to those who are responsible for maintaining the log.		

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
1	A written record of authorisation of PQ and FOI responses should be required in all cases, and held on TRIM. This written record could be in the form of minutes taken during meetings held with the authoriser or via an email or other form of written authorisation.	**Medium**	As confirmed in the key findings, formal written authorisation is not required within the HFEA SOPs. A written record of authorisation is not sustainable for either FOI or PQs (which are signed off by the Chief Executive) and would only serve to delay submission of responses. This is a particular risk with PQs given the short timeframe between the sign off meeting with the Chief Executive and the deadline for submission.	n/a		
2	Whilst it is understood that the nature of having a small team means staff availability will often be a key constraint, HFEA should ensure, where	**Medium**	The HFEA has missed the deadline twice in 75 cases for PQs. Given the size of the organisation and the small number of staff with	The requirement for resilience on data queries is covered under the Information for Quality programme.		

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

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№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
	possible, that there are always at least two staff members at the Authority who can respond to each type of request. HFEA should carry out an analysis into the types of requests received, and staff members who are able to respond to these requests, in order to identify request types where responses are currently reliant on one individual.		the knowledge and expertise in order to respond to PQs, this is an excellent record of meeting deadlines, as acknowledged by the Department of Health. With the resources available, it is therefore simply not currently possible to ensure there are always two staff members available to respond to each type of request. We can assure, however, that the IfQ programme will address this and enable more members of staff to have access in future to the relevant data in order to respond. It is also worth noting that the HFEA's reputation would be much			

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
			more at risk by providing less accurate responses simply to meet the deadline than failing to meet the deadline itself.			
3	Sufficient information should be stored on TRIM for HFEA to be able to demonstrate that it has followed its internal policies and procedures, as well as meeting the 48 hour deadline for PQ responses. Information held on TRIM should therefore include as a minimum: • Details of the date that the request was initially received from DoH. • Written evidence of authorisation of the initial response (as noted in Finding #1) sent to DoH.	**Low**	The details of the date that the request is initially received from the Department is captured in the PQ log, and saving the initial commissioning email would therefore duplicate issues and serve little purpose in the whole process. Written evidence of authorisation has been addressed in Finding#1. As part of the process it is agreed the email sent to the Department with the proposed response will be saved to Trim as	Information Access and Policy Manager; Log to be updated with TRIM refs for saved final returns; By 30/10/15		

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
	• Email evidence showing the initial response sent out to DoH (as it is this email that is used to demonstrate HFEA's compliance with the 48 hour deadline). • Details of the final response agreed between the DoH and HFEA (in the form of email exchanges), once email exchanges have taken place.		recommended. There would be little point, however in saving email exchanges with details of the final response. This would be labour intensive and could potentially confuse the issue with later, linked PQs. In any event, the only substantive, final response is that which is published in Hansard.			
4	Access to edit the PQ log should be restricted to those staff members who are responsible for keeping the log updated.	**Low**	. It is agreed that any editing rights for the PQ log should be restricted to those members of staff who are responsible for	Head of IT – editing rights to be changed by 30/10/15		

Health Group Internal Audit

Action Plan

Customer to provide details of planned action; owner and implementation date. Action taken will later be assessed by Health Group Internal Audit, and therefore the level of detail provided needs to be sufficient to allow for the assessment of the adequacy of action taken to implement the recommendation to take place.

To be completed by Health Group Internal Audit as part of the recommendation follow-up process

№	RECOMMENDATION	RATING	AGREED ACTION	OWNER & PLANNED IMPLEMENTATION DATE	OBSERVATIONS: RECOMMENDATION / AGREED ACTION IMPLEMENTED?	FURTHER ACTION REQUIRED?
			keeping the log updated.			

Report rating - Definitions

Substantial	In my opinion, the framework of governance, risk management and control is adequate and effective.
Moderate	In my opinion, some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.
Limited	In my opinion, there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.
Unsatisfactory	In my opinion, there are fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail.

Implementation of Audit Recommendations – Progress Report

Strategic delivery	**Setting standards**	☐	**Increasing and informing choice**	☐	**Demonstrating efficiency economy and value**	☒	
Meeting	Audit and Governance Committee						
Agenda item	09						
Paper number	[AGC (09/12/2015) 482 WEC]						
Meeting date	Wednesday, 9 December 2015						
Author	Wilhelmina Crown						
For information or decision?	Decision						
Recommendation	AGC is requested to review the enclosed progress updates and to comment as appropriate.						
Resource implications	As noted in the enclosed summary of outstanding audit recommendations						
Implementation	N/A						
Communication	CMG						
Organisational risk	As noted in the enclosed summary						
Annexes	Annex 1: Summary of Recommendations						

Annex 1: Summary of Recommendations

Recommendation Source	Status / Actions	2015/16	Total
Internal – *DH Internal Audit*	*Complete*	*2*	***2***
External Auditor – *NAO*	*Complete*	*-*	***-***
COUNT		***2***	***2***

1. Report

1.1. This report presents an update to the audit recommendations paper presented to this committee in October 2015.

1.2. The recommendations agreed as completed by this committee in October have been removed.

1.3. The final report and recommendations from the latest audits (Requests for information and Incident handling) will be presented to this meeting. Recommendations from the Requests for information audit are included in this report – Incident handling will be added next time.

1.4. Recommendations are classified as high (red), medium (amber) or low (green).

1.5. Four new recommendations were received with two each noted as medium and low.

1.6. One of the two recommendations classified as medium was noted as requiring no further action with the second forming part of the IFQ project. These have not been included as part of this document.

1.7. Two recommendations classified as low have been added to our progress report.

1.8. Recent updates received from Action Managers are recorded under a November 2015 heading in this document.

1.9. Both recommendations are noted as completed and there are no outstanding recommendations.

2. Recommendation

AGC is requested to review the enclosed summary of recommendations and updated management responses.

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Action Owner/ completion date
2015/16 – INTERNAL AUDIT CYCLE			
1. Requests for Information - Policies and Procedures	**The audit trail held on TRIM for PQs is not currently sufficient to show how policies and procedures have been adhered to**		
Discussion with management confirmed that due to the volume of email exchanges that can occur between the DoH and HFEA before the final response is sent, it is not deemed efficient to store all of this information on TRIM. Going forward, HFEA plan to include information relating to PQ responses on the new PQ log that is now in place which will list all PQs that are received, and the responses provided to these PQs. However, there is still scope to include key information on TRIM. It is noted that for FOI requests, the information currently included on TRIM includes details of the initial request received and the date received, as well as the final response sent out to the requestor, allowing HFEA to show that they complied with the 20 working day response timeframe for FOI requests *Without a clear audit trail on TRIM, there is a risk that key audit trail information relating to PQs may be lost, as it is currently stored in email inboxes. As a result, HFEA may be unable to demonstrate how it followed its policies and procedures as well as compliance with the 48 hour response deadline.*	Sufficient information should be stored on TRIM for HFEA to be able to demonstrate that it has followed its internal policies and procedures, as well as meeting the 48 hour deadline for PQ responses. Information held on TRIM should therefore include as a minimum: • Details of the date that the request was initially received from DoH. • Written evidence of authorisation of the initial response (as noted in Finding #1) sent to DoH. • Email evidence showing the initial response sent out to DoH request was responded to within the 48 hour deadline, to show that the KPI has been met. • Details of the final response agreed between the DoH and HFEA (in the form of email exchanges), once email exchanges have taken place.	***The details of the date that the request is initially received from the Department is captured in the PQ log, and saving the initial commissioning email would therefore duplicate issues and serve little purpose in the whole process. Written evidence of authorisation has been addressed in Finding#1. As part of the process it is agreed the email sent to the Department with the proposed response will be saved to Trim as recommended. There would be little point, however in saving email exchanges with details of the final response. This would be labour intensive and could potentially confuse the issue with later, linked PQs. In any event, the only substantive, final response is that which is published in Hansard.*** **November 2015 update**: Action completed – closed. **Recommendation completed**	Information Access and Policy Manager; Log to be updated with TRIM refs for saved final returns; By **30/10/15** **COMPLETE**

FINDING/*RISK*	Recommendation	Agreed actions / Progress Made	Action Owner/ completion date
2. Requests for Information - PQ Response log	**There is scope to improve the PQ log to allow for easier access to groups of similar requests, and access rights to the PQ log are not currently restricted**		
Shortly prior to the summer parliamentary recess, a PQ response log was introduced. Whilst the log is not yet fully operational, going forward the PQ log will list all PQs received, and responses given, and the log is designed to allow for easy searching of similar requests, so that HFEA ensures its responses are consistent with that of previous requests. It was noted that the log can currently be viewed and edited by any staff member in HFEA. The log is currently held in the Security and Access Policy folder on TRIM. Whilst it may be appropriate for the majority of staff to be able to view this log, editing of this log should be restricted to those who are responsible for maintaining the log. *If access to the PQ log is not sufficiently restricted, there is a risk that edits may be made to the log that are inaccurate, and that the log therefore does not accurately reflect PQs that HFEA have received and responded to.*	Access to edit the PQ log should be restricted to those staff members who are responsible for keeping the log updated.	***It is agreed that any editing rights for the PQ log should be restricted to those members of staff who are responsible for keeping the log updated.*** **November 2015 update:** Action completed – closed. **Recommendation completed**	Head of IT – editing rights to be changed by **30/10/15** **COMPLETE**

Annual review of committee effectiveness

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	11		
Paper number	AGC (09/12/2015) 483		
Meeting date	9 December 2015		
Author	Sam Hartley		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is invited to consider and comment on the Committee's effectiveness, using the supplied NAO checklist as a basis for discussions		
Resource implications	In budget.		
Implementation date	Any suggested changes to be fed into annual review of standing orders, reported to Authority in March 2016		
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Annex 1: NAO checklist for Audit Committees		

1. Introduction

1.1. It is now an established process for the HFEA's committees to conduct a review of their effectiveness annually. Such reviews are conducted in the autumn, with the results feeding in to the Authority, along with any changes to Standing Orders, in the following spring. While other HFEA committees have standard internal proformas as a guide to their annual review, the Audit and Governance Committee uses the NAO's Audit Committee checklist (at annex A) as a guide for its review.

1.2. This paper provides some prompts on the matters committee members may wish to reflect upon regarding the activities and performance of the committee in the past year.

2. Committee meetings, functions and agendas

2.1. Since the last annual review in 2014, the Committee has met four times, as planned. The Committee has been quorate at all meetings, and had a full complement of four members at two meetings. In addition, observers or representatives from DH have been present. Both internal and external auditors were represented at all meetings. The committee had recognised the challenge of achieving quoracy and has recently increased its membership to five, to reduce the burden on the existing members.

2.2. After a year of change (2014, with a new Chair and Director of Finance and Resources) this year has been one of stability and building capacity. Apart from the usual items taken to AGC, focus has been put on providing assurance for the IfQ project. Further work has been undertaken on a move to risk assurance mapping, which will continue in the future. Delegated powers and functions appear to be appropriate and lines of communication with the Authority will have improved with a formal report each year. There are two ongoing actions from last year's review – external member attendance at inspections and Authority meetings – which are dependent on members' availability.

3. Recommendation

3.1. The NAO checklist is seen as a guide for all public sector organisations, from the largest to the smallest, and therefore and must be applied in a proportionate way. It is not intended as having to be fully completed by every committee regardless of the organisations size; rather, it acts as a prompt for committees to follow in conducting their reviews.

3.2. AGC is invited to consider the NAO checklist in advance of the 9 December meeting, and feed back views at that meeting. The Authority and Committee Business Manager will capture views during the meeting, before circulating a final report for agreement remotely after the meeting.

National Audit Office

GOOD PRACTICE

The Audit Committee self-assessment checklist

2nd edition January 2012

Financial Management and Reporting

Our vision is to help the nation spend wisely.

We apply the unique perspective of public audit to help Parliament and government drive lasting improvement in public services.

The National Audit Office scrutinises public spending for Parliament and is independent of government. The Comptroller and Auditor General (C&AG), Amyas Morse, is an Officer of the House of Commons and leads the NAO, which employs some 860 staff. The C&AG certifies the accounts of all government departments and many other public sector bodies. He has statutory authority to examine and report to Parliament on whether departments and the bodies they fund have used their resources efficiently, effectively, and with economy. Our studies evaluate the value for money of public spending, nationally and locally. Our recommendations and reports on good practice help government improve public services, and our work led to audited savings of more than £1 billion in 2011.

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Contents

Introduction

1 This Checklist[1] has been designed to help Audit Committees in central government assess how well they apply good practice. The criteria we have used are derived largely from the Audit Committee Handbook (March 2007)[2] published by HM Treasury.

2 The Handbook highlights five good practice principles which aim to answer the following key questions:

- **Principle 1: The Role of the Audit Committee** – Does the Audit Committee effectively support the Board and the Accounting Officer by reviewing the completeness of assurances to satisfy their needs, and by reviewing the reliability and integrity of these assurances?
- **Principle 2: Membership, Independence, Objectivity and Understanding** – Is the Audit Committee suitably independent and objective, and does each member have a good understanding of the objectives, priorities and risks of the organisation, and of their role on the Audit Committee?
- **Principle 3: Skills** – Does the Audit Committee contain or have at its disposal an appropriate mix of skills to perform its functions well?
- **Principle 4: Scope of Work** – Is the scope of the Audit Committee suitably defined, and does it encompass all the assurance needs of the Board and Accounting Officer?
- **Principle 5: Communication** – Does the Committee engage effectively with Financial and Performance Reporting issues, and with the work of internal and external audit? And does the Audit Committee communicate effectively with the Accounting Officer, the Board, and other stakeholders?

3 For each principle, we have developed a series of Good Practice Questions to help Audit Committees conclude whether they are meeting these principles. These are set out in **Section I** of this checklist.

4 In addition, the role of the Chair and the provision of appropriate secretariat support are key for an effective Audit Committee. The Handbook details Good Practice Questions on these two roles. **Sections II** and **III** of this checklist include questions that will enable the Audit Committee to determine if they currently meet this guidance.

1 This Checklist was originally published in November 2009 and has been updated (January 2012) to reflect the requirement for departments, their executive agencies and arm's-length bodies to produce a Governance Statement in place of the Statement on Internal Control in their annual report and accounts for 2011-12 onwards. Guidance on the Governance Statement is set out in the revised Chapter 3 of Managing Public Money (HM Treasury, 2011)

2 *Corporate governance in central government departments: Code of good practice* (HM Treasury, July 2011) provides that Audit Committees should be established and function in accordance with the *Audit Committee Handbook* (HM Treasury, March 2007).

How to use this Checklist

5 To help Audit Committees conclude as to whether they are meeting the Principles highlighted above, we have developed Good Practice Questions to inform the thinking process. These Questions are phrased to identify 'yes', 'no' or 'not applicable' responses.

6 We recognise, though, that organisations and their Audit Committees vary considerably in their size and in the complexity of issues that they deal with. In some circumstances, it may therefore be more appropriate to only use the more important Questions to help inform debate – and we have highlighted these in **bold**.

7 Also, the checklist is not exhaustive, and should the Audit Committee or their organisation feel that they have experience of other good working practice that will make the Committee work more effectively, they should not be deterred from implementing these practices, after consulting with the Board, if appropriate.

NAO Facilitated Workshops

8 To help Audit Committees use this checklist, the National Audit Office, as part of its performance improvement work, offers **Facilitated Workshops** for Audit Committees to help them use a tailored version of this checklist and draw conclusions as to their effectiveness. In this way, the workshop provides an opportunity for individual Audit Committees to work together, away from their normal business, to assess how well they work and establish areas to develop further. The workshop is followed up with an Action Plan that draws from the decisions and actions raised. This Action Plan will be owned by the Audit Committee, and act as the means by which decisions are implemented and reviewed.

9 If you would like the NAO to facilitate a workshop for your Audit Committee, please ask your usual NAO contact or Client Lead.

10 This checklist is also available as a Word document to enable Audit Committees to record their responses electronically.

National Audit Office
November 2009

Section I

Good practice principles for Audit Committees

Principle 1: The role of the Audit Committee

The Audit Committee should support the Board and the Accounting Officer by reviewing the comprehensiveness of assurances in meeting the Board and Accounting Officer's assurance needs, and reviewing the reliability and integrity of these assurances.

Good Practice Questions

	Terms of Reference	**Yes**	**No**	**N/A**
1	Have all executive responsibilities, and making or endorsing of decisions been excluded from the roles and responsibilities of the Audit Committee members?	☐	☐	☐
2	Does the Audit Committee follow up recommendations regarding its effectiveness?	☐	☐	☐
3	**Does the Audit Committee's role include monitoring and reviewing the executive's processes for assessing, reporting and owning business risks and their financial implications?**	☐	☐	☐
4	**Has the role and responsibilities of the Audit Committee been clearly defined and communicated to all Audit Committee members, along with details of how the Committee supports the Board?**	☐	☐	☐
5	**Are the Terms of Reference reviewed at least annually by the Board and the Audit Committee, to ensure that the work of the Audit Committee is aligned with good practice and business needs?**	☐	☐	☐
6	**Do the Terms of Reference include rules for a quorum?**	☐	☐	☐
7	**Does the Audit Committee meet regularly (at least four times a year), and do meetings coincide with key dates in the financial reporting and audit cycle?**	☐	☐	☐

Additional Comments:

Conclusions

Do we achieve **Principle 1: The Role of the Audit Committee** – Does the Audit Committee support effectively the Board and the Accounting Officer by reviewing the comprehensiveness of assurances to satisfy their needs, and by reviewing the reliability and integrity of these assurances?

What do we need to do to enhance the Audit Committee?

Where we have carried out the self-assessment before, the audit committee has improved its performance against:

1 ☐ none of the good practice questions.
2 ☐ some of the good practice questions.
3 ☐ most, if not all of the good practice questions.

Principle 2: Membership, Independence, Objectivity and Understanding

The Audit Committee should be independent and objective; in addition, each member should have a good understanding of the objectives and priorities of the organisation and of their role as an Audit Committee member.

Good Practice Questions

	Independence	**Yes**	**No**	**N/A**
8	**Is the Chair of the Audit Committee different from the Chair of the Board?**	☐	☐	☐
9	**Are the Audit Committee members either independent non-executive Board members or independent external members, and have they been appointed for an appropriate period of time (e.g. three years)?**	☐	☐	☐
	Relationship with the Executive			
10	**Are the Executive members of the organisation invited to attend Audit Committee meetings, participate in discussions, and provide information to the Audit Committee as and when the Audit Committee deems it necessary?**	☐	☐	☐
	Other Participants			
11	Where appropriate, does a representative from the sponsoring body attend the Audit Committee meetings (e.g. if an Executive Agency, does a member of the Sponsoring Department attend the meeting)?	☐	☐	☐
12	**Does the Accounting Officer, Finance Director, Head of Internal Audit and the External Auditor routinely attend the Audit Committee, or attend at the request of the Audit Committee members?**	☐	☐	☐
13	**Are the numbers attending the Audit Committee meetings sufficient to deal adequately with the agenda, but not too many to blur issues?**	☐	☐	☐
	Conflict of Interest			
14	**Is the first agenda item of every meeting a request for the Audit Committee members to declare any potential conflict of interest with any of the business items on the Audit Committee's agenda?**	☐	☐	☐

Conflict of Interest (continued)		**Yes**	**No**	**N/A**
15	In instances where there is a declaration of interest in any of the agenda business items, are appropriate actions taken, e.g. is the member asked to leave the meeting while the business item is being discussed?	☐	☐	☐
16	In instances where the conflict of interest is likely to last for a long time, has the Audit Committee member been asked to relinquish his or her membership?	☐	☐	☐
17	Are the Audit Committee members required to declare their interest in a register of interests?	☐	☐	☐
Terms of Appointment				
18	**Do all Audit Committee members have a clear understanding of what is expected of them in their role, set out in a letter of appointment, including:**			
	a. their appointment and purpose;	☐	☐	☐
	b. the support and training that they will receive;	☐	☐	☐
	c. the commitment required;	☐	☐	☐
	d. their remuneration;	☐	☐	☐
	e. conflict of interest procedures;	☐	☐	☐
	f. expected conduct;	☐	☐	☐
	g. duration of appointment and how often it may be renewed;	☐	☐	☐
	h. how their individual performance will be appraised, including a clear understanding of what would be regarded as unsatisfactory performance; and	☐	☐	☐
	i. termination conditions?	☐	☐	☐

Additional Comments:

Conclusions

Do we achieve **Principle 2: Membership, Independence, Objectivity and Understanding** – Is the Audit Committee suitably independent and objective, and does each member have a good understanding of the objectives, priorities and risks of the organisation, and of their role on the Audit Committee?

What do we need to do to enhance the Audit Committee?

Where we have carried out the self-assessment before, the audit committee has improved its performance against:

1 ☐ none of the good practice questions.
2 ☐ some of the good practice questions.
3 ☐ most, if not all of the good practice questions.

Principle 3: Skills

The Audit Committee should collectively possess an appropriate skills mix to perform its functions well.

Good Practice Questions

	Range of Skills	**Yes**	**No**	**N/A**
19	Are there formal assessment criteria for the appointment of the Audit Chair, including attitudes to non-executives, strength of personality, experience of chairing, and time commitment?	☐	☐	☐
20	**Do the assessment criteria of Committee members include, or expect Audit Committee members to acquire as soon as possible after appointment:**			
	a. understanding of the objectives of the organisation and current significant issues for the organisation;	☐	☐	☐
	b. understanding of the organisation's structure, including key relationships such as that with a sponsoring department or major partner;	☐	☐	☐
	c. understanding of the organisation's culture;	☐	☐	☐
	d. understanding of any relevant legislation or other rules governing the organisation; and	☐	☐	☐
	e. broad understanding of the government environment, particularly accountability structures and current major initiatives?	☐	☐	☐
21	**Does the Audit Committee ensure that there are areas of collective understanding, including:**			
	a. accountancy – with at least one member having recent and relevant financial experience;	☐	☐	☐
	b. governance, assurance and risk management;	☐	☐	☐
	c. audit;	☐	☐	☐
	d. technical or specialist issues pertinent to the organisation's business;	☐	☐	☐
	e. experience of managing similar sized organisations;	☐	☐	☐
	f. understanding of the wider environments in which the organisation operates; and	☐	☐	☐
	g. detailed understanding of the government environment and accountability structures?	☐	☐	☐

Additional Skills		Yes	No	N/A
22	**Do the Audit Committee members feel empowered to:**			
	a. co-opt members for a period of less than one year to provide specialist skills that the members do not have to be an effective Committee;	☐	☐	☐
	b. procure specialist advice at reasonable approved expense to the organisation, on an ad-hoc basis to support them in relation to particular pieces of Committee business.	☐	☐	☐
Training and Development				
23	**Is there an induction checklist for new Audit Committee members that details key things that they must do e.g. visits to important business locations, meetings with Board, Risk Manager, Internal Audit and External Auditors?**	☐	☐	☐
24	Do all new members of the Audit Committee attend an induction training course for Audit Committee members run by the National School of Government, or other sector-related organisation?	☐	☐	☐
25	Does the Audit Committee ensure that new members have sufficient knowledge of the business to identify the key risk areas and to challenge both line management and internal and external auditors on critical and sensitive issues?	☐	☐	☐
26	Does the Audit Committee and the Chair make recommendations to the Board on the Committee's and individual members training needs?	☐	☐	☐
27	Does the Audit Committee keep abreast of best practice and developments in corporate governance in central government and more widely?	☐	☐	☐

Additional Comments:

Conclusions

Do we achieve **Principle 3: Skills** – Does the Audit Committee contain or have at its disposal an appropriate mix of skills to perform its functions well?

What do we need to do to enhance the Audit Committee?

Where we have carried out the self-assessment before, the audit committee has improved its performance against:

1 ☐ none of the good practice questions.
2 ☐ some of the good practice questions.
3 ☐ most, if not all of the good practice questions.

Principle 4: Scope of Work

The scope of the Audit Committee's work should be defined in its Terms of Reference, and encompass all the assurance needs of the Board and Accounting Officer. Within this, the Audit Committee should have particular engagement with the work of Internal Audit, the work of External Auditor, and Financial Reporting issues.

Good Practice Questions

	Relationship with Internal Audit	**Yes**	**No**	**N/A**
28	**Does the Audit Committee consider the independence and effectiveness of Internal Audit?**	☐	☐	☐
29	**Does the Audit Committee consider that the experience, expertise and professional standard of the Internal Audit team are appropriate for the size, complexity, and inherent risk of the organisation?**	☐	☐	☐
30	**Does the Audit Committee consider that the scope of Internal Audit work, the available resources at its disposal, and their access to information and people allow it to address significant risks within the organisation?**	☐	☐	☐
31	**Does the Audit Committee review and approve the Internal Audit plan before they commence any work and make suggestions regarding risk and problem areas that the audit could address in the short and long term?**	☐	☐	☐
32	Does the Audit Committee receive regular progress reports on studies/work undertaken by Internal Audit?	☐	☐	☐
33	**Does the Audit Committee review internal audit reports and management responses to issues raised, and monitor the progress made on Internal Audit's recommendations?**	☐	☐	☐
	Relationship with External Audit			
34	**Where relevant, does the Audit Committee consider the independence, objectivity, and effectiveness of the External Auditors?**	☐	☐	☐
35	Does the Audit Committee periodically obtain the views of the External Auditor on the work and effectiveness of the Audit Committee?	☐	☐	☐

Relationship with External Audit (continued)		**Yes**	**No**	**N/A**
36	Is the Audit Committee informed by the External Auditors on an annual basis as to their quality control procedures and compliance with applicable UK ethics guidance?	☐	☐	☐
37	**Does the Audit Committee consider the External Auditor's Audit Strategy before they commence work, and make suggestions regarding risk and problem areas the audit could address in the short and long term?**	☐	☐	☐
38	**Do the External Auditors inform the Audit Committee of key developments and issues at key stages of the audit?**	☐	☐	☐
39	Where relevant, does the Audit Committee review the audit fees?	☐	☐	☐
40	**Does the Audit Committee consider the management letter and other relevant reports (e.g. the NAO's Value for Money work), and the management's response, and monitor the progress made on the recommendations?**	☐	☐	☐
Relationship between Internal Audit and External Auditors				
41	Does the Audit Committee consider whether there are areas where joint working between Internal Audit and the External Auditors would be beneficial?	☐	☐	☐
42	Does the Audit Committee seek confirmation from Internal Audit and the External Auditors on the effectiveness of the relationship?	☐	☐	☐
Fraud				
43	**Does the Audit Committee consider whether effective anti-fraud and corruption policies and procedures are in place and operating effectively?**	☐	☐	☐
44	Does the Audit Committee consider whether there is a code of conduct and its distribution to employees?	☐	☐	☐
45	Does the Audit Committee consider whether management arrangements for whistle-blowing are satisfactory?	☐	☐	☐

Internal Control		**Yes**	**No**	**N/A**
46	Does the Audit Committee consider whether corporate governance is embedded throughout the organisation, rather than treated as a compliance exercise?	☐	☐	☐
47	Does the Audit Committee consider whether the system of internal reporting gives early warning of control failures and emerging risks?	☐	☐	☐
48	**Does the Audit Committee consider whether the Governance Statement is sufficiently comprehensive and meaningful, and the evidence that underpins it?**	☐	☐	☐
49	**Does the Audit Committee satisfy itself that the system of internal control has operated effectively throughout the reporting period?**	☐	☐	☐
50	Does the Audit Committee consider whether financial control, including the structure of delegations, enables the organisation to achieve its objectives and achieve good value for money?	☐	☐	☐
51	Does the Audit Committee monitor whether the organisation's procedures for identifying and managing business risk have regard for the relevant legislation and regulation?	☐	☐	☐
Financial Reporting				
52	**Does the Audit Committee review the first draft of the annual accounts before the External Auditors start work on them?**	☐	☐	☐
53	**Before the Accounting Officer signs off the Annual Report and Financial Statements, does the Audit Committee consider:**			
	a. that the accounting policies in place comply with relevant requirements, particularly the Treasury's Financial Reporting Manual and Accounts Direction;	☐	☐	☐
	b. that there has been a robust process in preparing the accounts and annual report;	☐	☐	☐

Financial Reporting (continued)		**Yes**	**No**	**N/A**
c.	**whether the accounts and annual report have been subjected to sufficient review by management and by the Accounting Officer and/or Board;**	☐	☐	☐
d.	**that when new or novel accounting treatments arise, whether appropriate advice on accounting treatment has been taken;**	☐	☐	☐
e.	**whether there is an appropriate anti-fraud policy in place, and whether losses are suitably recorded;**	☐	☐	☐
f.	**whether suitable processes are in place to ensure accurate financial records are kept;**	☐	☐	☐
g.	**whether suitable processes are in place to ensure regularity and propriety is achieved; and**	☐	☐	☐
h.	**whether issues raised by the External Auditors have been given appropriate attention.**	☐	☐	☐
54	**Where the accounts have been qualified, does the Audit Committee consider the action taken by the Board to deal with the causes of the qualification?**	☐	☐	☐
55	**Does the Audit Committee satisfy itself that the annual financial statements represent fairly the financial position of the organisation, regardless of the pressures on executive management?**	☐	☐	☐
56	Before the Accounting Officer signs off the Letter of Representation, does the Audit Committee review it and give particular attention to non-standard issues of representation?	☐	☐	☐

Additional Comments:

Conclusions

Do we achieve **Principle 4: Scope of Work** – Is the scope of the Audit Committee suitably defined, and does it encompass all the assurance needs of the Board and Accounting Officer?

What do we need to do to enhance the Audit Committee?

Where we have carried out the self-assessment before, the audit committee has improved its performance against:

1 ☐ none of the good practice questions.
2 ☐ some of the good practice questions.
3 ☐ most, if not all of the good practice questions.

Principle 5: Communication

The Audit Committee should ensure it has effective communication with the Board, the Head of Internal Audit, the External Auditor, and other stakeholders.

Good Practice Questions

	Reporting to the Board	**Yes**	**No**	**N/A**
57	Does the Audit Committee send regular reports or provide oral updates to the Board that they review at their meetings?	☐	☐	☐
58	**Does the Audit Committee provide an Annual Report to the Board, timed to support preparation of the Governance Statement?**	☐	☐	☐
59	**Does the Annual Report of the Audit Committee present the Committee's opinion about:**			
	a. the comprehensiveness of assurances in meeting the Board and Accounting Officers needs;	☐	☐	☐
	b. the reliability and integrity of these assurances;	☐	☐	☐
	c. whether the assurance available is sufficient to support the Board and Accounting Officer in their decisions taken and their accountability obligations;	☐	☐	☐
	d. the implication of these assurances for the overall management of risk;	☐	☐	☐
	e. any issues the Audit Committee considers pertinent to the Governance Statement, and any long-term issues the Committee thinks the Board and/or Accounting Officer should give attention to;			
	f. financial reporting for the year;	☐	☐	☐
	g. the quality of both Internal and External Audit and their approach to their responsibilities; and	☐	☐	☐
	h. the Audit Committee's view of its own effectiveness, including advice on ways in which it considers it needs to be strengthened or developed.	☐	☐	☐

Additional Comments:

Conclusions

Do we achieve **Principle 5: Communication** – Does the Committee engage effectively with Financial and Performance Reporting issues, and with the work of internal and external audit? And does the Audit Committee communicate effectively with the Accounting Officer, the Board and other stakeholders?

What do we need to do to enhance the Audit Committee?

Where we have carried out the self-assessment before, the audit committee has improved its performance against:

1 ☐ none of the good practice questions.
2 ☐ some of the good practice questions.
3 ☐ most, if not all of the good practice questions.

Section II

The role of the Chair: good practice

The Chair of the Audit Committee has particular responsibility for ensuring that the work of the Audit Committee is effective, that the Committee is appropriately resourced, and that it is maintaining effective communication with stakeholders.

Good Practice Questions

	Agenda Setting	**Yes**	**No**	**N/A**
60	Is the Board Secretary different from the Audit Committee Secretary?	☐	☐	☐
61	Does the Chair of the Audit Committee meet with the Committee Secretary before every meeting to discuss and agree the business for the meeting?	☐	☐	☐
62	Are inputs on Any Other Business formally requested in advance from Committee members and attendees?	☐	☐	☐
63	Are outline agendas planned one year ahead to cover core activities and specific issues on a cyclical basis?	☐	☐	☐
64	Does the agenda exclude executive business, so that there is no overlap with the work of the Board whilst linking to the main elements of the organisation's business?	☐	☐	☐
65	Are the meetings set for a length of time which allows all business to be conducted, yet not so long that the meeting becomes ineffective?	☐	☐	☐
66	Does the Chair encourage full and open discussion and invite questions at the Audit Committee meetings?	☐	☐	☐
	Communication			
67	**Does the Chair of the Audit Committee have open lines of communication with the Board, Head of Internal Audit, and the External Auditors?**	☐	☐	☐
68	Does the Chair encourage all Committee members to have regular interface with the organisation and its activities to help them understand the organisation, its objectives, and business needs and priorities?	☐	☐	☐
69	**Do reports to the Audit Committee communicate relevant information at the right frequency, time, and in a format that is effective?**	☐	☐	☐
70	Does the Audit Committee issue guidelines concerning the format and content of the papers to be presented to the Committee?	☐	☐	☐

	Monitoring Actions	Yes	No	N/A
71	**Does the Chair or the Secretariat ensure that all action points from Committee meetings are appropriately acted upon?**	☐	☐	☐
72	Does the Chair or the Secretariat ensure that members who have missed a meeting are appropriately briefed on the business conducted in their absence?	☐	☐	☐
73	Is a report on matters arising made and minuted at the Audit Committee's next meeting?	☐	☐	☐
	Appraisal	☐	☐	☐
74	Does the Chair ensure that the Committee members are provided with an appropriate appraisal of their performance as a Committee member?	☐	☐	☐
75	Does the Audit Committee Chair seek appraisal of their personal performance from the Accounting Officer or Chair of the Board?	☐	☐	☐
76	**Are Audit Committee meetings well attended, with records of attendance maintained and reviewed annually by the Board?**	☐	☐	☐
	Appointments	☐	☐	☐
77	Is the Chair involved in the appointment of new Committee members, including providing advice on the skills and experience required of the new individual?	☐	☐	☐

Additional Comments:

Conclusions

Do we meet **Good Practice: the Role of the Chair** – Is the Committee appropriately resourced, work planned in advance as far as possible, and effective communication with stakeholders maintained?

What do we need to do to enhance the Audit Committee?

Where we have carried out the self-assessment before, the audit committee has improved its performance against:

1 ☐ none of the good practice questions.
2 ☐ some of the good practice questions.
3 ☐ most, if not all of the good practice questions.

Section III

Committee support: good practice

The Audit Committee should be provided with appropriate Secretariat support to enable it to be effective. This is more than a minute-taking function – it involves providing proactive support for the work of the Committee, and helping its members to be effective in their role.

Good Practice Questions

	Does the Audit Committee Secretariat:	**Yes**	**No**	**N/A**
78	Commission papers as necessary to support agenda items?	☐	☐	☐
79	Circulate meeting documents to all Committee members, Internal Audit and External Auditors in good time before each meeting, to allow members time to study and understand the information e.g. at least one week before the meeting?	☐	☐	☐
80	Arrange for Executives/senior management to be available as necessary to discuss specific agenda items with the Audit Committee during meetings?	☐	☐	☐
81	**Keep records of meetings and minutes after they have been approved by the Audit Chair and circulate them to Committee members, Head of Internal Audit, External Auditors, Board, and the Accounting Officer on a timely basis e.g. within one week of the meeting?**	☐	☐	☐
82	**Ask for confirmation that the minutes are a true and fair representation of a summary of the business taken by the Audit Committee?**	☐	☐	☐
83	Ensure that the minutes clearly state all agreed actions, the responsible owner, when they will be done by and any advice given from any stakeholders?	☐	☐	☐

Does the Audit Committee Secretariat: (continued)		**Yes**	**No**	**N/A**
84	**Ensure action points are being taken forward between meetings?**	☐	☐	☐
85	Support the Chair in the preparation of Audit Committee reports to the Board?	☐	☐	☐
86	**Arrange the Chair's bilateral meetings with:**			
	a. the Accounting Officer, the Head of Internal Audit, Director of the External Auditors;	☐	☐	☐
	b. the Chair of the Board of sponsored NDPBs.	☐	☐	☐
87	Keep the Chair and members in touch with developments and relevant background information about developments in the organisation?	☐	☐	☐
88	Maintain a record of when members' terms of appointment are due for renewal or termination?	☐	☐	☐
89	Ensure that appropriate appointment processes are initiated when required?	☐	☐	☐

Additional Comments:

Conclusions

Do we meet **Good Practice: Support for the Committee** – Does the Committee receive appropriate support from its secretariat?

What do we need to do to enhance the Audit Committee?

Where we have carried out the self-assessment before, the audit committee has improved its performance against:

1 ☐ none of the good practice questions.
2 ☐ some of the good practice questions.
3 ☐ most, if not all of the good practice questions.

Where to find out more

The National Audit Office website is
www.nao.org.uk

Links to other websites
www.hm-treasury.gov.uk/audit_committee_handbook.htm
www.hm-treasury.gov.uk/d/mpm_annex3.1.pdf

If you would like to know more about
the NAO's work in this area please email
Z5-FMGP@nao.gsi.gov.uk

www.nao.org.uk/financial-management

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National Audit Office

Licensing appeals: an evaluation

Strategic delivery:	☒ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	12		
Paper number	AGC (09/12/2015) 484		
Meeting date	9 December 2015		
Author	Sam Hartley		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is invited to consider the evaluation of the recent licensing appeals process		
Resource implications	Low, unless a decision is taken to review regulations		
Implementation date	n/a		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Representations regulations Annex 2: Appeals regulations		

1. Introduction

1.1. As the committee will be aware, the HFEA is a licensing authority. Fertility treatment and research cannot be practised in the UK without the appropriate licence granted by the HFEA.

1.2. Decisions about whether to grant or refuse, vary, revoke, or apply conditions to a licence are subject to a statutory right of appeal by the applicant clinics. It is rare that licensing decisions are challenged; indeed, it is rare that a suitably punitive decision is taken that might invite challenge. The HFEA has recently been challenged on one particular licensing decision, which proceeded through both statutory stages of appeal. The Audit and Governance Committee asked for a 'lessons learned' exercise to be carried out on the running of those two stages of appeal.

1.3. This paper reflects on the regulations, process and operational running of the representations and appeals hearings. It does not consider the specifics of the case in question, nor address the lessons learned by the inspectorate in the way in which they approached that particular case.

2. Background and statutory footing

2.1. The Human Fertilisation and Embryology Act 1990 (as amended, 'the Act') sets out in some detail the process that must be gone through by the HFEA in taking licensing decisions. Although the Act refers to the HFEA as a whole, the HFEA has delegated its licensing functions to the Licence Committee and the Executive Licensing Panel – as either could take a the decision that would lead to an appeal being heard, these are referred to throughout as 'a licensing committee'.

2.2. Sections 16-20 of the Act dictate the process that any decision must go through. In short, the process is as follows:

2.2.1. A licensing committee takes a 'proposed decision' and issues a notice of that proposed decision to the applicant clinic;

2.2.2. The clinic has 28 days within which to give notice of its intention to make representations against that proposed decision, or to acknowledge and accept it;

2.2.3. If the clinic serves notice of its intention to make representations against the proposed decision, the regulations governing this process are activated (see section 3 below) and the first stage of appeal – referred to here as the 'representations' stage – is undertaken. By our own construct, these representations are considered by a Licence Committee;

2.2.4. In the case where the representations made by the clinic are unsuccessful (ie, the proposed decision by the licensing committee is upheld) then the 'proposed decision' becomes a 'decision' and notice is given to the clinic;

2.2.5. The clinic then has a further 28 days in which give notice of its intention to appeal against the decision, or to acknowledge and accept the decision;

2.2.6. If the clinic serves notice of its intention to appeal, the regulations governing the appeals stage are activated (see section 4 below). This appeal is considered by the Appeals Committee;

2.2.7. In the event of the appeal failing and the decision being upheld, that decision comes into effect.

2.3. It is important to note that the statutory scheme is such that no decision can be put into effect until the full two-stage process has been completed, or the clinic has acknowledged and accepted the proposed decision. A judicial review judgment against the HFEA in 2013 reinforced this point.

2.4. This process has only been employed to its full extent once, culminating in an appeals hearing in July this year. There had been a few previous cases that had progressed to the representations stage in the past, but none to the appeals hearing.

2.5. While this paper will not consider the particulars of the arguments on each side of the recent appeal, it is germane to be aware of the basic facts of the case. The clinic's licence was due for renewal in December 2013. At that time, the inspectorate could not recommend renewal given a number of concerns it had, and a decision regarding the licence was adjourned (twice) until May 2014, at which point the Licence Committee took the proposed decision to refuse to grant a renewed licence to the clinic. The clinic gave notice of its intention to make oral representations against this proposed decision – this hearing was held over five days in September and October 2014. The committee that heard the representations rejected them, and upheld the Licence Committee's proposed decision. The clinic then exercised its right of appeal, which was considered over a further five days at a hearing in July 2015. The committee that heard the appeal overturned the decision, and granted the renewed licence to the clinic, with a number of conditions attached.

3. Representations hearing

3.1. As mentioned above, the first stage of appeal for a clinic is to make representations against a proposed licensing decision. Once the clinic gives notice that it wishes to make representations, the regulations governing that process are invoked.

The regulations

3.2. The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 dictate the procedure governing the representations process (and are attached at Annex 1). For ease, these will be referred to as the 'representations regulations' in this paper. They are the HFEA's regulations (as opposed to the Secretary of State) in that they were made by the HFEA using its power under the Act to make regulations about the

representations process. It should be noted now, then, that it is also within our power to revoke/amend these regulations.

3.3. The representations regulations, among other things, stipulate that:

3.3.1. The Licence Committee that considers representations must sit with three or five members and be advised by a legal adviser;

3.3.2. The Committee must be assisted by a secretary who is not a member of the Authority nor the Secretary to the Appeals Committee;

3.3.3. A strict timetable must be adhered to and can only be deviated from by a direction from the chair of the committee;

3.3.4. If the representations are to be made orally, the procedure to be followed is a quasi-judicial one, akin to civil proceedings hearing;

3.3.5. The appellant and the HFEA may be represented by a barrister, advocate or solicitor;

3.3.6. Witnesses may be called to give evidence (but cannot be compelled to give evidence); and

3.3.7. The hearing must be recorded and transcripts made available to either party.

The regulations in practice

3.4. The representations hearing process is run by the HFEA Executive – specifically, the governance and licensing team, which ensures complete independence from the inspectorate. At the latest hearing the Head of Governance and Licensing acted as the Secretary to the representations committee, although in previous hearings committee secretaries have fulfilled that role. It was judged, given the importance of the hearing, that a more senior member of the team should fulfil that role, which is a model we should continue with.

3.5. The resource impact of adhering to the regulations is significant, and unpredictable. The administrative work involved in finding an appropriate portion of time – in the last case, four days was thought to be enough but wasn't – for which members of the committee and the legal adviser was difficult and led to delay. Both parties instructed senior counsel, whose availability added to the challenge. It is difficult to get around this issue, without the chair of the committee being absolutely inflexible with dates, and expecting both to find other counsel if their chosen ones are not available. This approach itself could be open to challenge.

3.6. The financial costs were not insignificant. As mentioned earlier, as the HFEA does not have many licensing challenges, there are no economies of scale to be achieved. When they occur, they are a significant portion of the annual budget. From an operational point of view, when factoring in venue hire, committee members fees and travel/subsistence, legal advisor fees, and transcription costs, the total cost of simply running the hearing was over £30,000. This does not account for the governance and licensing team's time, which would be considerable. Nor does it account for the HFEA's costs as a party to the hearing (inspectorate and legal time, and solicitors' and counsel's fees), which are

estimated to run to £150,000. This last figure sounds excessive; in fact, these are reasonable costs for defending a legal challenge. They do, however, beg the question as to whether mounting this sort of defence at the representations stage is a proportionate approach.

3.7. Notwithstanding the costs and staff resource implications, the Executive judges the running of the representations hearing, generally, as a success. To put it bluntly – everyone was in the right place at the right time, and the hearing proceeded without administrative delay. There were, of course, learning points. For example, as the Executive was responsible for compiling papers for the committee, there was some confusion on occasion as to the ordering of the bundles provided to the committee members (although blame must be shared by the two parties who were responsible for providing their own bundles). With some clear leadership from the committee's legal adviser this was, however, soon solved. Similarly, once the hearing ran over its allotted four-day timetable, there was a challenge in finding a suitable date for all parties concerned in which to conclude matters. Once a date was found (resulting in another delay of over a month) it was only through the generosity of the legal adviser to the committee who offered his chambers as a venue that further venue hire costs were avoided.

3.8. These, however, were solvable issues. Previous HFEA representations hearings have suffered from many worse administrative and operational issues and in that context the running of the hearing can be seen as a success. The committee members and legal adviser were complementary of the process and HFEA Executive staff after its conclusion.

4. Appeals hearing

4.1. The Human Fertilisation and Embryology (Appeals) Regulations 2009 govern the procedure for the next stage of challenge – the appeal. These will be referred to as the appeals regulations for ease, and are attached at Annex 2. Unlike the representations regulations, the appeals regulations are made by the Secretary of State and it is not within our gift to change them. They are similar in form and procedure to the representations regulations.

4.2. The appeals regulations stipulate, among other things, that:

4.2.1. The appeals committee must comprise seven members, the majority of whom should be lay, and the chair and deputy chair must be legally qualified;

4.2.2. The committee may sit with advisers (but does not have to);

4.2.3. Like the representations regulations, there is a strict procedure and timetable that must be followed, which can only be amended by directions from the chair;

4.2.4. If the appeal is to made orally (as opposed to on the papers only) the procedure to be followed is almost exactly the same as the representations regulations, with the both parties being able to appoint legal counsel and call witness evidence;

4.2.5. The appeal hearing shall be recorded and the transcripts available to both parties.

The regulations in practice

4.3. Despite the similarities in the design of the regulations, there are subtle but significant differences between the representations and appeals stage. First, the 1990 Act specifically states that the HFEA will establish and maintain an Appeals Committee – no such specification is made for how the representations stage is handled, and by whom. Second, the appeal procedure is by way of full reconsideration of the case, rather than a consideration of whether the proposed decision was the right one (as is the case for the representations hearing). One of the Appeals Committee members reflected that this was beneficial to the committee in that it allowed them freedom to reconsider the whole case with new evidence, rather than to in effect pass judgement on the reasonableness of the Licence Committee's initial proposed decision.

4.4. These differences, allied with the fact that these are the Secretary of State's regulations, and that the chair and deputy chair must be legally qualified, suggest to the Executive that the processes of challenging a licensing decision should be deliberately staggered in the judicial nature of their processes. The HFEA recognises this, to some extent, and keeps the appeals committee at arms length of all HFEA staff. The hearing process is managed by an external secretary (we used a barrister for the recent hearing) to ensure complete separation. Members of the governance and licensing team had no contact with the committee or its secretary with the exception of making venue hire arrangements, and administering fees and travel/subsistence.

4.5. This approach has strength and was commended by the members of the committee. It also avoids some pitfalls of the administration of the representations hearing, such as inelegant preparation of legal documents, as these are done within the secretary's chambers.

4.6. Financial costs are generally equivalent to those for the representations hearing. Both hearings were five days in duration, with comparable venue hire, transcription, and member costs. Although the cost of the external secretary for the appeals hearing is higher than the in-house approach of the representations hearing, this is off-set by the committee not requiring an external legal adviser (as it did for the representations hearing). The costs to the inspectorate of legal advice and counsel representation were lower at this stage, but still considerable. HFEA Executive time resource was less within the governance and licensing team, as the secretarial work was outsourced, but would have been roughly equivalent on the inspectorate side.

5. Lessons and conclusions

5.1. The lessons from the running of the two processes – representations and appeals – are similar. Because there is no embedded process nor staffing to handle the administration of these rare events, when they do occur the costs are notably and disproportionately high. The representations process, being run in-house by the governance and licensing team, was extremely resource-intensive

(the appeals hearing less so, given the out-sourcing of the secretary role). In the event that two representations hearings ever occurred at the same time, the governance and licensing team would not have the capacity to run them and additional resource would need to be sought.

5.2. The fact that the lessons from each process are similar goes to the heart of arguably the most striking point of the experience – the almost identical procedures (and similar costs) involved in both processes. The recent experience suggests that the representations process has attained almost the same quasi-judicial status and procedure as the appeals hearing itself. Barristers are hired, external venues are sought, a senior QC is used as legal adviser to the committee – these are all permitted in the representations regulations (drafted by the HFEA) but inevitably lead to increased complexity and cost. The Executive would observe that there may be a proportionate first step of right of challenge for clinics than moving straight to this quasi-judicial procedure. As a comparator, the Human Tissue Authority's representations stage is consider by its Director of Regulation, and cases are presented by Inspectors. We do not advocate this approach, but make the point to illustrate the scale of options available under the regulations.

5.3. AGC is invited to consider and note the evaluation of the recent appeals experience. It is clearly a valuable and fair way of allowing clinics that suffer a detrimental decision to challenge that decision. In the context of the HFEA, though, which does not have the throughput of challenges of, say, the professional regulators and their Fitness to Practice Panels, it represents a significant drain on resources. As detailed above, it might be appropriate to reflect on, in particular, the representations process, considering whether it is a proportionate first step of appeal. The committee may want to consider whether there is a more proportionate model for the first stage of the challenge process, especially in light of the fact that the representations regulations are within the powers of the HFEA itself to change.

5.4. However, as the Committee is aware, there are many and various resource pressures facing the HFEA Executive currently. Reviewing the representations regulations would be contentious within the sector – care would have to be taken to ensure that it was not seen to be a watering down of clinics' legitimate and statutory right to make representations against licensing decisions. It would be likely to require both legal advice and some consultation with the sector. The committee is invited to consider its appetite for such a review in light of the challenges and priorities facing the HEFA in the next year to eighteen months.

Annex 1: The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009

Annex 2: The Human Fertilisation and Embryology (Appeals) Regulations 2009

STATUTORY INSTRUMENTS

2009 No. 1397

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009

Made - - - -	*29th May 2009*
Coming into force - -	*1st October 2009*

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The Human Fertilisation and Embryology Authority makes these Regulations in exercise of powers conferred by sections 19(6); 45(3) and (3A) of the Human Fertilisation and Embryology Act 1990(a).

PART 1

General

Citation and commencement

1. These Regulations may be cited as the Human Fertilisation and Embryology Authority (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 and shall come into force on 1st October 2009.

Interpretation

2.—(1) In these Regulations—

"the 1991 Regulations" means the Human Fertilisation and Embryology Authority (Licence Committee and Appeals) Regulations 1991(b);

"the Act" means the Human Fertilisation and Embryology Act 1990(c) ;

"case officer" means the person representing the Authority in matters prior to any hearing (and may be the same person as the presenter);

"committee" means the Licence Committee;

"chair" means the chair of the committee;

"hearing" means proceedings of the committee which the parties to the proceedings may attend or at which they may be represented;

"Licence Committee" means the committee established under section 9A (2) of the Act, to which the Authority has delegated its functions under sections 18(2); 18A (3) and (5); and considering representations made under section 19(4) of the Act;

"notice of exercise of right" means the notice referred to in section 19(5) of the Act;

"notice of hearing" means a notice complying with the requirements of Regulation 6;

"person concerned" means a person who has the right to make representations to the Authority in accordance with section 19(4) of the Act or a licence holder in respect of whose licence a recommendation has been made that the licence be suspended;

"person with a professional interest" means a person who is—

(a) a registered medical practitioner,

(b) concerned with keeping or using gametes or embryos outside the body, or

(c) directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so;

"parties" means the Authority and the person concerned (or, where appropriate, the representatives of the Authority and the person concerned);

"the presenter" means the representative of the Authority presenting the case at a hearing (and includes employees of the Authority); and

"secretary" means the secretary to the committee.

(2) For the purposes of these Regulations—

(a) 1990 c.37 section 19(6) was substituted by section 19 of the Human Fertilisation and Embryology Act 2008. c.22 ("the 2008 Act"). Sections 45(3) and (3A) were substituted by section 30(4) of the 2008 Act.
(b) S.I. No. 1991/1889.
(c) 1990 c.37 as amended by the Human Fertilisation and Embryology Act 2008 c.22.

(a) a hearing of the committee, other than when it is deliberating in private, is considered to be "in private" if it is held in the presence of—

(i) the parties and any person representing a party (where present),

(ii) the person acting as secretary,

(iii) any witness giving evidence,

(iv) any legal, clinical, scientific or specialist adviser,

(v) any person responsible for the recording of the proceedings, or

(vi) any other person whose presence is deemed necessary by the chair,

but excluding everyone else; and

(b) the private deliberations of the committee are considered to be "in private" if they are held in the presence of—

(i) the person acting as secretary, or

(ii) any legal, clinical, scientific or specialist adviser,

but excluding everyone else.

PART 2

Procedure of Committee

Consideration of representations made under section 19(4) of the Act

3.—(1) Representations received from the person concerned shall be considered by the committee.

(2) When considering representations received from the person concerned, the committee —

(a) shall—

(i) sit with either 3 or 5 members, including the chair or deputy chair,

(ii) sit with a majority of members who are not persons with a professional interest,

(iii) participate in the decision making equally (and no member shall abstain from voting on any issue where a vote is required),

(iv) take decisions by simple majority (and the chair shall not have a casting vote),

(v) sit with a legal adviser,

(vi) be assisted by a secretary (provided that the secretary is not a member of the Authority or person acting as secretary to the Appeal Committee); and

(b) may sit with a clinical, scientific or specialist adviser where the chair considers it desirable to do so.

(3) No member of the committee shall consider representations received from the person concerned, if that member has a conflict of interest in relation to that case.

(4) The legal, clinical, scientific or specialist advisers referred to in paragraph (2) above—

(a) shall advise the committee on any areas within the adviser's expertise;

(b) may intervene to advise the committee on an issue where it appears that without an intervention there is the possibility of an error being made;

(c) at the request of the chair, may be present during the private deliberations of the committee but shall not participate in the decision making of the committee (and are not entitled to vote);

(d) subject to sub-paragraph (e), shall tender any advice at a hearing in the presence of each of the parties in attendance at that hearing;

(e) where at a hearing the committee has begun to deliberate on its decision and needs to obtain advice in the course of its deliberations, may tender advice to the committee notwithstanding the absence of the parties; and

(f) where advice has been tendered in accordance with sub-paragraph (e), shall repeat the advice before the parties in attendance at the hearing.

(5) Where any advice tendered by an adviser to the committee is not accepted by the committee—

(a) if the advice is tendered at a hearing before the committee, the chair shall announce the reasons for not accepting the advice tendered;

(b) the chair shall ensure that a written record is kept of the advice tendered, and the reasons why the committee refused to accept that advice; and

(c) a copy of the record of the advice tendered and the reasons why the committee refused to accept that advice shall be sent to the parties.

(6) The secretary shall—

(a) not participate in the decision making of the committee (and is not entitled to vote); and

(b) keep a record of—

(i) the committee's decision and of the reasons for such decision,

(ii) any advice tendered by the legal, clinical, scientific or specialist advisers (or any interventions made by them when they are present during the private deliberations of the committee); and

(iii) any declarations of interest (or potential conflicts of interest) made by a member during the proceedings.

(7) Subject to the Act and these Regulations, the committee may regulate its own proceedings.

Notice of exercise of right and accompanying documents

4.—(1) Where a person wishes to require the Authority to give him an opportunity to make representations, the person must provide to the Authority the information and documents specified in paragraph (2) at the same time as service of the notice of exercise of right required by section 19(5) of the Act.

(2) The information and documents that must be provided are—

(a) the full name and correspondence address of the person concerned;

(b) a daytime telephone number at which the person concerned can be contacted;

(c) the licence number of the person concerned (where applicable);

(d) a statement as to whether or not the person concerned is to be represented in the course of the proceedings, and if so, the contact details of any representative;

(e) any written representations that the person concerned wishes to make to the committee;

(f) copies of all material on which the person concerned intends to rely in the course of the proceedings before the committee;

(g) a skeleton argument setting out the submissions that the person concerned wishes to make to the committee;

(h) a statement as to whether the person concerned wishes to rely on any witness evidence, and if so, the names and occupations of such witnesses;

(i) a statement as to whether the person concerned wishes the matter to be considered on the papers or at a hearing; and

(j) in a case where the person concerned wishes a hearing to be held, a statement as to whether he wishes a case management meeting to be convened, and if so, the issues that the person concerned wishes to be considered at that meeting.

(3) At a case management meeting, the chair may—

(a) extend the time for delivery of the skeleton argument and any additional material necessary to determine the appeal; and

(b) allow the person concerned to amend the details regarding representation.

(4) A person concerned may withdraw his notice of exercise of right at any time prior to the first day of the hearing, or the first day that the committee considers the case on the papers, as applicable, by written notice to the Chair.

(5) Where a person concerned has not fully provided the information and documents set out in paragraph (2), the committee shall not be required to consider his representations.

Action following receipt of notice of exercise of right

5.—(1) The Authority shall provide to the secretary any notice of exercise of right received by the Authority and the information and documents provided with that notice pursuant to regulations 4(1) and (2) within 7 days beginning with the date of receipt of the notice.

(2) Following receipt of the notice of exercise of right from the Authority, the secretary shall—

(a) acknowledge receipt of the notice of exercise of right and any accompanying material submitted by the person concerned within 7 days beginning with the date of receipt of the notice;

(b) (where not already provided) provide copies of the notice of exercise of right and any accompanying material to a case officer within 7 days beginning with the date of receipt of the notice;

(c) require the case officer to provide him with copies of all documents on which the Authority intends to rely on in the proceedings before the committee within 21 days of receipt of papers by the case officer under sub-paragraph (b);

(d) send copies of any documents provided by the case officer under paragraph (c) to the person concerned or (where applicable) the representative of the person concerned within 7 days of receipt from the case officer;

(e) as soon as possible, serve notice on the parties of the date on which the committee will consider the matter (which, in the case of a hearing, unless the parties agree otherwise, shall be no less than 28 days after the date on which the secretary serves the notice of hearing);

(f) where the person concerned has stated that he wishes the committee to consider the matter at a hearing, send a notice of hearing to the parties, which shall be in the format described in Regulation 6; and

(g) require the parties to submit any further written submissions no later than 14 days before the date of the hearing or the date on which the committee is to meet.

Notice of hearing

6. The notice of hearing shall—

(a) state the date, time and venue of the hearing;

(b) inform the person concerned of his right to attend and to be represented or accompanied at the hearing in accordance with Regulation 14;

(c) inform the person concerned that the committee may proceed with the hearing in his absence;

(d) inform the person concerned of the provisions relating to—

(i) evidence set out in Regulation 9 ,

(ii) procedure at hearings set out in Regulation 13, and

(iii) witness evidence set out in Regulations 13(4) and 15(2); and

(e) require the person concerned to inform the secretary, within 14 days of service of the Notice of Hearing, whether he intends to—

(i) attend the hearing,

(ii) be represented at the hearing, and if so, by whom, and

(iii) seek to call any witnesses at the hearing, and if so, whom.

Case management meetings

7.—(1) Where a hearing is to be held, a case management meeting may be convened by the chair of his own motion or at the request of one or both of the parties.

(2) Where a case management meeting is to be convened, the secretary shall give the parties such notice of it as is reasonable (in the opinion of the chair) in all the circumstances of the case.

(3) The format of the case management meeting, the procedure to be followed and the persons required to attend that meeting shall be determined by the chair, in consultation with the parties.

(4) Case management meetings shall be held in private.

(5) At a case management meeting, the chair may issue such directions as he considers necessary for the just and expeditious management of the case.

Multiple representations

8. After obtaining the advice of the legal adviser, the committee may consider and determine together two or more representations made under section 19(4) of the Act by the same person concerned, or by different persons concerned, where it is satisfied that it would be fair and appropriate to do so.

Evidence

9.—(1) All questions of admissibility of evidence and law before the committee shall be decided by the committee, after obtaining the advice of the legal adviser.

(2) Upon obtaining the advice of the legal adviser, and subject only to the requirements of relevance and fairness, the committee may receive—

(a) subject to paragraph (3), any documentary or physical evidence; and

(b) subject to regulations 13(2)(d) and (e), 13(4), and 15(2), where a hearing is held, any oral evidence,

whether or not such evidence would be admissible in civil proceedings in that part of the United Kingdom where the meeting or hearing is to take place.

(3) Where a party wishes to adduce written evidence from a witness other than a letter of testimonial, the committee shall only receive such evidence if the document—

(a) contains an attestation, in a format acceptable to the committee, that the statement is true; and

(b) is signed by the person making it.

(4) Where a person concerned has been convicted of a criminal offence in the British Islands (and has not successfully appealed against the conviction), a copy of the certificate of conviction certified by a competent officer of the court (or in Scotland, an extract conviction) shall be admissible as conclusive proof of that conviction and the findings of fact on which it was based.

(5) The only evidence which may be adduced by the person concerned in rebuttal of a conviction certified or extracted in accordance with paragraph (4) is evidence for the purpose of proving that he is not the person referred to in the certificate or extract.

(6) A formal notification of a determination about a person concerned's fitness to practise made by a body responsible under any enactment for the regulation of a health or social care profession (in the United Kingdom or elsewhere), and signed by an officer authorised by that body to sign such a notification, shall be sufficient evidence, unless the contrary is proved, of any facts found proved by that regulatory body.

(7) The chair shall only allow a party to adduce written evidence at a hearing which has not been submitted in accordance with this regulation in exceptional circumstances which could not reasonably have been foreseen at the time of the service of the notice of exercise of right or of any case management meeting.

Power to summons witnesses and require production of documents

10.—(1) Subject to paragraph (3) and regulation 15(1), the committee may by summons require any person (P) in the United Kingdom to attend as a witness at a hearing before it at such time and place as may be specified in the summons and P must do so.

(2) Subject to paragraph (4) the committee may by summons require any person including the person concerned (P) in the United Kingdom to produce any documents in P's custody or control which the committee considers relevant to the proceedings before it and P must do so.

(3) P shall not be required in obedience to any summons issued in accordance with paragraph (1) to attend and give evidence or to produce any document unless—

(a) he has been given at least 7 days notice of the hearing or, if less than 7 days, he has informed the committee that he accepts such notice as he has been given, and

(b) he has been provided with confirmation that his reasonable and necessary travel and subsistence expenses will be paid by the Authority.

(4) P shall not be compelled to give any evidence or produce any document or other material that he could not be compelled to give or produce on a trial of any action in a civil court of law in that part of Great Britain in which the proceedings before the committee are to take place.

(5) Each summons under paragraph (1) and (2) above must—

(a) contain a statement to the effect that the person to whom it is addressed may apply to the committee to vary or set aside the summons; and

(b) refer to the fact that by virtue of section 41(7) of the Act a person who without reasonable excuse fails to comply with the requirement of that paragraph is guilty of an offence and is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both.

Burden and standard of proof

11.—(1) The Authority shall bear the burden of establishing that a licence should be revoked, varied (otherwise than on an application) or that a licence should be suspended.

(2) The person concerned shall bear the burden of establishing that a licence should not be refused.

(3) Where facts are in dispute, the committee shall consider whether they have been established in accordance with the civil standard of proof.

Consideration on the papers

12.—(1) The committee shall determine a matter referred to it on the papers unless the person concerned has requested a hearing when providing notice of his exercise of right.

(2) No later than 7 days before the meeting, the secretary shall provide the committee with an agenda and the documents relevant to the proceedings before the committee.

(3) Before making its decision, in addition to considering the material submitted by the parties, the committee may obtain advice from a legal, clinical, scientific or specialist adviser.

(4) Before making its decision, the committee may adjourn and require the person concerned and the Authority to provide further information or documents.

(5) Before making its decision, the committee may adjourn and require—

(a) an inspection to be made by employees of the Authority of any premises where the licensed activity is or is to be carried out;

(b) an inspection to be made by employees of the Authority of any premises that are or will be relevant third party premises; and

(c) a report to be presented to it of any inspection made in accordance with sub-paragraphs (a) and (b).

(6) The secretary shall record—

(a) any advice tendered by a legal, clinical, scientific or specialist adviser (where present);

(b) any rulings on questions of law or admissibility made by the chair;

(c) the decision of the committee; and

(d) the reasons for the committee's decision.

Procedure at hearings

13.—(1) No later than 7 days before the hearing, the secretary shall provide the committee with an agenda and the documents relevant to the proceedings before the committee.

(2) The order of proceedings at the hearing shall be as follows—

(a) the chair shall declare the hearing open;

(b) where the person concerned is not present or represeuted at the hearing, the chair—

(i) shall require the secretary to adduce evidence that all reasonable efforts have been made to serve the notice of hearing on the person concerned, and

(ii) having consulted the committee, may—

(aa) if he is satisfied that the notice of hearing has been duly served, proceed with the hearing in the absence of the person concerned, or

(bb) adjourn the hearing and issue appropriate directions;

(c) the presenter shall make an opening statement, outlining what he considers to be the relevant circumstances of the case;

(d) the person concerned may adduce evidence, and may call witnesses (provided that the chair is satisfied that the witness is in a position to provide relevant testimony and subject to paragraph (4));

(e) the presenter may adduce evidence in rebuttal of the position of the person concerned and in support of the position of the Authority, and may call witnesses (provided that the chair is satisfied that the witness is in a position to provide relevant testimony and subject to paragraph (4));

(f) the person concerned may make a closing statement;

(g) before making its decision, the committee may—

(i) seek advice from a legal, clinical, scientific or specialist adviser (provided that the parties are provided with an opportunity to comment on such advice before the committee makes its decision),

(ii) adjourn and require a party to provide further information or documents,

(iii) adjourn and require an inspection to be made by employees of the Authority of any premises where licensed activity is or is to be carried out,

(iv) adjourn and require an inspection to be made by employees of the Authority of any premises that are or will be relevant third party premises, and

(v) adjourn and require a report to be presented to it of any inspection made in accordance with (iii) and (iv) above;

(h) the committee shall deliberate in private and shall then announce its decision in the presence of the parties (where present), together with the reasons for its decision.

(3) The conduct of the hearing shall otherwise be at the discretion of the chair, who may (amongst other matters) invite the parties to make additional submissions to those outlined in paragraph (2).

(4) The chair may refuse to allow a witness to give oral evidence, or to give evidence on a particular matter, if he is satisfied that all or part of the evidence that the witness is to provide, or is to provide on that matter, should have been disclosed to the party not calling the witness at an earlier stage in the proceedings.

(5) Subject to paragraph (6), hearings shall be held in public.

(6) After consulting with the legal adviser, the chair may require some or all of the hearing to be held in private, where he is satisfied that an interest of a party in maintaining privacy outweighs the public interest in holding the hearing or part of it in public.

(7) The chair may require any member of the public attending the hearing to be excluded from the hearing, where he considers that the continued presence of that person may disrupt the proceedings before the committee.

Representation and entitlement to be heard

14.—(1) The presenter shall be a person who is—

(a) a barrister, advocate or solicitor; or

(b) an employee of the Authority,

or both.

(2) The person concerned may be represented by a person who is—

(a) a barrister, advocate or solicitor; or

(b) a representative from his or its defence organisation or his trade union,

or both.

(3) Where the person concerned is not represented, he may be accompanied and advised by a supporter, but the supporter—

(a) shall not be—

(i) a member or employee of the Authority, or

(ii) a witness at the hearing; and

(b) shall only be entitled to address the committee with the permission of the chair.

(4) The presenter and the person concerned or his representative shall be entitled to attend any hearing before the committee of which notice is given in accordance with Regulation 6, and to be heard by the committee at that hearing.

Witness evidence

15.—(1) The Authority may not compel the person concerned to be a witness.

(2) A party may not call a person to be a witness unless that party has provided to the other party a written statement of evidence provided by the witness at least 7 days before the hearing (which meets the requirements of Regulation 9(3)), unless the chair determines otherwise.

(3) The committee may, upon the application of the party calling the witness, direct that any details which may identify that witness should not be revealed in public.

(4) Witnesses—

(a) shall first be examined by the party calling them;

(b) may be cross examined;

(c) may then be re-examined by the party calling them;

(d) may then be questioned by the committee through the chair, and with the leave of the chair, by a legal, clinical, scientific or specialist adviser.

(5) The parties may then question the witnesses on matters arising out of the committee's questions, with the party calling the witness being given the last opportunity to do so (as between the parties).

(6) Any further questioning of witnesses shall be at the discretion of the chair.

(7) Except for expert witnesses and the person concerned, witnesses shall not be allowed to attend the proceedings until after they have completed giving their evidence and been formally released by the chair.

Postponements and adjournments

16.—(1) The chair may, of his own motion, or upon the application of a party, postpone any meeting or hearing of which notice has been given under these Regulations before such meeting or hearing begins.

(2) The chair may, of his own motion or upon the application of a party, adjourn the proceedings at any stage, provided that—

(a) no injustice is caused to the parties; and

(b) the decision to adjourn is made after hearing representations from the parties (where present).

(3) In considering whether or not to grant a request for postponement or adjournment, the chair shall, amongst other matters, have regard to—

(a) the public interest in the expeditious disposal of the proceedings;

(b) the potential inconvenience caused to a party or any witnesses to be called by that party;

(c) the conduct of the party seeking the postponement or adjournment; and

(d) fairness to the parties.

(4) Where the proceedings have been postponed or adjourned, the secretary shall, as soon as practicable, notify the parties of the date, time and venue of the postponed or resumed meeting or hearing.

Decision of the committee

17.—(1) The committee shall provide the notice referred to in section 19A (2) to (5) of the Act, in writing, together with a statement of its reasons for the decision, no later than 7 days after the date on which it has made its decision.

(2) The committee may serve notice of its decision, and the statement of its reasons for that decision, on any other person whom it considers, in the public interest, ought to be informed of the committee's decision.

(3) When serving the notice referred to in section 19A of the Act, the committee shall at the same time serve a written record of—

(a) any advice tendered by a legal, clinical, scientific or specialist adviser;

(b) any rulings on admissibility of evidence made by the committee.

Notes and transcripts of hearings

18.—(1) Subject to paragraph (3), the Authority shall arrange for all hearings to be recorded in writing or electronic form.

(2) Any party to the proceedings shall, on application to the secretary, be furnished with a transcript of the record of any part of the hearing at which he was entitled to be present.

(3) The private deliberations of the committee shall not be recorded.

Report of committee's activities

19. The chair shall prepare an annual written report to the Authority detailing the activities of the committee.

Made by the Authority this 29th day of May 2009

Lisa Jardine
Chair,
29th May 2009 Human Fertilisation and Embryology Authority

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under Sections 19(6) and 45(3) and (3A) of the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008).

The Regulations set out set out the procedure to be followed when a person wishes to make representations against certain decisions made by the Human Fertilisation and Embryology Authority.

Part 1 deals with preliminary matters, including commencement and interpretation (regulations 1 and 2).

Part 2 sets out the procedure for consideration of representations.

Regulation 3 provides that representations are to be considered by a Licence Committee of the Human Fertilisation Authority. This regulations sets out details of the quorum and voting procedure to be followed by the Committee, and provides for the Committee to be assisted by advisers and a secretary. This regulation further specifies the roles of the advisers and of the secretary.

Regulation 4 specifies the information and documents to be provided to the Authority at the same time that the person wishing to make representations serves the notice of exercise of right that is required by the Act.

Regulation 5 sets out the actions that need to be taken by the respective parties after service of the notice of exercise of right, and the required time limits for such actions. Regulation 6 sets out the information that must be contained in a notice of hearing (including information relating to the right to be represented and the procedure to be followed at a hearing) that is to be served on the person wishing to make representations, where that person has requested that a hearing be held.

Regulation 7 makes provision for case management meetings to be held, in order to ensure that hearings proceed smoothly and that effective use of time is made at the hearing. Regulation 8 provides for multiple representations to be considered by the same committee, where the committee are satisfied that it is fair and appropriate to do so.

Regulation 9 sets out detailed requirements relating to the evidence that the committee can consider. Regulation 10 provides for a power to summons witnesses (other than the person making representations) and to require production of documents. Regulation 11 sets out the burden and standard of proof to be considered by the committee.

Regulation 12 and 13 set out the respective procedures to be followed by the committee when it is considering representations on the papers, and when it is considering representations at a hearing.

Regulation 14 makes provision for representation and the entitlement of the person making representations to be heard before the committee and regulation 15 makes provision for witness evidence. Regulations 16-19 deal with administrative matters such as adjournments, format of decision notices, transcripts of hearings, and a requirement for the committee to provide an annual report of its activities to the Human Fertilisation and Embryology Authority.

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This Statutory Instrument has been made in consequence of defects in S.I. 2009/1397 and is being issued free of charge to all known recipients of that Statutory Instrument.

STATUTORY INSTRUMENTS

2009 No. 2088

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) (Amendment) Regulations 2009

Made - - - -	*29th July 2009*
Coming into force - -	*1st October 2009*

The Human Fertilisation and Embryology Authority makes these Regulations in exercise of powers conferred by sections 19(6) and 45(3) and (3A) of the Human Fertilisation and Embryology Act 1990(a)—

Citation and commencement

1. These Regulations may be cited as the Human Fertilisation and Embryology Authority (Procedure for Revocation, Variation or Refusal of Licences) (Amendment) Regulations 2009 and shall come into force on 1st October 2009.

Amendment of the Human Fertilisation and Embryology Authority (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009

2.—(1) The Human Fertilisation and Embryology Authority (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009(b) are amended as follows.

(2) In regulation 4(1) (notice of exercise of right and accompanying documents), omit "required by section 19(5) of the Act".

(3) Omit regulation 10 (power to summons witnesses and require production of documents).

(4) Omit regulation 15(1) (summonsing the person concerned to be a witness).

Made by the Authority this 29th day of July 2009

Lisa Jardine

Chair,
Human Fertilisation and Embryology Authority

29th July 2009

(a) 1990 c. 37 Section 19(6) was substituted by section 19 of the Human Fertilisation and Embryology Act 2008 (c. 22) ("the 2008 Act"). Section 45(3) and (3A) was substituted by section 30(4) of the 2008 Act.
(b) S.I. 2009/1397.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under sections 19(6) and 45(3) and (3A) of the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008) and correct errors in the Human Fertilisation and Embryology Authority (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 (S.I. 2009/1397).

In particular, regulation 4 (which sets out the documents to accompany the notice of exercise of right) is amended to reflect the definition of the notice set out in regulation 2 (interpretation) and regulation 10 (power to summons witnesses and require production of documents) is omitted. Regulation 15(1) (which provides that the Authority may not compel the person concerned to be a witness) is omitted in consequence of the omission of regulation 10.

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STATUTORY INSTRUMENTS

2009 No. 1891

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Appeals) Regulations 2009

Made - - - -	*15th July 2009*
Coming into force	
Regulations 4 to 6, and 2 so far as it relates to them	*16th July 2009*
Remainder	*1st October 2009*

CONTENTS

PART 4

Procedure on reconsideration

The Secretary of State for Health makes these Regulations in exercise of the powers conferred by sections 20A(3), 20B(2) and 45(1), (3) and (3A) of the Human Fertilisation and Embryology Act 1990(**a**).

A draft of this instrument has been approved by a resolution of each House of Parliament pursuant to section 45 of that Act.

PART 1

General

Citation and commencement

1.—(1) These Regulations may be cited as the Human Fertilisation and Embryology (Appeals) Regulations 2009 and subject to paragraph (2) shall come into force on 1st October 2009.

(2) Regulations 4 to 6, and regulation 2 so far as it relates to them, shall come into force on the day after that on which these Regulations are made.

Interpretation

2. In these Regulations—

"the 1991 Regulations" means the Human Fertilisation and Embryology Authority (Licence Committee and Appeals) Regulations 1991(**b**);

"the Act" means the Human Fertilisation and Embryology Act 1990;

(**a**) 1990 c. 37. Sections 20A and 20B were inserted by section 21 of the Human Fertilisation and Embryology Act 2008 c. 22 ("the 2008 Act"). Section 45(3) was substituted by section 30(4) of the 2008 Act.
(**b**) S.I. No.1991/1889.

"adviser" means an adviser appointed by the Authority in accordance with regulation 10;

"an appeal" means the reconsideration of a licensing decision;

"the appellant" means the person requiring the Authority to reconsider a licensing decision in accordance with section 20(1), (2) or (4) of the Act (right to reconsideration of licensing decisions)(**a**);

"the Chair" means the Chair of the Committee;

"the Committee" means an appeals committee as defined by section 20A(2) of the Act (appeals committee);

"the Deputy Chair" means the Deputy Chair of the Committee;

"hearing" means proceedings of the Committee which the parties to the proceedings may attend or at which they may be represented;

"legally qualified" means holding at least a ten year general qualification (within the meaning of section 71(3)(c) of the Courts and Legal Services Act 1990(**b**) (qualification for judicial and certain other appointments)) or being an advocate or solicitor in Scotland of at least ten years standing;

"licence holder" means a person granted a licence by the Authority under section 16 of the Act (grant of licences)(**c**);

"notice of exercise of right" means the notice referred to in section 20(3) or (5) of the Act (right to reconsideration of licensing decisions);

"notice of hearing" means a notice complying with the requirements of regulation 18;

"parties" means the Authority and the appellant (or where appropriate, the Authority's or the appellant's representatives);

"person responsible under a licence" has the meaning given by section 17(1) of the Act (the person responsible)(**d**);

"person with a professional interest" means a person who is—

(a) a registered medical practitioner,

(b) concerned with keeping or using gametes or embryos outside the body, or

(c) directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so;

"private deliberations" means meetings of the Committee held in the presence of any adviser and any person acting as secretary to the Committee, but excluding everyone else;

"the presenter" means the representative of the Authority presenting the case at a hearing (and includes employees of the Authority); and

"witness" means a person giving oral evidence at a hearing, and includes an appellant giving oral evidence.

General

3. Subject to the provisions of the Act and of these Regulations, the Committee may regulate its own proceedings.

(**a**) Section 20 was substituted by section 21 of the 2008 Act.
(**b**) 1990 c. 41.
(**c**) Section 16 was amended by section 16 of the 2008 Act.
(**d**) Section 17(1) was amended by section 17 of the 2008 Act.

PART 2

The Committee

Composition of the Committee

4.—(1) Except where provided for in paragraph (2), the Committee shall have seven members appointed by the Authority including a Chair and Deputy Chair.

(2) Subject to paragraph (3) the Authority may appoint an additional member or members to the Committee for the purposes of a particular case where in the opinion of the Chair it is necessary or desirable to do so.

(3) The majority of members of the Committee must not be persons appointed under paragraph (2).

(4) A person must not be appointed as a member of the Committee if that person is—

(a) a current employee or member of the Authority;

(b) a former employee or member of the Authority;

(c) fulfilling, or has fulfilled, any function of the Authority pursuant to arrangements under section 8B (agency arrangements and provision of services) or 8C (contracting out functions of the Authority) of the Act(**a**);

(d) a licence holder; or

(e) a person responsible under a licence.

(5) The Chair and Deputy Chair must be legally qualified.

(6) The majority of members of the Committee must not be persons with a professional interest.

(7) The Committee may continue to act even if there is a temporary vacancy amongst its members.

Terms of office of members

5.—(1) Members of the Committee shall not serve more than two consecutive terms in office.

(2) Each term of office shall be for three years.

(3) Paragraphs (1) and (2) shall not apply to a member appointed under paragraph (2) of regulation 4 who shall hold office until the case is determined by the Committee and the notice of decision is provided under regulation 29.

(4) A member of the Committee may at any time resign office by notifying the Authority in writing.

Suspension and removal of Committee members

6.—(1) The Authority shall remove from the Committee any member who, in the Authority's opinion—

(a) has seriously or persistently failed to meet the standards of performance, conduct or attendance required of a member of the Committee in the ordinary course of duties;

(b) is unable to perform duties because of ill health;

(c) has improperly disclosed confidential information obtained in the course of membership of the Committee;

(d) has brought the Authority into disrepute;

(e) should no longer continue to be a member of the Committee in the public interest;

(**a**) Sections 8B and 8C were inserted into the Act by section 8 of the 2008 Act.

(f) has otherwise ceased to be an appropriate person (for example, by reason of misconduct or criminal conviction); or

(g) falls within any of the categories set out in regulation 4(4)(a) to (e).

(2) The Authority may suspend a member of the Committee while investigations are being undertaken as to whether that person is suitable to remain as a member.

(3) The Authority shall afford any member of the Committee who is under investigation the opportunity to make written and oral representations before reaching a decision on whether that person should be removed from the Committee.

(4) The procedure for the suspension or dismissal of a member of the Committee shall otherwise be determined by the Authority.

Quorum and voting

7.—(1) Subject to paragraph (2) the quorum for any hearing of the Committee to determine an appeal or meeting, apart from a case management meeting, is three and must include—

(a) the Chair or Deputy Chair; and

(b) at least one member who is a person with a professional interest.

(2) The Committee, when determining an appeal, may not consist of an even number of members.

(3) A member who has not been present throughout a hearing of an appeal may not take part in the determination of the appeal and will not count towards the quorum (or for the purpose of paragraph (2)).

(4) Decisions of the Committee shall be taken by a simple majority of the members.

(5) A member of the Committee may not abstain from voting.

Validity

8. The validity of any proceedings of the Committee shall not be affected by any defect in the appointment of a Committee member.

Annual Report

9.—(1) The Chair shall ensure that an annual written report on the activities of the Committee is prepared for—

(a) the period beginning the 1st October 2009 and ending on 31st March 2011; and

(b) each succeeding period of 12 months ending with 31st March.

(2) The Chair shall ensure that the annual report under paragraph (1) is provided to the Authority as soon as is practicable after the end of the relevant period.

PART 3

Advisers to the Committee

Appointment of advisers to the Committee

10. The Authority may make arrangements to appoint one or more advisers to the Committee as it deems appropriate from time to time.

Functions of advisers

11.—(1) At the request of the Chair an adviser may attend any meeting of the Committee or any hearing before the Committee.

(2) The function of an adviser shall be to—

(a) advise the Committee on any areas within the adviser's expertise; and

(b) intervene to advise the Committee on an issue where it appears that without an intervention there is the possibility of an error being made.

(3) At the request of the Chair, an adviser who is present at a meeting or hearing referred to in paragraph (1) may be present during the private deliberations of the Committee, but the adviser shall not participate in the decision making of the Committee (and is not entitled to vote).

Requirement to give or repeat advice in public

12.—(1) Subject to paragraph (2), any advice tendered by an adviser at a hearing shall be tendered in the presence of each of the parties in attendance at the hearing.

(2) Where the Committee has begun to deliberate on its decision and needs to obtain advice in the course of its deliberations, an adviser may tender advice to the Committee notwithstanding the absence of the parties.

(3) Where the advice is tendered in the absence of the parties in accordance with paragraph (2)—

(a) the adviser shall repeat the advice tendered to the Committee before the parties in attendance at the hearing; and

(b) the parties in attendance at the hearing shall be provided with reasonable opportunity to comment on the advice given by the adviser, before the Committee makes its decision on the issue under consideration.

Requirement to keep records of advice and interventions

13.—(1) The Chair shall ensure that a written record is kept of any advice tendered to the Committee by an adviser.

(2) The Chair shall ensure that a written record is kept of any interventions made by an adviser during the private deliberations of the Committee.

(3) The Chair shall ensure that a copy of any advice tendered by an adviser to the Committee is sent to the parties to the proceedings.

Advice of an adviser not accepted by the Committee

14. Where any advice tendered by an adviser to the Committee is not accepted by the Committee—

(a) if the advice is tendered at a hearing before the Committee, the Chair shall announce the reasons for not accepting the advice tendered;

(b) the Chair shall ensure that a written record is kept of the advice tendered, and the reasons why the Committee did not accept that advice; and

(c) a copy of the record of the advice tendered and the reasons why the Committee did not accept that advice shall be sent to the parties.

Questioning of witnesses by advisers

15. An adviser advising the Committee in accordance with these Regulations may, with the permission of the Chair, question any witness appearing before the Committee.

PART 4

Procedure on reconsideration

Notice of exercise of right and accompanying documents

16.—(1) Where a person wishes to make an appeal, the person must provide to the Authority the information and documents specified in paragraph (2) at the same time as service of the notice of exercise of right.

(2) The information and documents that must be provided are—

(a) the full name, address and telephone number of the appellant;

(b) the appellant's licence number (where applicable);

(c) whether or not the appellant intends to be represented at any hearing and if so, the full name, address and telephone number of any representative and whether the Committee should send replies or notices concerning the appeal to the representative rather than the appellant;

(d) a copy of the original decision to be reconsidered;

(e) the grounds on which the appellant requires the Committee to reconsider the decision;

(f) a copy of the material submitted by the appellant to the Authority prior to the decision which is the subject of reconsideration;

(g) a copy of new material not submitted by the appellant to the Authority which the appellant wishes the Committee to consider;

(h) a skeleton argument;

(i) whether the appellant intends to call any witnesses and if so the names and occupations of those witnesses;

(j) whether the appellant wishes the reconsideration to be considered on the papers or at a hearing; and

(k) in a case where a hearing is requested, whether the appellant would like a case management meeting and the issues to be considered at such a meeting.

(3) The Authority must provide to the Committee any notice of exercise of right received by the Authority and the information and documents provided with that notice pursuant to paragraphs (1) and (2) within 7 days beginning with the date of receipt.

(4) An appellant may withdraw a notice of exercise of right by written notice to the Chair at any time prior to the first day of the hearing, or the first day the Committee considers the case on the papers, as applicable.

Action following receipt of notice of exercise of right and accompanying documents

17.—(1) Following receipt of the notice of exercise of right and the information and documents specified in regulation 16(2) the Committee must—

(a) acknowledge receipt of the notice of exercise of right and accompanying information and documents to the appellant or, where appropriate, the appellant's representative within 7 days beginning with the date of receipt of the notice;

(b) require the Authority to provide to the Committee within 21 days of receipt by the Authority of the notice of exercise of right and the information and documents specified in regulation 16(2) copies of any documents the Authority intends to rely on in relation to the reconsideration; and

(c) provide to the appellant or, where appropriate, the appellant's representative copies of any papers received under sub-paragraph (b) within 7 days of receipt from the Authority.

Audit and Governance Committee Paper

Paper Title:	**AGC Forward Plan**
Paper Number:	[AGC (09/12/2015) 485]
Meeting Date:	9 December 2015
Agenda Item:	**13**
Author:	Sue Gallone
For information or decision?	Decision
Resource Implications:	None
Implementation	N/A
Communication	N/A
Organisational Risk	Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information
Recommendation to the Committee:	The Committee is asked to review and make any further suggestions and comments and agree the plan.
Evaluation	Annually, at the review of Committee effectiveness (but the forward plan is reviewed briefly by the Committee at each meeting)
Annexes	N/A

AGC Forward Plan

Item↓ Date:	**Mar 2016**	**June 2016**	**October 2016**	**9 December 2016**
Following Authority Date:	**May 2016**	**July 2016**	**November 2016**	**January 2017**
Meeting 'Theme/s'	**Finance and Resources**	**Annual Reports, Information Governance, People**	**Strategy & Corporate Affairs, AGC review**	**Register and Compliance, Business Continuity**
Reporting Officers	**Sue Gallone**	**Peter Thompson**	**Juliet Tizzard**	**Nick Jones**
High Level Risk Register	Yes	Yes	Yes	Yes
Information for Quality (IfQ) Programme	Yes	Yes	Yes	
Annual Report & Accounts (inc Annual Governance Statement)	Plan & review any drafts	Approval		
External audit (NAO) strategy & work	Interim Feedback	Audit Completion Report	Audit Planning Report	Update
Information Assurance & Security		Yes		
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Early Results, approve draft plan	Results, annual opinion	Update	Update
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes		Yes		
Strategy & Corporate Affairs management			Yes	

Item↓ Date:	Mar 2016	June 2016	October 2016	9 December 2016
Regulatory & Register management				Yes
Resilience & Business Continuity Management				Yes
Finance and Resources management	Yes			
Reserves policy			Yes	
Review of AGC activities & effectiveness, terms of reference				Yes
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes
Other one-off items				