Audit and Governance Committee Agenda

Wednesday, 18 March 2015
The Royal Statistical Society, 12 Errol Street, London EC1Y 8LX

Meeting starts: 10:00 am

1. Welcome, Apologies and Declarations of Interest

2. Minutes of 10 December 2014
   [AGC (18/03/2015) 442]

3. Matters Arising
   [AGC (18/03/2015) 443 SG]

4. Finance and Resources – Risks and Shared Finance Resources
   [AGC (18/03/2015) Presentation SG]

5. Finance Policies (including Counter-fraud policy)
   [AGC (10/12/14 444) and Presentation SG]

6. Information for Quality (IfQ) Programme – Managing Risks
   [AGC (18/03/2015) 445 NJ]

7. Strategic Risks
   [AGC (18/03/2015) 446 PR]

8. Internal Audit

   a. Progress Report and Internal Audit Plan [AGC (18/03/2015) 447 JH]

   b. Final Audit Reports 2014/15
      i. Standing Financial Instructions
         [AGC (18/03/2015) 448 JH]
      ii. Internal Policies Review
         [AGC (18/03/2015) 449 JH]

9. External Audit - Interim Feedback
   [AGC (18/03/2015) 450 SE]

10. Implementation of Recommendations – Progress Report
    [AGC (18/03/2015) 451 MA]

11. Annual Report & Accounts (including Annual Governance Statement)
    [Oral MA and SH]

12. AGC Forward Plan
    [AGC (10/12/14) 452 SG]

13. Any Other Business

14. Session for members and auditors only

Close: 1:00 pm (Refreshments & Lunch Provided)
Next meeting: 10:00 am Wednesday, 10 June 2015, London

Audit and Governance Committee Paper

Paper Title	**DRAFT Minutes of the meeting 10 December 2014**
Agenda Item	**2**
Paper Number	[AGC (18/03/2015) 442]
Meeting Date	Wednesday, 18 March 2015
Author	Dee Knoyle
For information or decision?	Decision
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting.

Members present
Rebekah Dundas (Chair)
Jane Dibblin
Gill Laver
Jerry Page

External attendees
Catherine Hepburn – NAO
Kim Hayes – DH
Lynn Yallop, PWC – DHIA
James Hennessey – PWC - DHIA

Staff in attendance
Sue Gallone – Director of Finance and Resources
Morounke Akingbola – Head of Finance
Sam Hartley – Head of Governance and Licensing
Adam Ashiwaju – Accounts Officer
Dee Knoyle – Committee Secretary

Apologies
None

Attendance for specific items:
Nick Jones – Director of Compliance and Information
Paula Robinson – Head of Business Planning
Rachel Hopkins – Head of Human Resources

1. Welcome, Apologies and Declarations of Interests

1.1 The Chair welcomed all attendees to the meeting.

1.2 The Chair introduced Jane Dibblin, Authority Member to the meeting and announced that Jane had agreed to become a member of the Audit and Governance Committee (AGC) for the next two meetings.

1.3 The Chair announced that Alan Thornhill was no longer a member of AGC due to other commitments.

1.4 The Chair also announced that Jerry Page had agreed to extend his term as a member of AGC, which would aid continuity.

1.5 The Chair announced that new Authority members had recently been successfully recruited. Kate Brian and Dr Anthony Rutherford had officially joined the Authority on 12 November 2014, while Margaret Gilmore and Dr Yacoub Khalaf had agreed to commence their roles on 1 April 2015, to replace other members whose terms would end at that time.

1.6 There were no apologies for absence.

2. Minutes of the Meeting held on 1 October 2014

2.1 The Minutes of the meeting held on 1 October 2014 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 status of the various matters arising and good progress made to date.

3.2 Most of the matters arising had now been completed with a few exceptions which were being monitored:

- 3.2.1 Eight Authority members had completed the online governance training and other members were due to complete it.
- 3.2.2 The business continuity cascade exercise was completed on 3 December 2014.
- 3.2.3 The Executive is awaiting a response from the Department of Health (DH) to conclude negotiations on the minimum levels of reserves.
- 3.2.4 An annual review of effectiveness action plan, which included matters such as circulating AGC minutes to all Authority members for background information and implementing an annual appraisal for external members, has been prepared for discussion later in this meeting.

4. Regulatory and Register Management – Compliance and Information Risks

4.1 The Director of Compliance and Information provided the Committee with a presentation and briefing.

4.2 The Committee noted that the core activities of the Compliance and Information Directorate were licensing, inspecting/auditing for compliance and maintaining the organisation's statutory Register of patient/donor information. The Directorate also processed Pre- implantationGenetic Diagnosis (PGD)/Human Leukocyte Antigen (HLA) tissue typing applications for approval by an HFEA Committee. The Directorate was responsible for the organisation's IT systems, including the

risk based assessment tool used to monitor centres' performance. The responsibility for the organisation's internal database and desktop support to office and home-based staff was also held with this Directorate.

4.3 The HFEA's Corporate Management Group and Authority members were updated regularly on the Directorate's key performance indicators. Performance had proved to be good with one or two exceptions.

4.4 There had recently been an increase in reported non-compliances. This may have been due to the criteria for non-compliance being reviewed in order to drive up standards and the HFEA's wider remit to inspect areas of practice passed from the Care Quality Commission (CQC).

4.5 There had been an increase in PGD applications and the Directorate had been successful in processing applications quickly and meeting key performance indicator targets.

4.6 The Committee discussed the following concerns relayed by the Director of Compliance and Information:

4.6.1 **Register Infrastructure** - The IT infrastructure for the statutory Register of patient/donor information was in need of improvement. The Information for Quality (IfQ) programme would address this.

4.6.2 **Auditing and correcting errors** - Audits were usually carried out at centres during the renewal inspections and the number of errors identified remained unchanged despite guidance from the Inspectorate. There were approximately 60,000 treatment cycles carried out across the centres each year and therefore a high level of data entry. Although the majority of the errors were minor data entry errors, correcting them consumed quite a lot of HFEA staff time. Again IfQ would address this.

4.6.3 **Non-Compliances – long standing issues** –Informed consent was a recurring problem in some clinics. The recent workshops organised by the HFEA had helped, especially having a barrister present to give further guidance and clarity about the potential impacts for clinics of getting this important matter wrong. The HFEA was reviewing some aspects of consent forms but there needed to be a cultural shift among clinics, to attain a better understanding that their practices had a lifelong relevance for patients/donors.

4.6.4 **Representations and Appeals** - Handling representations and appeals against licensing decisions took significant staff and member time. Lessons learned were always considered, to identify any needed improvements to procedures.

4.6.5 **Resources** – The Directorate had lost a number of staff within a short period of time. There has been a small restructure to strengthen resilience and recruitment is underway. There are some issues with staff morale in the IT Team, as a result of potential changes arising from IfQ. Better communication between staff and management had helped to alleviate some anxiety and it was agreed that this open communication would continue..

5. Information for Quality (IfQ) Programme – Managing Risks

5.1 The Director of Compliance and Information provided the Committee with a presentation and briefing.

5.2 The Committee were reminded of the McCracken report and the recommendations made relating to information. The IfQ programme would help the HFEA fulfil these recommendations in relation to the information collected, how that data was received and verified and information such as success rates was published.

5.3 Meetings, consultations and workshops had been held and the Authority would consider the recommendations from the Advisory Group in January 2015.

5.4 Two additional and necessary pieces of work (business requirements and approval of the business case by the Department of Health) had caused some delay to the planned timeline. Key stages were:

5.4.1 December/January 2015 - Business case approval

5.4.2 January 2015 – Authority approval of the Programme initiation document

5.4.3 January to March 2015 - Design of technical architecture

5.4.4 April 2015 to March 2016 - Implementation of core components

5.4.5 Throughout – work on Register migration and data warehousing.

5.5 The Internal Auditors had suggested that some improvements to the IfQ programme were required, to ensure the programme was defined clearly and that funding was in place. These challenges from IA were helpful to the ongoing development of the programme and further third party assurance was planned.

5.6 The Committee discussed spend so far on the programme, work completed and the realism of future plans. They were supportive of the work completed to date and agreed that it was necessary to have a degree of flexibility in the programme at this stage. They suggested that the HFEA might consider whether the Gateway review should start before the planned date in March, although that date had been determined by the lead-in period required by the Gateway review team.

5.7 The Annual Conference in March 2015 would be used as another platform to communicate information to the sector on the IfQ programme and how it was progressing.

5.8 AGC would continue to receive reports on the IfQ Programme and Peter Thompson, HFEA Chief Executive, would attend the March 2015 meeting.

ACTION:

5.9 Director of Compliance and Information to consider the optimum timing for the Gateway review.

6. Internal Audit

6a Progress Report Audit

DH Internal Audit presented their report:

6.1 **Information for Quality (IfQ)** – The IfQ audit report was issued with recommendations and guidance on risks for assurance over the programme. The report gave a moderate rating.

6.2 **Standing Financial Instructions** – a draft was under quality review and the final report would be submitted to AGC to review in March 2015.

6.3 **Internal Policies** – the terms of reference had been agreed and fieldwork would start in January 2015.

6.4 **Register of Treatments** – work was currently being scoped.

6.5 The Panel noted the report ratings in use, following a change of definitions.

6b IfQ Audit Report

6.6 DH Internal Audit presented this report. The opinion was a moderate rating. Good governance was in place for the programme, however there were some areas that required improvement.

6.7 The Committee noted that, overall, the key issues were the data migration and the finances underpinning the Programme.

6.8 The National Audit Office (NAO) would carry out their audit in February 2015 and the scope of this would include the effectiveness of sign off and approvals procedures.

6c Implementation of Recommendations – Progress Report

6.9 The Committee noted the progress made with the recommendations, and that there were just two recommendations outstanding from 2011/12. The Committee expected these to be completed by March 2015. Good progress was being made with more recent recommendations in the areas of risk management and corporate governance.

7. External Audit

7.1 The NAO provided the Committee with an update of their plans for the interim audit in February and March.

7.2 The NAO would be visiting clinics to undertake their tests to confirm income.

7.3 The NAO would also be looking at the treatment of IfQ costs during the interim audit.

8. Risks

a. Strategic Risk Register

8.1 The Head of Business Planning presented proposals for the new high level risk register for the Committee's comments.

8.2 The Strategic Risk Register was now in a new format to align with the HFEA Strategy for 2014-2017, and included various high level risks including Information for Quality (IfQ) programme risks. The redesign had also taken in some of the key points from the internal audit report on the HFEA's risk management framework, including a less composite approach to articulating the risks, and improved read-across between risk sources, controls, and implementation dates.

8.3 High level risks, operational risks and project risks were all monitored through the Corporate Management Group (CMG) and Programme Board. There would also

be a CMG workshop in January 2015 to look in detail at the tolerance levels, residual and inherent risk scores and controls in the new version of the risk register, since Directors and Heads had so far had only limited opportunities to comment through items considered at CMG meetings.

8.4 The Committee agreed that the new format for the Strategic Risk Register was an improvement and that this gave a sense of the top risks.

8.5 The potential risk of inconsistent legal advice in relation to decision-making, when there is a rotation of legal advisers to Committees, was raised. It was suggested that minutes of previous hearings might be shared with subsequent legal advisors and that the Executive should look at other ways of increasing consistency of legal advice to Committee's.

8.6 The Committee agreed that the Risk Register reviewed in December 2013 would be published shortly.

ACTION:

8.7 Committee Secretary to Publish Risk Register reviewed in December 2013.

8.8 Head of Governance and Licensing to approach the organisation's legal advisers to discuss any actions to aid consistency in legal advice for the Authority's committees.

9. Public Interest Disclosure ("Whistleblowing") Policy

9.1 The Head of Human Resources presented the updated policy to the Committee.

9.2 The Whistleblowing Policy had been updated, guided by the Public Concern at Work code of practice. The staff forum and CMG had approved the policy.

9.3 Staff had been made aware of the Whistleblowing Policy and how to use it via all staff meetings, the intranet and email, and the updated policy would be similarly promoted.

9.4 The Committee discussed the approach outlined in paragraph 6.8 of the policy if a member of the Senior Management Team (SMT) was implicated in a case. Paragraph 6.10 of the policy sets out the relevant people to be consulted in each case.

9.5 The Committee noted that the policy is a formal document and by nature may appear off-putting to staff. Further guidance could be provided when it was discussed with staff and it was suggested that there should be a statement up front on the intranet to encourage staff to raise any concerns and feel assured during the process.

ACTION:

9.6 Amend paragraph 6.8 of the policy to show that in the event that an SMT member was implicated in a case, the Chair should be approached with concerns.

9.7 Head of Human Resources to add a statement to the intranet to encourage staff to raise concerns.

10. Resilience and Business Continuity

10.1 The Director of Finance and Resources presented developments to the Committee.

10.2 A more streamlined approach had been taken to identify critical activities, resources needed to manage in an emergency and to update the business continuity plan. This approach was more proportional to the type of organisation the HFEA was. The HFEA's assessment and approach had been shared with the Department of Health. A proportionate approach was required as the HFEA was a small organisation.

10.3 The Committee were informed of the key components taken into account to achieve business continuity in the event of a disaster happening. These components included maintaining essential communications, availability of the emergency site and staff working from home.

10.4 The Committee were informed of the results of the recent communications test. It had worked well generally, although there were some issues that the organisation had learned from and would improve.

10.5 The Committee were pleased with the progress made, the testing and improved communication channels, and that the needs of staff working out of the office were covered.

10.6 The Committee encouraged the Executive to be ever mindful of the possibility of sabotage to IT systems including through viruses and to guard against these.

ACTION:

10.7 Director of Finance and Resources to raise the issue of the possible sabotage of IT systems and how these possibilities are identified and mitigated, for the Executive to consider.

11. Action Plan following review of AGC activities and effectiveness

11.1 The Head of Governance and Licensing provided the Committee with a completed NAO checklist and an action plan following the annual review of AGC's effectiveness in October 2014.

11.2 The Committee noted that actions were in hand and would be reported on in Matters Arising at future meetings.

11.3 The Committee referenced point 8 of the Action Plan and clarified that the discussions planned should be with both internal and external auditors.

11.4 The Committee discussed the executive role Authority members had when sitting on panels and that this should be noted on the NAO checklist.

ACTION:

11.5 The Head of Governance and Licensing to add external audit to the AGC Action Plan point 8.

11.6 The Head of Governance and Licensing to add a comment to the response to the first question in the NAO checklist, to reflect Authority members' executive role.

11.7 Director of Finance and Resources to add actions to Matters Arising.

12. AGC Forward Plan

12.1 The Director of Finance and Resources provided the Committee with an updated forward plan of topics to be discussed at future meetings.

12.2 The Committee suggested that the number of meetings to be held each year should be reviewed in June 2015.

12.3 The Committee agreed the future topics.

13. Any Other Business

13.1 The Chair noted that the Committee Secretary had circulated the 2015 Committee Dates and asked AGC members to confirm their availability for those meetings, to ensure quoracy. Lynn Yallop gave her apologies for the March 2015 meeting – James Hennessey would attend instead for DH Internal Audit.

13.2 There were no further items of business.

Date of the next meeting:

Date: Wednesday, 18 March 2015

Time: 10:00 am

Location: The Royal Statistical Society, 12 Errol Street, London EC1Y 8LX

I confirm this to be a true and accurate record of the meeting.

Chair _____

Date _____

Audit and Governance Committee Paper

Paper Title:	**Matters arising from previous AGC meetings**
Paper Number:	[AGC (18/03/2015) 443 SG]
Meeting Date:	18 March 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:

- 9 items added from December 2014 meeting, 4 carried over from earlier meetings
- 12 items closed
- 10 items added from AGC self –assessment of performance, 6 completed

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 have completed the training except for the two new Members that joined the Authority in November. A further two Members join in April and will be asked to take the training then.

Matters Arising from Audit and Governance Committee – actions from 1 October 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
13.6 Conclude negotiations on minimum levels of reserves with DH	Director of Finance and Resources		**Completed**
14.10 Consider providing the Authority with AGC minutes as background to inform update from the AGC Chair	Head of Governance and Licensing	December 2014	**Completed** – minutes circulated immediately after sign-off
14.13 Implement annual appraisals for external members	Head of Governance and Licensing	March 2015	**Completed** – dates confirmed for annual appraisals

Matters Arising from Audit and Governance Committee – actions from 10 December 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
5.9 Consider the optimum timing for the Gateway review	Director of Compliance and Information		**Completed** - The IfQ and senior management team have agreed that a date prior to the signing of contracts with external suppliers will be optimal. The Review (Gateway 2) has been booked for March 25-27 2015.
8.7 Publish risk register reviewed in December 2013	Committee Secretary		**Completed**

Matters Arising from Audit and Governance Committee – actions from 10 December 2014 meeting			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
8.8 Discuss actions to aid consistency in legal advice for committees with legal advisers	Head of Governance and Licensing		**Completed** – HoGL attendance, plus pre-brief with legal adviser, plus client update meetings with Head of Legal, mitigate against risk.
9.6 Amend 6.8 of the Whistleblowing policy to show that the Chair should be approached if SMT implicated	Head of HR		**Completed**
9.7 Add a statement to the intranet to encourage staff to raise concerns (Whistleblowing policy)	Head of HR		**Completed**
10.7 Executive to consider how risk of possible sabotage of IT systems is identified and mitigated	Director of Finance and Resources		**Completed** – SMT considered the risk and will keep it under review
11.5 Add external audit to AGC performance action plan point 8	Head of Governance and Licensing		**Completed**
11.6 Reflect Authority Members' executive role in first question of AGC performance checklist	Head of Governance and Licensing		**Completed** - This is an NAO template but noted to tailor in this way for next year's review.
11.7 Add AGC performance actions to matters arising	Director of Finance and Resources	March 2015	**Completed** – Actions added below

Matters Arising from Audit and Governance Committee review of performance December 2014			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
a) Keep with plan to hold four meetings per year, and re-visit proposal for three meetings per year in six months' time.	Director of Finance & Resources	March 2015	**Completed** – forward plan, including discussion of number of meetings, on agenda for March 2015 meeting.

Matters Arising from Audit and Governance Committee review of performance December 2014			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
b) Ensure an action plan is kept in order to follow up on reviews of effectiveness.	Head of Governance & Licensing	December 2015	**Completed** – Now added to matters arising.
c) Ensure Accounting Officer attends June meeting of the committee every year, as a minimum.	Chief Executive	June 2015	**Completed** – Accounting Officer to attend March and June 2015 meetings and will continue to attend regularly.
d) Circulate committee minutes to all Authority members once signed off to ensure visibility of work carried out by committee.	Secretary to the Committee	From sign-off after December meeting	**Completed** – see 14.10 above
e) Arrange for external members to attend Authority meeting as observers	Head of Governance & Licensing	March 2015	**Ongoing** – members invited to meetings, suitable dates to be agreed.
f) Arrange for external members to observe an inspection	Head of Governance & Licensing	March 2015	**Ongoing** – Inspectorate's business support team in contact with external members and attempting to find suitable dates.
g) Arrange for members to have an annual appraisal with the Chair, adhering to the Authority member appraisal timescales	Chair of AGC	March 2015	**Completed** – Dates confirmed for annual appraisals, see 14.13 above
h) The committee must have time and space for discussions with Internal Audit only, which could be at the end of a meeting. It was noted that this was unlikely to be necessary, but would be built in to the consideration of agendas	Secretary to the Committee	December 2015	**Completed** – Initiated in December 2014 and now regular item in forward plan.

Matters Arising from Audit and Governance Committee review of performance December 2014			
ACTION	**RESPONSIBILITY**	**DUE DATE**	**PROGRESS TO DATE**
in future nevertheless.			
i) Institute formal annual report to Authority board	Head of Governance & Licensing	March 2015	**Ongoing** – initial plan is to formally report to May Authority meeting each year.
j) Give thought to improving communication from external appeals committees to AGC/Authority board, while maintaining independence of those committees.	Head of Governance & Licensing	March 2015	**Ongoing** – pending completion of current Appeals process.

Audit and Governance Committee Paper

Paper Title:	**Finance policies**
Paper Number:	[AGC (18/03/2015) 444 SG]
Meeting Date:	18 March 2015
Agenda Item:	**5**
Author:	Sue Gallone
For information or decision?	Decision
Recommendation to the Committee:	To note developments of Finance polices. To comment on and approve the Counter-fraud and anti-theft policy
Evaluation	To be reviewed annually

Background

1. Finance policies set out the principles and rules governing key areas of finance activity. The whole suite of policies, instructions from the Department of Health, accounting policies set out in the annual report and accounts, Standard Operating Procedures (SOPs) for the finance team and intranet guidance for staff, has been known in the HFEA as Standing Financial Instructions.

2. A key document in use in the HFEA was the Financial procedures. This included policies and procedures for a range of finance topics, including travel and subsistence and procurement. It was not always easy for staff to find the information they needed and there have been plans to update this for some time. In 2014 the HFEA requested that internal Audit provided advice to inform the update.

3. The Financial procedures have been replaced by a range of policies, supplemented by SOPs and guidance provided in the intranet. This approach, and the content of the policies, takes account of staff views and Internal Audit advice.

Finance policies

4. The policies now in use are:

   Reserves – approved by AGC in October 2014
   Expenses – approved by CMG in September 2014
   Budgetary control – approved by CMG in February 2015
   Procurement (including tendering) – approved by CMG in February 2015
   Counter-fraud and Anti-theft – presented to AGC in March 2015
   Licence fees – in progress

5. The policies for Reserves and Counter-fraud and anti-theft are presented to AGC for approval, as is the Whistleblowing policy (an HR policy). AGC review the accounting policies set out in the annual report and accounts, annually. In this way AGC can fulfil their duty of advising the Accounting Officer and Authority that suitable arrangements are in place for anti-fraud and whistleblowing and that there are proper accounting policies in place.

Counter-fraud and anti-theft policy

6. The policy has been reviewed and minor updates made. It is enclosed with this paper.

7. The key changes have been to:
   - Include specific reference to theft and bribery
   - Reflect the role of and assistance available from the DH Anti-fraud Unit
   - Make general updates to reflect current HFEA roles
   - Streamline the policy

Recommendation

8. That AGC notes the developments of Finance policies and approves the Counter-fraud and anti-theft policy.

Human Fertilisation & Embryology Authority

Counter Fraud and Anti Theft Policy

In this policy:

Counter Fraud and Anti-Theft Strategy

Counter Fraud and Anti-Theft Policy

1. Introduction

1.1 This strategy has been produced in order to promote and support the framework within which the HFEA tackles fraud and theft. It sets out the aim and objectives of the HFEA with respect to countering fraud and theft, whether it is committed externally or from within. Awareness of, and involvement in, counter-fraud and anti-theft work should be a general responsibility of all, and the support of all staff is needed with clear direction from the CEO that there will be a zero-tolerance attitude to fraud within the HFEA.

Definitions

1.2 Fraud has three general elements: false representation; failing to disclose information; and abuse of position. Fraud includes obtaining services dishonestly and possessing, together with making and supplying articles for use in frauds, and can encompass forgery, computer misuse and corruption. A person is guilty of theft if he dishonestly appropriates property belonging to another with the intention of permanently depriving the other of it.

Aim

1.3 It is the HFEA's aim to generate a counter-fraud and anti-theft culture that promotes honesty, openness, integrity and vigilance in order to minimise fraud and theft and its cost to the HFEA.

Objectives

1.4 In respect of the risk of fraud and theft, the HFEA seeks to:

- promote and support an counter-fraud and anti-theft culture;
- deter, prevent and discover fraud and theft effectively;
- carry out prompt investigations of suspected fraud and theft;
- take effective action against individuals committing fraud and theft;
- support the core values and principles set out in the *Civil Service Code*.

2. Protecting the HFEA from the Risk of Fraud and Theft

Promoting and supporting an counter-fraud and anti-theft culture

2.1 The HFEA seeks to foster an counter-fraud and anti-theft culture in which all staff are aware of what fraud and theft are, and what actions constitute fraud and theft. Staff should know how to report suspicions of fraud and theft with the assurance that such

suspicions will be appropriately investigated, and any information supplied will be kept in confidence.

2.2 Two key elements of an effective anti-fraud and theft culture are promotion and awareness, to ensure staff understand what fraud and theft is and know what standards of behaviour are expected. This will be achieved on an ongoing basis through:

- Staff inductions to ensure all new starters are clear about the HFEA's attitude to fraud and theft, and who they should contact if they have any suspicions;
- in house presentations to provide information on the nature of fraud and theft, and how it applies to the HFEA and it's employees;
- case studies to provide real examples of frauds and thefts and to demonstrate its prevalence within public sector organisations;
- maintenance of up to date policies and procedures, to ensure that the roles and responsibilities of all staff are clear, with special emphasis placed on the process for reporting suspicions of fraud and theft.

Deterring, preventing and discovering fraud and theft

2.3 The preferred way of minimising fraud and theft is to deter individuals from trying to perpetrate a fraud or theft in the first place. A counter-fraud and anti-theft culture whereby such activity is understood as unacceptable, combined with effective controls to minimise the opportunity for fraud and theft, can serve as a powerful deterrent. The main deterrent is often the risk of being caught and the severity of the consequences. One of the most important aspects about deterrence is that it derives from perceived risk and not actual risk.

2.4 If it is not possible to deter individuals from committing frauds and thefts, then the next preferable course of action is to prevent them from succeeding before there is any loss. Potential/possible frauds and thefts will be identified and investigated through a defined counter-fraud and anti-theft assurance programme addressing the areas where the HFEA is most vulnerable to fraud and theft. Any gaps in control or areas where controls are not being applied properly that are identified by this work will be addressed accordingly.

2.5 It is the responsibility of managers to ensure that there are adequate and effective controls in place. Internal Audit can provide assurance on the adequacy and effectiveness of such controls. In addition to the annual programme of internal audits (which provide

assurance on the controls identified in the Strategic and Operational Risk Registers), Internal Audit will also carry out advisory work on request, and seek to ensure appropriate controls are built into new systems and processes through its project assurance role.

2.6 It will not always be possible to prevent frauds and thefts from occurring. Therefore, the HFEA must have the means to discover frauds and thefts at the earliest opportunity. All staff should be vigilant and aware of the potential for fraud and theft and report any suspicions in accordance with the HFEA's Whistle Blowing Policy.

Prompt investigation of suspected frauds and thefts

2.7 All suspected and actual frauds and thefts will be investigated promptly in line with the Whistleblowing Policy in the first instance. The effective investigation of suspected and actual frauds and thefts depends upon the capability of the appropriate staff conducting these investigations. The Department of Health Anti-fraud Unit have the necessary skills to investigate once initial information has been obtained.

2.8 Unless inappropriate in all the circumstances, initial investigations will normally be undertaken by the following post holders:

Allegation against :	**Investigated by** :
Directors	Chief Executive
Chief Executive	Chair
Member	Chair
Audit Committee Member	Audit Committee Chair
Chair	Department of Health*

*Via Senior Sponsor at the DH (currently Paul McNaught, Director, Health Science and Bioethics (tel. 0207 210 6304 / paul.macnaught@dh.gsi.gov.uk)

Taking effective action

2.9 In the case of a proven allegation of fraud or theft, effective action will be taken in respect of those investigated in accordance with the HFEA's Disciplinary Policies and Procedures. The HFEA will always seek financial redress in cases of losses to fraud and theft and legal action will be taken where appropriate.

3. Policy Statement

3.1 The HFEA requires all staff at all times to act honestly and with integrity and to safeguard the public resources for which they are responsible. The HFEA will not accept any level of fraud, corruption or theft. Consequently, any suspicion or allegation of fraud or theft will be investigated thoroughly and dealt with appropriately. The HFEA is committed to ensuring that opportunities for fraud, corruption or theft are reduced to the lowest possible level.

3.2 Staff should have regard to related policy and procedures including (but not restricted to):

a. Expenses policy
b. Procurement policy
c. Financial Procedures
b. HFEA Staff Handbook
c. Disciplinary and Whistle Blowing Policies
d. Registering Staff Gifts and Interests
e. Homeworking

3.3 This policy applies to all staff including contractors, temporary staff and third parties delivering services to and on behalf of the HFEA.

3.4 The circumstances of individual frauds and thefts will vary. The HFEA takes fraud and theft very seriously. All cases of actual or suspected fraud or theft against the HFEA will be thoroughly and promptly investigated and appropriate action will be taken.

4. Definitions of Fraud and Theft

4.1 The Fraud Act 2006 created the general offence of fraud which can be committed in various ways. The main areas are by false representation, by failing to disclose information where there is a legal duty to do so, and by abuse of position. It also created offences of obtaining services dishonestly and of possessing, making and supplying articles for use in frauds.

4.2 The term fraud also encompasses bribery - an inducement or reward offered, promised or provided in order to gain any commercial, contractual, regulatory or personal advantage. The advantage sought or the inducement offered does not have to be financial or remunerative in nature, and may take the form of improper performance of an activity or function. Further guidance is at http://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf

4.3 A person is guilty of theft if he dishonestly appropriates property belonging to another with the intention of permanently depriving the other of it.

5. Avenues for reporting Fraud and Theft

5.1 The HFEA Whistle Blowing policy sets out how staff should report suspicions of fraud and thefts. All frauds, thefts, or suspicions of fraud or theft, of whatever type, should be reported in accordance with the Whistle Blowing policy. All matters will be dealt with in confidence and in strict accordance with the terms of the Public Interest Disclosure Act 1998. This statute protects the legitimate personal interests of staff and seeks to ensure that staff will not face any recriminations from voicing reasonably held suspicions.

6. Responsibilities

6.1 The responsibilities of HFEA staff in respect of fraud and theft are determined by the Treasury publication "Managing Public Money" (MPM), supplemented by the HFEA's policies and procedures.

Accounting Officer (Chief Executive)

6.2 As "Accounting Officer", the Chief Executive is responsible for managing the organisation's risks, including the risks of fraud and theft, from both internal and external sources. The risks of fraud or theft are usually measured by the probability of them occurring and their impact in monetary and reputational terms should they occur. In broad terms, managing the risks of fraud and theft involves:

a. assessing the organisation's overall vulnerability to fraud and theft;

b. identifying the areas most vulnerable to fraud and theft;
c. evaluating the scale of fraud and theft risk;
d. responding to the fraud and theft risk;
e. measuring the effectiveness of managing the risk of fraud and theft;
f. reporting fraud and theft to the Department of Health;
g. in consultation with the Director of Finance and Resources, Head of HR and Head of Legal, reporting any thefts against the HFEA to the police.

6.3 In addition, the Chief Executive must:

a. be satisfied that the internal control applied by the HFEA conforms to the requirements of regularity, propriety and good financial management;

b. ensure that adequate internal management and financial controls are maintained by the HFEA, including effective measures against fraud and theft.

6.4 The Chief Executive will be responsible for making a decision as to whether:

a. an individual who is under suspicion of fraud or theft should be suspended;

b. criminal or disciplinary action should be taken against an individual who is found to have committed a fraud or theft.

Such decisions should be taken in conjunction with the relevant Director and the Head of HR, with advice from the Head of Legal and Director of Finance and Resources where appropriate, to ensure consistency across the organisation. Should there be any disagreement over the appropriate action to be taken, the Chief Executive will be the final arbiter in deciding whether criminal or disciplinary action should be taken against an individual.

Director of Finance and Resources

6.5 Responsibility for overseeing the management of fraud and theft risk within the HFEA has been delegated to the Director of Finance and Resources, whose responsibilities include:

b. ensuring that the HFEA's use of resources is properly authorised and controlled;

c. developing fraud and theft risk profiles and undertaking regular reviews of the fraud and theft risks in order to ensure the HFEA can identify, itemise and assess how it might be vulnerable to fraud and theft;

d. evaluating the possible impact and likelihood of the specific fraud and theft risks the HFEA has identified and, from this, determining action to manage the HFEA's fraud and theft risks;

e. designing an effective control environment to prevent fraud and theft commensurate with the fraud and theft risk profiles. This will be underpinned by a balance of preventive and detective controls to tackle and deter fraud, corruption and theft;

f. ensuring that appropriate reporting of fraud and theft takes place within the organisation, to the Audit and Governance Committee and to the Department of Health;

g. measuring the effectiveness of actions taken to reduce the risk of fraud and theft, including by assurances from auditors and internal monitoring;

h. establishing the HFEA's response to fraud and theft risks including:

- developing a counter-fraud and anti-theft policy and response arrangements;
- developing and promoting a counter-fraud and anti-theft culture;
- allocating responsibilities for the overall management of fraud and theft risks and for the management of specific fraud and theft risks so that these processes are integrated into management generally;
- establishing cost-effective internal controls to detect and deter fraud and theft, commensurate with the identified risks;
- developing skills and expertise to manage fraud and theft risk effectively and to respond to fraud and theft effectively when it arises;
- establishing well publicised avenues for staff and members of the public to report their suspicions of fraud and theft;
- responding quickly and effectively to fraud and theft when it arises using trained and experienced personnel to investigate where appropriate;

- establishing systems to monitor the progress of investigations;
- referring suspected fraud cases to the Department of Health Anti-fraud Unit and drawing on their experience to strengthen control to reduce the risk of recurrence of frauds and thefts;
- seeking to recover losses;
- continuously evaluating the effectiveness of counter-fraud and anti-theft measures in reducing fraud and theft respectively;
- working with stakeholders to tackle fraud and theft through intelligence sharing, joint investigations and so on.

i. enforcing compliance with financial procedures across the organisation while guarding against fraud and theft and delivering continuous improvement in financial control;

j. In consultation with the Chief Executive, Head of HR and Head of Legal, reporting any thefts against the HFEA to the police.

Management (Directors, Heads of service)

6.6 Managers are responsible for:

a. ensuring that an adequate system of internal control exists within their areas of responsibility and that controls operate effectively, in order to assist in their role of preventing and detecting fraud and theft;

b. assessing the types of risk involved in the operations for which they are responsible;

c. reviewing and testing the control systems for which they are responsible regularly;

d. ensuring that controls are being complied with and their systems continue to operate effectively;

e. implementing new controls to reduce the risk of similar frauds and thefts taking place;

f. ensuring that all expenditure is legal and proper and in accordance with policies and guidance;

g. reporting any fraud, or suspicion of fraud in accordance with the Whistle Blowing Policy;

Staff

6.7 All staff, individually and collectively, are responsible for avoiding loss and for:

a. acting with propriety in the use of official resources and the handling and use of public funds whether they are involved with cash or payments systems, receipts or dealing with suppliers;

b. acting in accordance with policies and guidance;

c. conducting themselves in accordance with the seven principles of public life set out in the first report of the Nolan Committee "Standards in Public Life". These are:

- Selflessness: Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends;
- Integrity: Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties;
- Objectivity: In carrying out public business, including making public appointments or recommending individuals for rewards and benefits, holders of public office should make choices on merit;
- Accountability: Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office;
- Openness: Holders of public office should be as open as possible about all the decisions and action that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands it;
- Honesty: Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest;
- Leadership: Holders of public office should promote and support these principles by leadership and example.

d. being alert to the possibility that unusual events or transactions could be indicators of fraud or theft;

e. reporting details immediately through the appropriate channel if they suspect that a fraud or theft has been committed or see any suspicious acts or events;

f. co-operating fully with whoever is conducting internal checks or reviews, or investigations of fraud or theft.

6.8 Staff are specifically not responsible for investigating any allegations of fraud or theft. Suspicions should be reported in accordance with the HFEA's Whistle Blowing Policy.

Board Members

6.9 Authority Members have a responsibility to:

a. comply at all times with the Code of Conduct that is adopted by the Authority and with the rules relating to the use of public funds and to conflicts of interest, and declare any interests which are relevant and material to the HFEA;

b. not misuse information gained in the course of their public service for personal gain or for political profit, nor seek to use the opportunity of public service to promote their private interests or those of connected persons or organisations;

c. comply with the HFEA's rules on the acceptance of gifts and hospitality and of business appointments.

Internal Audit

6.10 Internal Audit's primary responsibilities in relation to fraud are:

a. delivering an opinion to the Chief Executive on the adequacy of arrangements for managing the risk of fraud and ensuring that the HFEA promotes an anti-fraud culture;

b. assisting in the deterrence and prevention of fraud by examining and evaluating the effectiveness of control commensurate with the extent of the potential exposure/risk in the various segments of the HFEA's operations;

c. ensuring that management has reviewed its risk exposures and identified the possibility of fraud as a risk.

Audit and Governance Committee

6.12 The Audit and Governance Committee is responsible for:

a. Receiving reports on any actual or suspected fraud, theft or losses, and action in response to these;

b. Ensuring that the HFEA has in place an appropriate fraud policy and fraud response plan.

7. References

Managing Public Money – Chapter 4 and Annex 4.7 (HM Treasury);

Managing the Risk of Fraud (HM Treasury) :

www.hm-treasury.gov.uk

Core Values and the Civil Service Code :

www.civilservice.gov.uk/about/values/index.aspx

Doc Name and Reference number:	FIN00X Counter Fraud and Anti Theft Policy
TRIM number:	2012/007300
Latest Version No:	2
Release date:	
Author:	Head of Finance
Approved by:	CMG/AGC/
Next review due:	February 2016
Total pages:*	14

Version/revision control

Version	Changes	Updated by	Approved by	Release date
1	New Policy	Rachael Henry	Rachel Hopkins	1st July 2010
2	Revised Policy	Rachael Henry	CMG/AGC/Staff Forum	10th May 2012
3	Reviewed	M Akingbola	AGC	March 2015

Audit and Governance Committee paper

How this paper relates to our strategy	Setting standards	☐	Increasing and informing choice	☑	Demonstrating efficiency, economy and value	☑
Paper title	Information for Quality – managing risks					
Agenda item	**6**					
Paper number	[AGC (18/03/14) 445) NJ]					
Meeting date	18 March 2015					
Author	Nick Jones, SRO & Director of Compliance and Information					
For information or decision?	Information					
Recommendation	The Committee is asked to note this update					
Resource implications						
Implementation	In progress.					
Communication	Extensive stakeholder communication					
Organisational risk	Medium.					
Annexes	N/a					

1. Introduction

This report updates the Audit & Governance Committee (AGC) on the progress of the programme specifically in the areas covered by the AGC terms of reference.

2. Progress

i. Since the last meeting of the AGC the business case, along with associated digital expenditure controls, was submitted to Department of Health (DH) on 18 December 2015. The DH itself is subject to wider

Cabinet Office controls that exist to raise the standard of digital and technology projects across government. New projects must meet the 'Digital by Default Service Standard' - ensuring designs meet the needs of users. As such, in our submission and subsequently at meetings with DH colleagues, we have sought to address these expectations.

ii. Approval has not yet been given, despite an early indication that the process should by relatively quick. There is some frustration on our part as to the delay and there has been insufficient clarity as regards how best to amend or revise our submission.

iii. Inevitably, the delay to approval has a knock-on consequence both on the delivery schedule of the overall Programme (it was expected that work would be completed by the end of 2016/17) and costs.

iv. In relation to costs, Authority has agreed to expenditure of £720,000 to end of March 2015. This is not going to be exceeded as programme management costs are predictable – with programme technical expenditure scheduled from April 2015. However delays incurring additional programme management expenditure reduce the amount available next year – putting at risk the improvements we can achieve. Delays to date are likely to incur approximately £40,000 in additional costs in 2016/17.

v. We are working hard with DH to ensure these risks are mitigated, in particular that as far as possible all necessary information required is clarified and submitted to satisfy DH and Cabinet Office colleagues and we continue to review costs and options to minimise the impact on original proposals. A further oral update on progress will be provided at the meeting.

vi. At its January 2015 meeting, the Authority noted the above approved the overall and revised IfQ budget of £1.85m to the Programme completion date of end March 2016 (that is £720,000 committed to date with a further £1.1m expenditure in 2015/16 financial year) and to receive progress reports on this expenditure at each meeting of the Authority.

vii. At that meeting the Authority also agreed the principal outcomes from the report of the extensive consultation undertaken in 2014 and the recommendations from the IfQ Advisory Group that met in December 2014 to consider the report. The Authority agreed the following, in summary:

- The Register: To a 'data dictionary' and the establishing of a standing group to maintain the integrity of the data the HFEA collects and holds – together with the mandating of a NHS number for patients (to act as a single identifier);

- Data submission: A root and branch review of the basis by which information is submitted by centres, including a new clinic portal providing enhanced functionality enabling clinics to 'see' their submitted data; and the implementation of a secure mechanism for the electronic submission of donor goodwill messages and pen portrait information.

- Website: The HFEA website should, amongst other things, be redeveloped with a more intuitive design to make information more user-friendly, less complex and organised around a typical user journey.

- Choose a Fertility Clinic (CaFC) structure, information and outcome data: A raft of changes relating to simplifying data presentation; patients' feedback about clinics' performance to be given greater prominence; and to the outcome measures given prominence.

viii. Since the last meeting of AGC good progress has been made with the strategy for data migration. Members are reminded that data migration has not taken place and is not anticipated to start until the 2015-16 business year. Avoca, a specialist healthcare data specialist has been commissioned to support the development of our migration strategy. A draft report has been submitted setting out the key risks (to our proposed approach) to date – and the IfQ Programme Board looks forward to interrogating the report and management response on 16 March 2015.

3. Governance

i. The IfQ programme board has continued to meet and has reported progress to the December 2014 and January February 2015 meeting of the Corporate Management Group (CMG).

ii. At the last meeting we reported that a Government Gateway Review has been commissioned. This is on track to take place on 25 – 27 March 2015 inclusive – with the review feedback provided to the SRO on the final afternoon. The review team (less one member unavoidably detained elsewhere) met with the SRO and colleagues on 5 March 2015 for a preparation and orientation meeting. The team is led by a senior official from the Ministry of Defence supported by two colleagues experienced in information and technology - from NHS England and from a local provider body.

iii. An issue relating to the risk of 'sabotage' raised at the last meeting is covered under Matters Arising.

4. Internal Audit

i. Progress as regards internal audit recommendations received at the December meeting of AGC is shown elsewhere in the papers.

ii. The next phase of the IfQ internal audit programme is to observe deliberations as regards the data migration strategy and implementation (see above). The first key milestone - for a member of the internal audit team to observe the next meeting of the IfQ Programme Board is on 16 March 2015. The contractors engaged to develop a migration strategy will be presenting their findings here, and subsequent actions and milestones will be agreed at that point.

5. Report from the our tender panel

In accordance with Standing Financial Instructions the committee is requested to note that one contract has been awarded since the last meeting, to Avoca Systems Ltd for the development of a data migration strategy for £10,000 plus VAT, £12,000 inclusive.

Recommendation

The Committee is asked to note this report.

Audit and Governance Committee paper

Strategic delivery	**Setting standards**	☐	**Increasing and informing choice**	☐	**Demonstrating efficiency, economy and value**	☑
Paper title	**Strategic Risk**					
Agenda item	**7**					
Paper number	AGC (18/03/2015) 446					
Meeting date	18 March 2015					
Author	Paula Robinson					
For information or decision?	Information and comment					
Recommendation	AGC is asked to note the latest edition of the risk register, and the information about planned further developments to our risk system, set out in the covering paper.					
Resource implications	In budget.					
Implementation	Strategic Risk Register and operational risk monitoring: ongoing. Risk assurance mapping: to be introduced in stages over the coming two-three years.					
Communication	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. Comments from the 11 March Authority meeting will be fed back verbally at the meeting..					
Organisational risk	Captured in document.					
Annexes	A: Strategic Risk Register					

1. Strategic Risk Register

1.1. CMG review - February 2015

1.2. CMG reviewed the new Strategic Risk Register (SRR) on 5 February. Five of the twelve risks are currently above tolerance, and CMG discussed those risks, and their controls, in particular. Risk scores were also reviewed throughout. CMG's specific comments are contained in the attached SRR at Annex A.

1.3. CMG also discussed the following matters.

Assessing inherent risk

1.4. 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'.

1.5. However, in reality, the very existence of an organisational infrastructure and associated general functions, systems and processes does impose some control over risks, even if no other mitigating action were ever taken, and even with no particular risk in mind.

1.6. Therefore, in order for our estimation of inherent risk to be meaningful, CMG would like to redefine 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.'

1.7. CMG agreed that an internal audit view would be extremely useful concerning the appropriateness of the HFEA having its own working definition, as above, since this varied from the standard approach.

1.8. It was also acknowledged that there would need to be a shared management understanding of which things constituted 'pre-existing ongoing organisational systems and processes'. This would not, for instance, imply an assumption that good line management procedures were always automatically in place and followed (since those might be the very things that needed to be improved and developed, as a control for a given risk). It would, however, assume that it was a given that HR policies did exist and that people had line managers. Imagining a world where people did not have line managers and the organisation had no HR policies was unrealistic and would not lead to a good baseline estimation of risk before risk-specific controls were added. Indeed, regarding inherent risk in a purist way tended sometimes to lead to an inherent risk rating which seemed unduly alarmist and did not feel justified.

Response to AGC comments

1.9. At the December AGC meeting, it was raised that using various legal advisers, rather than just one, could involve a risk of inconsistent advice and interpretations of the law. CMG acknowledged that this is indeed the case. However, the HFEA has no choice but to use many such advisers, owing to the very high volume of legal work and the need to be able to draw on the right legal expertise for different sorts of legal and governance situations. Having a panel to draw on, and using other specific experts such as particular QCs from time to time, is critical to delivery (and to avoiding conflicts of interest), and using a single legal adviser is not a viable option. It is also necessary for the HFEA to have enough resilience in its legal advice pool to ensure that advice can always be obtained when needed, including on multiple matters at once.

1.10. We control for consistency in our legal advice by ensuring all those on the panel understand our Act, our decision trees, our standing orders (SOs), and relevant processes (particularly licensing and related decisions, representations and appeals). They were trained as a group following the work done on decision trees, processes and the SOs during and after the delivery of the Governance Transition Programme two years ago.

1.11. Another question was raised regarding business continuity in relation to data and systems risks. Most organisations include controls for the potential risk of system sabotage by key staff with access.

1.12. CMG discussed this and agreed that although we do have some controls in place, we need to give further thought to this, and will do so. A paper will be prepared by the Director of Compliance and Information, initially for discussion at SMT. Feedback will be brought to a future AGC meeting on this issue. This paper will include consideration of the Register data migration strategy, which forms an important part of the Information for Quality programme.

1.13. Our existing main controls at present are off-site back ups; and the considerable disincentive that damaging Register data in any way would be a criminal act. The real risk at the HFEA would be code sabotage – for which there would be more opportunity here than in other comparable organisations. We will seek assurance that the off-site back ups are not vulnerable to sabotage.

1.14. CMG also welcomed advice received from AGC in December about building the 'three lines of defence' model into our approach to risk assurance mapping, and about including the frequency, as well as the timing, of assurances. This has been noted for the future.

2. Operational risk and risk assurance mapping

2.1. Operational risk system

2.2. CMG agreed that operational risk and risk assurance mapping should go hand in hand (providing that the separate purpose of each is clearly understood), and that it was time to re-energise our approach to operational risk management.

2.3. Given the current emphasis within the organisation on the importance of operational planning for the coming year, the accompanying operational risk log for each team will also be important.

2.4. The current operational risk process has been in place for many years, and recent organisational structure changes mean that there are now inconsistencies of approach across the system. For instance, some teams reporting into the quarterly CMG review of operational risks are very small (two people), while others are larger, with all teams, regardless of size, reporting just a 'top three operational risks'. Some teams have continued to update old risk logs, which are not necessarily contained within the correct TRIM classification, making them hard to find on the system. Therefore some general housekeeping is necessary as well as some clarity about expectations.

2.5. CMG also agreed that it would be helpful to the overall consistency of teams' operational risk assessments if the risk log template was restructured slightly to reflect the strategy, and also the likely headings for consideration in future risk assurance mapping (see below). This redesign work is in progress now and will be completed and in use in time for the new business year. This will be discussed again at the next CMG risk meeting in May.

2.6. **Risk assurance mapping**

2.7. CMG heard that assurance mapping would constitute a new and additional activity for HFEA staff. CMG agreed that there was no prospect of capacity to spend significant time in meetings looking in detail at risk assurance as a whole group. However CMG recognised that it was important that the Executive should be able to assure the Authority that risks were being properly and effectively controlled and that this would require the development of a risk assurance map. Therefore, it was proposed that risk assurance should be developed gradually, with some immediate steps being taken so as to lead us in the right direction.

2.8. CMG noted that the Care Quality Commission (CQC), who were also introducing this concept into their organisation for the first time, had kindly shared their draft approach. CMG agreed that the CQC's headings could be used, both in operational risk templates and as areas of focus for risk assurance. These headings are as follows:

- planning
- performance and risk management
- quality management
- financial management, systems and controls
- information and evidence management
- people management
- accountability
- oversight and scrutiny.

2.9. The HTA, which is in a similar position, recently conducted a small pilot exercise with a range of staff and with internal audit facilitation, looking at just one area (people management) in depth. This was useful but time consuming so the HTA has decided to look at other areas over a longer time span.

2.10. CMG agreed that there may be merit in adopting the HTA method of doing a deep dive periodically, even though it would take some years to complete this cycle for all areas. However, CMG was also in agreement that such an approach could not be implemented now in light of current capacity strains.

2.11. It would be more feasible in the HFEA to start with a lighter touch approach that would help to introduce staff to the concepts, perhaps through an interim 'self-assessment' framework that Heads could use with teams alongside regular consideration of their operational risk logs. It might then be possible to start to implement a 'deep dive' approach at team level, taking the above listed themes one by one, once staff had begun to be familiar with the activity.

2.12. CMG agreed that Directors and Heads should start to discuss risk and risk assurance on a regular basis at team and one-to-one meetings, and that the Head of Business Planning should next put together some more detailed thoughts for the CMG risk meeting in May on how the HFEA might approach this, but ensuring, in light of earlier capacity discussions, that no further overload for staff was entailed, since this would cause more risk than it would manage.

3. Recommendation

3.1. The Audit and Governance Committee is asked to note the above update on recent CMG discussions about risk. The Authority will also discuss the risk register and surrounding developments at its meeting one week before AGC, and members' comments will be reported verbally to this meeting.

3.2. Further comments are invited on the latest edition of the risk register, and on the other matters set out in this paper.

Annex A

HFEA Strategic Risk Register 2014/15

Risk Summary: High to Low Residual Risks

Rank	Risk Area	Risk Title	Strategic Linkage[1]	Residual risk	Current status	Trend*
1	Legal challenge	LC 1: Resource diversion	Efficiency, economy and value	15 – High	Above tolerance.	⊙⇩
= 2	Information for Quality	IfQ 1: Improved information access	Increasing and informing choice: information	12 – High	Above tolerance	⊙⇔
	Data	D 2: Incorrect data released	Efficiency, economy and value	12 – High	Above tolerance.	⊙⇔
	Capability	C 1: Knowledge and capability	Efficiency, economy and value	12 – High	Above tolerance.	⊙⇔
	Financial viability	FV 1: Income and expenditure	Efficiency, economy and value	12 – High	Above tolerance.	⊙⇔
6	Data	D 1: Data loss or breach	Efficiency, economy and value	10 – Medium	At tolerance.	⊙⇔
= 7	Information for Quality	IfQ 3: Delivery of promised efficiencies	Efficiency, economy and value	9 – Medium	At tolerance.	⊙⇔
	Donor conception	DC 2: Support for OTR applicants	Setting standards: donor conception	9 – Medium	At tolerance.	⊙⇔
= 9	Regulatory model	RM 1: Quality and safety of care	Setting standards: quality and safety	8 – Medium	At tolerance.	⊙⇔
	Regulatory model	RM 2: Loss of regulatory authority	Setting standards: quality and safety	8 – Medium	At tolerance.	⊙⇔
	Information for Quality	IfQ 2: Register data	Increasing and informing choice: Register data	8 – Medium	At tolerance.	⊙⇔
12	Donor conception	DC 1: OTR inaccuracy	Setting standards: donor conception	4 – Low	At tolerance.	⊙⇔

* This column will track the four most recent reviews by AGC, CMG, or the Authority (e.g. ⇧⇔⇩⇔). At present we have only had one formal review since the start-point (⊙), which was in November 2014.

[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)

CMG Overview

Discussion - 5 February CMG Risk meeting:

Our current biggest risk (and issue) is capacity and resulting operational strain. This can be seen throughout the risk register. The current combination of turnover, churn, minimal resilience and high workloads means there is a lot to manage at the moment.

Five of the risks are currently above tolerance, despite controls being in place. In some instances (eg, certain legal cases) these may be completely outwith our control. With other risks, such as morale, it will take time for controls to be developed and to take effect. Other risks have good controls, but also have impactful external dependencies that are central to the risk's landscape and are not in the HFEA's power to mitigate (such as budget or business case approval times; certain legal matters).

Overall, operational risk is considerable at present, with a fairly high proportion of strategic risks that cannot be completely mitigated by the HFEA. This results in a lot of pressure, since we now have little resilience for flare-ups or for managing all of the various recruitments and associated churn. Managers are under particular pressure, with much less time available for business as usual.

Since this is the case, as an overall measure, we are placing high importance on operational planning, particularly early planning for the next year (2015/16). We are involving teams in this to ensure they are clearly sighted on the links between their own jobs and the strategic vision, and that individual staff, who are the most familiar with the detail of the operational activities connected to their role, have the opportunity to suggest different ways of working, or work that could be deprioritised or done to a lower level of quality, so as to reduce the strain on resources without compromising delivery of the Authority's strategic objectives and vision.

Progress with service delivery planning was subsequently discussed in detail at the February monthly CMG meeting, and good progress is being made. It is important that planning for next year's delivery is very much managed from a risk perspective. This will not involve any aggressive cutting of the business plan for 2015/16, which expresses only our strategic and core statutory activities, and articulates these in a high level way. The detail of delivery is set out in service delivery plans, and so it is on that level where resource prioritisation needs to be considered.

With regard to the legal risk, LC1, some risks of legal challenge are out of our scope to control. CMG agreed that legal challenge and legislation implementation were expected elements of the Authority's business that need to be dealt with continually, at times culminating in peaks of work that may be difficult to handle, but nonetheless have to be prioritised. This is unavoidable, but is an especially noteworthy fact of life, now that resilience and capability are a real issue.

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, CMG would like to define 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**.'

Note: An Internal Audit view on this definition will be sought shortly.

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	At tolerance.
	Audit of Epicentre to reveal any data errors.	In progress – Mar 2015 – Sam Hartley	
	Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor	
Monitoring failure.	Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor	
Unresponsiveness to or mishandling of non-compliances or grade A incidents.	Update planned to Compliance and Enforcement Policy.	End of Mar 2015 – Debra Bloor	
	Staffing model being changed to build resilience in inspection team for such events - dealing with high-impact cases, additional incident inspections, etc..	In progress - Debra Bloor – Mar 2015	
Insufficient inspectors or licensing staff	Recruitment in progress for 2 more clinical inspectors; 2 scientific inspectors recently recruited.	Recruitment stage completed – Debra Bloor - Feb 2015 2 x new scientific inspectors started on 5 Jan 2015 – Debra Bloor 2 x new clinical inspectors – start dates 9 Feb, 23 March	
	Temp cover in place for vacancy in licensing team, recruitment in progress.	In progress – Sam Hartley – now at external recruitment stage – Mar 2015	

Strategic Risk
9

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 have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment.	Managed as the situation evolves – Debra Bloor	
	NHS Jobs account to be changed so that vacancies appear under an HFEA identity rather than a CQC identity (still for CQC to administer), to address misunderstandings about who the employer is.	Active chasing in progress with NHS Jobs – Mar 2015 – Rachel Hopkins	
	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	
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation of work an option.	In place – Paula Robinson	
Unexpected fluctuations in workload (arising from e.g. 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).	New staffing model being developed, to release an extra inspector post out of existing establishment. This will increase general resilience so as to enable more flex when there is an especially high inspection/report writing/application processing workload.	In progress – Debra Bloor – Mar/Apr 2015 (Will be put fully in place once the new clinical inspectors have both joined)	
	PGD workshop annually with the sector to increase their insight into our PGD application handling processes and decision-making steps; coupled with our increased processing times from efficiency improvements since 2013 (acknowledged by the sector).	In place and annual – Debra Bloor	
Some unanticipated event occurs that has a big diversionary impact on key resources, e.g. several major Grade A incidents occur at once.	As above.	In progress – Debra Bloor – Mar 2015	
	Compliance and Enforcement policy to be reviewed to improve handling processes for incidents and non-compliance.	End of Mar 2015 – Debra Bloor	

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	At tolerance.
	Learning from recent Representations experience incorporated into processes.	In place – Sam Hartley	
	Appeals Committee membership maintained – vacancy being filled.	In progress Feb 2015 – Sam Hartley	
	Staffing structure for sufficient Committee support.	In place – Sam Hartley	
	Decision trees; Legal Advisers familiar.	In place – Sam Hartley	
	Proactive management of quoracy for meetings.	In place – Sam Hartley	
	Further delegations planned to ELP, and new Licensing Officer role.	Plan considered at Jan 2015 Authority – in progress - Sam Hartley	
Failing to demonstrate competence as a regulator	Review of Compliance & Enforcement Policy.	End of Mar 2015 – Debra Bloor	
	Inspector training, competency-based recruitment, induction process, SOPs, Quality Management System (QMS), and quality assurance all robust.	In place – Debra Bloor	
Effect of publicised grade A incidents.	Staffing model being changed to build resilience in inspection team for such events - dealing with high-impact cases, additional incident inspections, etc..	In progress, for implementation when the new inspectors have all started – Debra Bloor – Mar/Apr 2015	
	SOPs and protocols with Communications team.	In place – Debra Bloor	
	Fairness and transparency in licensing committee information.	In place – Debra Bloor	
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor	

Administrative or information security failure, e.g. document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen (next round is due in Q1 of 2015/16)	
	TRIM training, and guidance/induction in records management and handling FOI requests, available to all staff.	In place – Sam Hartley	
	Further work to be planned on records management, to ensure our documents remain searchable and well organised.	Timescale to be confirmed – Sam Hartley	
Negative media or criticism from the sector in connection with legally disputed issues or major adverse events at clinics.	HFEA approach is only to go into cases on the basis 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.	In place - Peter Thompson	
HFEA process failings that create or contribute to legal challenges, or which weaken cases that are otherwise sound.	Licensing SOPs, Committee decision trees in place.	In place – Sam Hartley.	
	Update planned to Compliance and Enforcement Policy.	End of Mar 2015 – Debra Bloor.	
	QMS and quality assurance in place in inspection team.	In place – Debra Bloor	

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 is in development. 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 progress – Nick Jones (IfQ business case submitted Dec 2014; decision awaited)	Above tolerance. Much of this is actively being worked out now, and is still in progress. Managing these risks forms an intrinsic and essential part of the detailed project planning and tendering. Delivery also depends on the still-awaited decision on the business case, which was submitted in December. Additional information has been provided.
Unable to work out how best to improve CAFC, and/or failure to find out what data/information patients really need.	Stakeholder engagement is in place as intrinsic part of Programme approach.	In place and ongoing - Dec 2014 onwards – Nick Jones	
Stakeholders not on board with the changes.	In-depth stakeholder engagement 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 taken into account as an important factor in consideration of contract tenders.	In place - Dec 2014-Mar 2015 – Nick Jones	
Website redevelopment project fails to deliver or new website is inadequately designed.	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.	In progress – delivery by end of Mar 2016 – Juliet Tizzard	

Government and DH permissions structures are complex, multi-stranded, and sometimes change mid-project.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme submitted.	In place – Nov 2014 – Juliet Tizzard In place – Dec 2014 – Nick Jones (decision awaited)	
Resource conflicts between delivery of website and Business as Usual (BAU).	Backfilling to free up the necessary staff time, e.g. Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options being scrutinised as part of project.	In progress – Jan/Feb 2015 (depending on approval) – Juliet Tizzard	
Communications infrastructure incapable of supporting the planned changes.	Needs to be updated as part of IfQ in order to support the changes.	In place - set out in business case – Juliet Tizzard – Dec 2014	
Contractor failure - delivery is highly contractor dependent.	Programme Management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery.	In place – Nick Jones	

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. Intensive planning in progress, including detailed research and external assistance with planning the detailed migration strategy.	In progress – Nick Jones/Dave Moysen – Jan 2015	At tolerance. This risk is being intensively managed – a major focus of current IfQ detailed planning work.
Historic data cleansing is needed prior to migration.	A detailed migration strategy is being produced, and a data cleansing step will form part of this (the migration itself will occur much later).	In progress – Nick Jones/Dave Moysen – Jan 2015	
Increased reporting needs mean we later discover a problem, 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 also being agreed. Decisions being made now about the required data quality for each field are being 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In progress – Nick Jones – Feb-Mar 2015	
Reliability of existing infrastructure systems – (e.g. 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.	In progress – Nick Jones – January 2015	

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 coming to an end, but a new stakeholder group for implementation phase is planned.	In place – Nick Jones/Juliet Tizzard	
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.	Scoping and specification are being elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery will be a critical part of the decision when awarding the contract.	In progress – Nick Jones – Jan 2015	
Efficiencies cannot, in the end, be delivered.	Detailed scoping phase with stakeholder input to identify clinic users' needs. Specific focus in IfQ projects on efficiencies in data collected, submission and verification, etc.	In progress – Nick Jones – Jan 2015	
Cost of improvements becomes too prohibitive	Contracts will only be awarded to bidders who make an affordable proposal.	In progress – Nick Jones – Jan 2015	

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.
	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 - e.g. external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin	
Lack of clarity in 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..	In place – Sam Hartley	
	More work planned on enhancing Committee tools to incorporate recent lessons learned.	In progress as at Feb 2015 – Catherine Drennan / Sam Hartley	
Subjectivity of judgments means the 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.	Scenario planning has recently proved useful, and a process for this will be put in place.	For development during Feb/Mar 2015 – Catherine Drennan / Peter Thompson	

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.	
	Work planned to explore other relevant processes in light of lessons learned following a recent Judicial Review judgment.	In progress as at Feb 2015 – Catherine Drennan / Sam Hartley	

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 development in progress, including a thorough investigation of the Cloud option, security, and reliability. Decision to move to Cloud solution not yet final.	In progress – Dave Moysen – Feb-Apr 2015	
	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 as indicated – Dave Moysen Further consideration to follow – Nick Jones and SMT – timescale to be confirmed.	
Business continuity issue.	BCP in place and staff communication procedure tested.	In place – Jan 2015 – Sue Gallone	

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	**4**	**12 High**		
			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.	In progress – for completion Mar 2015 - Sam Hartley	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 are currently among the highest we have ever experienced.
	TRIM review and retention policy implementation work	In progress but delayed to Mar 2015 – Sam Hartley	
	Audit of Epicentre information	In progress – for completion Mar 2015 – Sam Hartley	
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	
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. This, and ongoing issues with the very high volume being received at present, will be raised with DH when the framework agreement is next reviewed.	In place – Sam Hartley/Peter Thompson Date of next review tbc – 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	

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, and establish more efficient processes.	In progress – Jan 2015 - 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 being established with external contractor.	Set-up in progress – Nick Jones – Jun 2015	At tolerance. The pilot counselling service is not yet in place, and should bring the risk below tolerance from June 2015 onwards.
Insufficient register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries.	In place – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	

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 can be met from reserves.
	Fees Group created enabling dialogue with sector about fee levels.	First meeting 29-10-14; and Apr and Oct each year, 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 after business planning.	December annually – Sue Gallone (but not yet confirmed as at Feb 2015)	
	Further discussions planned with DH to obtain budget confirmation.	Feb 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 e.g. legal, 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.	Monthly – Sue Gallone	
Upwards scope creep during projects, or emerging during early development of projects e.g. IfQ.	Finance presence at Programme Board (PB) level. Periodic review of actual and budgeted spend by PB.	Ongoing – Wilhelmina Crown	
	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:			⊙	Peter Thompson
			Likelihood	Impact	Inherent Risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual Risk		
			4	**3**	**12 High**		
			Tolerance threshold:		6 Medium		

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.	People Strategy in progress – delivery by end Mar 2015 – Rachel Hopkins	Above tolerance. The residual impact remains at 3 for the time being, since we are going through a period of turnover and transitions. This risk and the set of controls focuses 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.
	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 5 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	
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 and implementation in progress – Mar 2015 – CMG/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 being given to team-level service delivery planning for 2015, with active involvement of team members.	In place – Jan 2015 – 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	

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 MANAGEMENT SCORING MATRIX						
IMPACT	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
		1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
		LIKELIHOOD				

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 MANAGEMENT SCORING MATRIX						
IMPACT	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
		1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
		LIKELIHOOD				

HFEA Internal Audit Progress Report

1) Purpose of paper

This paper sets out the following for consideration by the HFEA Audit and Governance Committee on 18th March 2015:

- Progress to date against the 2014/15 Audit Plan; and
- Draft Internal Audit Plan 2015/16.

2) Progress against 2014/15 Internal Audit Plan

2.1 Status of agreed plan:

The table below summarises the progress against each of the review areas in the 2014/15 Audit Plan.

Reviews per 2014/15 IA plan	Audit scope per 2014/15 plan	Status	Findings				Overall report rating	Audit days per plan	Actual audit days
			Critical	High	Medium	Low			
IfQ	This review will provide assurance over the IfQ programme using PwC's 'Twelve Elements Top Down Project Assurance Model'. This approach provides a high-level analysis into the immediate and future risks that could affect the delivery of the IfQ programme, and will deliver recommendations and guidance around risk treatment.	Final report issued 01/12/14	0	1	6	1	**Moderate**	10	10
Standing Financial Instructions	This review will provide assurance over current standing financial instructions, including a comparison with HFEA's existing arrangement versus good/best practice. Results of this review will feed into the forthcoming management review of standing financial instructions.	Final report issued 19/01/15	N/A – This is an advisory report and as such carries no ratings					10	10
Internal Policies	We will review the HFEA register of policies and related documents and comment on:	Final report issued	0	2	0	0	**Limited**	12	12

Reviews per 2014/15 IA plan	Audit scope per 2014/15 plan	Status	Findings				Overall report rating	Audit days per plan	Actual audit days
			Critical	High	Medium	Low			
	• Whether processes to determine the frequency and ownership of policy reviews, including version control, are effective and appropriate; • Whether revised/refreshed policies are subject to appropriate authorisation by the relevant forum; • Whether standing orders and committee terms of reference are refreshed on a sufficiently regular basis and are fit for purpose; • Whether policies are appropriately linked with other related policies, standing orders and committee terms of reference; and • Where a refresh to policy is made there are prompt communications to all relevant staff informing them of the policy update.	07/03/15							
Register of Treatments	HFEA is embarking on a significant IT project to improve clinical interfaces with fertility clinics. A high risk element of this project will be the data migration from the current Register of Treatment database to a new database which will be more user friendly and provide a more effective and efficient means of ensuring complete and accurate reporting. This will not be a compliance review; instead internal audit will attend key milestone project management meetings and provide challenge to the project team on progress against milestones and how risks are being mitigated, with a focus on the data migration element of the project. The output from internal audit will be external file notes giving updates from these meetings to the HFEA executive team and Audit and Governance Committee.	Final ToR agreed. PwC to attend IfQ Programme Board on 16/03/15						12	0

Reviews per 2014/15 IA plan	Audit scope per 2014/15 plan	Status	Findings				Overall report rating	Audit days per plan	Actual audit days
			Critical	High	Medium	Low			
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 2015/16 audit plan; • Resourcing and risk management; and • Contingency.	Ongoing	-					10	8
		Total Findings:	**0**	**3**	**6**	**1**			
							Total days	**54**	**40**

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

Since the last Audit and Governance Committee in December 2014 we have issued:

- The final Standing Financial Instructions report on 19th January 2015;
- The Final Internal Policies report on 7th March 2015 (and separate file note relating to an incidental issue found); and
- We have formulated the draft plan for 2015/16, which is attached at Section 3 of this report.

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 critical or high priority recommendations. This approach was agreed with the Director of Finance and Resources.

However, since there are no actions relating to critical or high priority findings remaining from 2013/14 reports, and none which have arisen during 2014/15 to date, we have not performed follow-up to date.

2.4 Impact on Annual Governance Statement:

All reports issued with a critical or high risk rating or report findings that are individually rated critical or high risk will have an impact on the Authority's Annual Governance Statement (AGS). To date, we have identified one high risk in the area of IfQ and management should consider referencing this, and subsequent management actions taken, within its AGS. We will provide independent assurance over the completion of this action following its agreed implementation date on 1st April 2015.

3) Draft 2015/16 Internal Audit Plan

Below we consider the current strategic risks facing HFEA in section 3.1 before setting out our draft Internal Audit Plan for 2015/16 in section 3.2.

3.1) Current risks:

The table below summarises the five risks in the latest HFEA Strategic Risk Register (January 2015) which have a residual risk of 'High' and a status of 'above tolerance.

Risk Area	Description and impact	Residual risk level	Status	Causes/sources
Legal Challenge	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	**15 (High)**	Above tolerance	• Complex and controversial area; • Lack of clarity in 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; • Decisions and actions of the HFEA and its Committees may be contested; • Subjectivity of judgments means the 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; • HFEA could face unexpected high legal costs or damages which it could not fund; • Legal proceedings can be lengthy and resource draining; and • Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.
Information for Quality	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.	**12 (High)**	Above tolerance	• Inability to extract reliable data from the Register; • Unable to work out how best to improve CAFC, and/or failure to find out what data/information patients really need; • Stakeholders not on board with the changes; • Cost of delivering better information becomes too prohibitive; • Website redevelopment project fails to deliver or new website is inadequately designed; • Government and DH permissions structures are complex, multi-stranded, and sometimes change mid-project; • Resource conflicts between delivery of website and Business as Usual; • New CMS (content management software) is ineffective or unreliable; • Communications infrastructure incapable of supporting the planned

Risk Area	Description and impact	Residual risk level	Status	Causes/sources
				changes; and • Contractor failure – delivery is highly contractor dependent.
Data	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.	**12 (High)**	Above tolerance	• Poor record keeping; • Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors; • DH altering careful drafting prior to submission, without always checking the response back with us; and • 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.
Income and Expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k).	**12 (High)**	Above tolerance	• Fee regime makes us dependent on sector activity levels; • GIA funding could be reduced due to changes in Government/policy • Budget setting process is poor due to lack of information from directorates; • Unforeseen increase in costs e.g. legal, or extra in-year work required; and • Upwards scope creep during projects, or emerging during early development of projects e.g. IfQ.
Capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	**12 (High)**	Above tolerance	• High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps; • Poor morale leading to decreased effectiveness and performance failures; • Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance; and • Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.

3.2) Proposed audit reviews for inclusion in 2015/16 plan:

Based on the assessment of current risks above and discussions with HFEA senior management on 3rd February 2015 and the Audit and Governance Committee Chair, the table below sets out which reviews we propose for inclusion in the final 2015/16 internal audit plan.

Suggested review	Rationale for inclusion	Proposed scope	Estimated Audit days	Review date
Requests for Information	Links to the Data risk area	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 controls.	10	Mid-August 2015
Incident Handling	Key regulatory activity	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:	12	September 2015

Suggested review	Rationale for inclusion	Proposed scope	Estimated Audit days	Review date
		• 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 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	Links to the IfQ risk area	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.	12	January 2016
Audit management		All aspects of audit management to include: • Attendance at liaison meetings and HFEA Audit & Governance Committees; • Drafting committee papers/progress reports; • Follow-up work; • Drafting 2016/17 audit plan; • Resourcing and risk management; and • Contingency.	6	-
		Total	**40**	

3.3) Three person IVF:

Legislation permitting the creation of babies from the DNA of three persons passed the House of Lords in February 2015. The HFEA now has until October 29th 2015 to have in place a new regulatory process to license establishments for these treatments. Internal Audit proposes to undertake an audit of this new process in 2016/17, once it has had been established for a number of months.

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: HFEA201415002
FINAL REPORT
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY
JANUARY 2015

Health Group Internal Audit provides an objective and independent assurance, analysis and consulting service to the Department of Health and its arm's 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 arm's 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:

Bronwyn Baker

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STANDING FINANCIAL INSTRUCTIONS

Overall report rating: N/A – This is an advisory review

CONTENTS **PAGE**

Date fieldwork completed:	**28 November 2014**
1st draft report issued:	**29 December 2014**
Management responses received:	**12 January 2015**
Final report issued	**19 January 2015**

Report Author:	James Hennessey
Version №:	3
Date:	19/01/2015

Health Group
Internal Audit

Distribution List – Draft Report

Main recipient

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Lynn Yallop (Head of Audit)

Distribution List – Final Report

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Executive Summary

1. Introduction

1.1 This review is being undertaken as part of the 2014/15 Internal Audit Plan which was approved by the Human Fertilisation and Embryology Authority's (HFEA) Audit and Governance Committee in October 2014.

1.2 The Standing Financial Instructions (SFIs) are key document(s) in any governmental body. Their scope and content varies greatly across entities with no standard prescribed format. HFEA are currently in the process of updating their SFIs to ensure that they accurately reflect current working practices and support the achievement of the Authority's strategic and operational objectives.

1.3 We have been instructed to review the SFIs of other Arm's Length Bodies (National Institute of Clinical Excellence, Monitor, The Trust Development Authority and NHS England) to identify areas of good practice which could be incorporated into the SFIs for HFEA, with a specific focus on Procurement and Budgetary Policies. In addition we have identified any sections of the SFIs of the arm's length bodies (ALBs) not included in HFEA's current SFIs to be considered for insertion.

2. Review Conclusion

Due to the nature of review, we have not provided an overall assurance rating for this area since HFEA are currently in the process of reviewing and updating their SFIs. We have instead confined ourselves to providing examples of good practice from the SFIs of other Arm's Length Bodies to inform the Authority's internal review.

3. Summary of key findings

Our findings are set out in detail in Section 2 below. We have also included examples of best practice in Appendix A and links to external guidance where it has been possible to do so. A summary of our key findings are below:

3.1 Procurement Policy

In total, we found 12 areas where the HFEA's current Procurement Policy could be updated to better reflect good practice seen in other ALBs. These are:

- Increasing the use of flowcharts and tables to improve the policy's usability;
- Implementing a standard five-step business case approach;
- Mapping procurement expenditure across departments
- Drafting clear contracts and invoice approval matrices;

- Summarising details of services provided by Crown Commercial Services;
- Summarising OJEU procurement rules and key thresholds;
- Outlining the key area of the Authority's procurement process, to include links to standard templates and guidance on the staff intranet;
- Standardising pre-qualification questionnaires;
- Introducing a sample evaluation matrix for tenders;
- Clarifying the length of time for which tender documentation must be held;
- Detailing contract and supplier management arrangements;
- Setting out clear rules for post-implementation reviews of contracts; and
- Ensuring standard contract terms and conditions are available to all staff via the intranet.

3.2 Budgetary Control

We found eight areas where the HFEA's current Budgetary Control procedures could be updated to better reflect good practice seen in other ALBs. These are:

- Clearly setting out a timetable and responsibility for key budgetary processes;
- The drafting of budgets should be brought forward to allow sufficient time for robust discussion and involvement of key stakeholders;
- Communicating budgets to all relevant staff in advance of the applicable year;
- Budget management to be allocated to appropriately trained staff only;
- Formalising the budget monitoring process, including regularity of review, responsible individuals and example remedial actions;
- Formalising the processes for approving changes to budgets/ virements;
- Setting out the governance and oversight arrangements for overall budget approvals; and
- Specifying the approval processes for any significant amounts of expenditure required outside of agreed budgets.

3.3 Other areas:

We also identified the following sections of the SFIs of other ALBs which are not currently included by HFEA:

- Income, fees and charges and security of cash, cheques, banking arrangements, cash limit control and petty cash;
- Capital expenditure including disposals;
- Non-pay expenditure;
- Payroll expenditure; and
- Stores and receipt of goods.

Executive Summary

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 Members and management for their help and assistance during this review.

2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	Procurement Policy		
1	**(i) Use of flowcharts and tables** The HFEA's current Procurement and Tendering document is highly detailed, with key processes set out in numbered paragraphs of text. We would suggest that in preparation of the updated SFIs the use of flowcharts, diagrams and tables should be favoured to replace or supplement text. This is considered to be a more effective method to ensure staff obtain a quick and effective understanding of key processes and therefore that SFIs are used in the manner that they are intended. **(ii) Business case templates and approach** There are no business case templates available to managers. We would suggest the implementation of an adapted version of the five-step business case approach. This approach has been in use across the public sector including NHS and local government. The approach in summary consists of the following areas : 1. Business cases are supported by a robust case for change – **the Strategic Case**; 2. Optimise Value for Money – **the Economic Case**; 3. Commercially viable – **the Commercial Case**; 4. Financially affordable – **the Financial Case**; and 5. Can be delivered successfully – **the Management Case**. In addition to the above, the development of business cases over time should also be set out within the SFIs. There are three suggested changes being : • The business case develops over time with **three distinct stages :** 1. Strategic Outline case - the scoping stage 2. Outline Business case - detailed planning phase	(i) N/A (ii) See Ref A1	Consideration should be given for the inclusion of each of the areas (i) – (xii) set out to left in HFEA's updated SFIs.

Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	3. Full Business case - detailed final phase. For HFEA there should be a clear distinction between the stages required for more significant projects versus those required for smaller projects, to ensure that these processes are proportionate. **(iii) Mapping procurement expenditure across the organisation** We would encourage HFEA to state or diagrammatically represent the expenditure incurred by various areas/departments or type of expenditure. This is exemplified by section 13.1.1 of the SFIs of NHS England which divides expenditure into 'clinical services', 'overheads' and 'capital' before breaking this down further into department, 'pay' and 'non-pay' expenditure, contracted and non-contracted expenditure, and recurrent and non-recurrent expenditure. This will illustrate to those charged with overall responsibility for procurement where to focus their attention to optimise value for money through procurement activity. **(iv) Contracts approval and invoice approval** We have identified in other ALBs' documentation several instances where a simple table specifies which contracts and invoices can be approved by an appropriate level of management. Consideration should also be given to both the value of such items and also the level of risk (e.g. reputational) associated with such approvals. **(v) Frameworks and Crown Commercial Services** Details of the services provided by the Crown Commercial Services should be summarised within the policy and the key framework agreements expected to be used should also be noted. This will provide a clear indication of the expected approach to be taken for procurement of the key areas of expenditure, limit the time taken for research where a favoured supplier is highlighted and ultimately provide cost savings.	(iii) N/A (iv) N/A (v) N/A	

2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	(vi) OJEU procurement process The EU Procurement Directives implemented into UK law by The Public Contract Regulations 2006 apply to the award of contracts by public bodies. A brief description of the OJEU process should be included within the policy. This should indicate a brief flowchart of the process and the thresholds at which OJEU procedures must be undertaken. It should also state or link to the processes to be followed where the values fall below the OJEU limits. **(vii) Flowchart/Table of procurement process** An overall summary showing five key areas of the procurement process should be included within the policy. These five stages are summarised below, but see Appendix A (ref. 7) for further details: • Define business need; • Develop procurement strategy; • Supplier evaluation and selection; • Negotiation and award; and • Implementation of contract and monitoring. This will provide an overview and allow quick access to the key information required including templates and intranet links where relevant. **(viii) Pre-qualification questionnaires** The inclusion of standard pre-qualification questionnaire templates would be useful to allow a standard approach to be followed but also allow managers to adapt them for their particular project.	(vi) See Ref A2 (vii) See Ref A3 (viii) See Ref A6	

2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	(ix) Evaluation matrix The inclusion of a standard evaluation matrix for tenders and/or a list of common suggested criteria which can be used by managers will allow consistency and state those areas of particular importance which align to the overall HFEA Strategic and Operational objectives. **(x) Retention of documentation** There is a requirement to hold tender documentation for a period after the process has ended. This is to ensure that any subsequent claims or enquiries can be adequately evidenced and reduce the risk of financial penalties following a successful claim against HFEA. This also allows demonstration that HFEA is meeting the key requirements of the procurement process which includes the requirement to be fair and transparent. Currently the retention period is not documented. **(xi) Post-Implementation of Contract reviews** Greater detail of the contract management and supplier management process should be stated. We would suggest different processes for those low risk/low value contracts with more robust review process and contractor meetings where the values are higher or they expose HFEA to a greater degree of organisational risk. (We understand that HFEA have fortnightly Programme Meetings and additionally that these programme meetings are included within the Audit and Governance Committee bimonthly meetings which subsequently feed relevant information to the Board). **(xii) Contract terms and conditions** The availability of standard contract terms and conditions which are available on the intranet would ensure consistency across all contracts entered into with suppliers.	(ix) See Ref A4 (x) See Ref A5 (xi) N/A (xii) N/A	

2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	Budgetary Control		
2	From our review of the documentation within four other Arm's Length Bodies we have noted these areas of good practice for consideration for inclusion in HFEA's Standing Financial Instructions: • A summary one page timetable should be included that sets out sufficient detail of the processes to be followed for the formulation and approval of budgets and the responsibility for these processes allocated to individual employees; • Draft budgets to be initially set out well in advance of the financial year to allow HFEA to achieve their strategic and operational objectives. There should be sufficient challenge and discussion to allow a reasonable budget to be set. This should allow involvement of key stakeholders and budget holder should be empowered by Finance to feel that a fair compromise has been reached; • Budgets approved months in advance of the beginning of the financial year and communicated effectively to budget holders and uploaded into the financial management system to allow monitoring; • Responsibility for managing budgets should be allocated to those staff with the appropriate training and/or appropriate level of seniority; • Budgets are monitored on a regular basis with the titleholders involved stated in the policy, variances analysed using specified reports and action taken to correct over- or underspend; • Any changes to budgets or virements are appropriately approved. (We understand that at HFEA all virements, including payroll items, are approved by the Finance team, although this is not stated in the existing SFIs); • There is oversight and approval of the entire budget cycle by an appropriate senior management group or Committee. (At HFEA we have been advised that Directors, Director of Finance and Resources and the Chief Executive are involved in the approval	N/A	Consideration should be given for the inclusion of each of the areas set out to left in the HFEA's updated SFIs.

2 Detailed Findings

NO	FINDING/OBSERVATION	APPENDIX LINK TO APPENDIX A (Good Practice) (AS APPLICABLE)	RECOMMENDATION
	process although this is not stated in the current SFIs); and • Clearly specify if any large amount of expenditure outside the budget has to be approved and by whom. (At HFEA we have been advised that this is approved by the Chief Executive or the Director of Finance and Resources although this is not stated in the current SFIs).		
	Additional Sections		
3	Our review of the SFIs for four other Arm's Length Bodies identified the following sections which are commonly included but which are not currently detailed in HFEA's existing SFIs: • Income, fees and charges and security of cash, cheques, banking arrangements, cash limit control and petty cash; • Capital expenditure including disposals; • Non-pay expenditure; • Payroll expenditure; and • Stores and receipt of goods.	N/A	Consideration should be given for the inclusion of each of the areas set out to left in the HFEA's updated SFIs.

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	Consideration should be given for the inclusion of each of areas (i) – (xii) set out in Finding 1 in HFEA's updated SFIs.	N/A	The areas will be considered for proportionate inclusion in the HFEA's procurement and tendering policy	Sue Gallone 31 March 2015		
2	Consideration should be given for the inclusion of each of the areas set out in Finding 2 in HFEA's updated SFIs.	N/A	The areas will be specified in the HFEA's budgetary control policy	Sue Gallone 31 March 2015		
3	Consideration should be given for the inclusion of each of the areas set out in Finding 3 in HFEA's updated SFIs.	N/A	These areas will be described in the HFEA's financial procedures	Morounke Akingbola 31 March 2015		

Appendix A – Examples of good practice and links to further guidance

<table>
<tr><th>Ref</th><th>Evidence</th></tr>
<tr><td>A1</td><td>a. Green book guidance on creating a business case:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/277345/green_book_guidance_on_public_sector_business_cases_using_the_five_case_model_2013_update.pdf

b. Summary guide to business cases including their assessment:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/190609/Green_Book_guidance_short_plain_English_guide_to_assessing_business_cases.pdf</td></tr>
<tr><td>A2</td><td>Example table specifying the values at which different procurement paths should be followed. (though NB values should of course be tailored to HFEA):

<table>
<tr><th>Risk</th><th>Value Range</th><th>Typical Procedure</th></tr>
<tr><td>LOW RISK</td><td><£2000</td><td>Government Purchase Card (PCard)</td></tr>
<tr><td>LOW RISK</td><td>£2000 - £50,000</td><td>(At least)Three Quotes</td></tr>
<tr><td>MEDIUM RISK</td><td>£50,001 – OJEU threshold</td><td>Basic Tender with advertisement</td></tr>
<tr><td>HIGH RISK</td><td>>OJEU threshold - £10 million</td><td>EU Procedure</td></tr>
<tr><td>VERY HIGH RISK</td><td>>£10 million</td><td>EU Procedure</td></tr>
</table>

The relevant legislation is detailed within:

http://www.legislation.gov.uk/uksi/2006/5/contents/made</td></tr>
</table>

Appendix A – Examples of good practice and links to further guidance

A3

1. Define Business Need	2. Develop Procurement Strategy	3. Supplier Evaluation & Selection	4. Negotiation & Award	5. Implementation
1a) Developing Business Case Identify Budget Holder – Which work stream, key stakeholder Business Requirement – Details/Context of Requirements, Benefits of proposal Specification build – potential future business projects Financial Case -Agree budget allocated to project -Benefits/Returns Submit Business Case to xx Committee. - If under £xxk the business case can be signed off by signatory with sufficient delegated authority without having to go to xx Committee. **1b) Sourcing Strategy** Determine Procurement Route : OJEU Tender/Other tender/Quote	**2a) Team Kick off** - Mutually agree project objectives - Project Plan - Supplier Base - Agree governance - Timelines agreed -Communications plan **2b) Define Success** - Agree evaluation criteria - Define the minimum quality criteria and maximum budget **2c) Finalise ITT and secure selection panel** - Review specification, evaluation criteria, chosen procurement route and timescales - Financially viable suppliers - Diarise/invite evaluation panel according to agreed timescales. - Advertise work package via channel specified - Respond to any clarification questions - Receive supplier responses	**3a) Individual Evaluation** - Based on supplier responses, the evaluation team will score each response against the weighted selection criteria - Individual evaluation to be completed ahead of group consensus meeting **3b) Evaluation Consensus** - Group Consensus meeting – to clarify any issues with responses and agree shortlisted suppliers - Notify successful suppliers for shortlist and unsuccessful suppliers offering rationale for non-selection after group consensus **3c) Supplier Presentations** - Interviews with shortlisted suppliers if required - Review and select supplier	**4a) Award Letters** - Send award letters to successful/unsuccessful suppliers - Provide feedback to unsuccessful suppliers as required **4b) Contract negotiation** - Finalise commercial agreement and contractual terms with supplier - Negotiate as necessary on T&C's and pricing (commercial) **4c) Approval and Sign Off** - Gain legal approval of T&C's if necessary - Receive sign off from supplier and sign off internally at HFEA. - Circulate signed contracts to finance/stakeholder/supplier - Physical copy of contract to be sent to finance to archive - Scanned copies to be retained in central secure drive.	**5a) Project Handover** - Project handover to implementation team - On going implementation review by procurement at key milestones/deliverables - Post implementation review **5b) Stakeholder review of procurement** - Stakeholder satisfaction review to provide feedback to procurement about the process
Templates: Project Initiation Document Sourcing Strategy Business Case templates Minutes templates	**Templates**: Project Plan iTT	**Templates**: PQQ/ Evaluation Matrix	**Templates**: Standard T&C's, Award Letter	**Templates**: Stakeholder Satisfaction Review form

Templates to be used across the whole procurement process:

-Procurement Tracker Intranet Link : \\Gdrive\policies\template1
-Risk/Issues Log : \\Gdrive\policies\template2
-Procurement Policy Intranet Link : \\Gdrive\policies\ProcurementPolciy

Appendix A – Examples of good practice and links to further guidance

A4	**Sample criteria for the assessment of tenders are set out below:** • Experience; • Insurances; • Financial stability; • Forward planning; • Market share; • Competitiveness; • Value for money; • Health and safety; • Sustainability / environmental planning and practices; • References; • Technical ability; • Quality and quality assurance; • Delivery; • Other service aspects; • Equal opportunities; • Ethical trading; and • Inspection visit to supplier's premises.
A5	Sample documentation retention periods is set out in the NHS guidance below: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200139/Records_Management_-_NHS_Code_of_Practice_Part_2_second_edition.pdf
A6	The guidance includes a sample annex A showing what a pre-qualification questionnaire should include: https://www.gov.uk/government/publications/procurement-policy-note-0814-use-of-pre-qualification-questionnaires

Health Group Internal Audit

REFERENCE NUMBER: HFEA201415003
FINAL REPORT
HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY
MARCH 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:

Bronwyn Baker

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INTERNAL POLICIES

Overall report rating: LIMITED

CONTENTS **PAGE**

Date fieldwork completed:	**09 February 2015**
1st draft report issued:	**13 February 2015**
Management responses received:	**26 February 2015**
Final report issued	**06 March 2015**

Report Author:	James Hennessey
Version №:	3
Date:	06/03/2015

Health Group
Internal Audit

Distribution List – Draft Report

Main recipient

Sue Gallone

Cc:

Sam Hartley

Lynn Yallop (Head of Audit)

Distribution List – Final Report

Main recipient

Sue Gallone

Cc:

Sam Hartley

Lynn Yallop (Head of Audit)

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1. Introduction

1.1 This review is being undertaken as part of the 2014/15 Internal Audit Plan which was approved by the Human Fertilisation and Embryology Authority's (HFEA) Audit Committee.

The Head of Governance and Licensing is currently in the process of reviewing the HFEA's internal policies, with a view to assessing:

- Whether current policies and procedures cover all relevant operational areas and are fit for purpose;
- If approval and review processes are appropriately designed and clear to all relevant stakeholders;
- Whether standing orders and committee terms of reference reflect and support current working practices;
- The Authority's appetite for changes to its scheme of delegation; and
- The extent to which policies appropriately cross-refer across the organisation.

2. Review conclusion

2.1 The overall rating for the report is **Limited** - there are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective.

3. Summary of key findings

3.1 **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.

3.2 **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. 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.

Summary of Findings

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

	Total recs	High	Medium	Low
Key Policies	1	1	0	0
Review and Approval	1	1	0	0
Policy Alignment	0	0	0	0

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

3.5 Appendix A provides good practice guidance on the formulation of a policy for the development and management of procedural documents and has been included to inform the HFEA's response to the findings raised in this report.

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.

2 Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
High	1	**Key Policies** **The Register of Policies is not complete.**		
		The Register currently contains a mixture of 47 strategies, policies and procedures. These are split across various operational areas, including Human Resources, Health and Safety, Compliance, Information Management, and Communication and Finance. From our review of the register we have made the following observations: • There are multiple documents that have not been included within the register such as the HFEA's Standing Financial Instructions and documents found within the Authority Standing Orders (for example, Guidance for Authority and Committee members on Handling Conflicts of Interest); • There is a lack of consolidation across HR policies, with 24 of the total 46 documents on the Register relating to this area alone. As an example we have noted that there exists a Working from Home document, Homeworking policy and an Occasional Homeworking Policy; • One policy ('*Health and Safety in the*	An incomplete register prevents HFEA from ensuring that all strategies, policies and procedures are being monitored and reviewed on a regular basis. This may lead to policies not being in line with the current updated working practices and legislation. This issue is compounded where the responsibility for ensuring policies are updated has not been assigned. The existence of a significant number of HR policies increases the risk of duplication or contradictions between them. Additionally this may reduce their usage of by staff and negatively impact on the implementation of controls that they are designed to aid.	A complete list should be made of all strategies, policies and procedures currently in existence across the HFEA. This would be facilitated through searching the organisation's document management system (TRIM) and liaison with individual department heads. All documents in the Register should clearly state, as a minimum, the following information to facilitate monitoring: • Relevant department, document owner, and TRIM reference; • Approval details, including date and details of approver; and • Future dates of review. A set process should be introduced to ensure that document owners are contacted with sufficient time prior to expiry of the document for them to coordinate review prior to approval. Once a complete list of policies has been compiled, consideration should

2 Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		Service') relates to another Government department (the Insolvency Service). We also note that there are no controls in place to action upcoming expiry dates for documents listed on the register. We have been informed that a single co-ordinator for the Register has been assigned from January 2015, who will inform individual document owners of expiry dates of documents and who will also ensure that the register is complete.		be made for the streamlining of policies (including consolidating a number into one policy or removal from the Register). Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.
High	**2**	**<u>Review and Approval</u>** **The majority of strategies, policies and procedures on the register evidenced are past their review date and are not subject to version control.**		
		We reviewed the 47 documents on the Register and found that only two were currently up to date - i.e. had been reviewed and appropriately approved with an expiry date past the date of fieldwork for this review (January 2015). Of the remaining 44 documents owned by HFEA (i.e. discounting the policy from the Insolvency Service identified in Finding 1 above) we noted that:	Where documents are not updated regularly these may not reflect current working practices and may not be in line with applicable regulatory or legislative parameters. Additionally without a set policy for version control, including review and approval processes, the quality and consistency of strategies, policies and procedures may be poor and	The HFEA should develop a set process for the production, approval and version control of its policies which ensures consistency across operational areas in the HFEA. This process should include the requirement that documents are assessed for their alignment to the HFEA's three strategic objectives and how they align with other policies. We have shared examples of best practice

2 Detailed Findings

IMPORTANCE	NO	FINDING/OBSERVATION	RISK/IMPLICATION	RECOMMENDATION
		• 25 of these had projected dates for review to be performed prior to January 2015, of which: o One was due for review in 2010 o Nine were due for review in 2011; o 14 were due for review in 2012 o One was due for review in 2013. • 19 documents did not specify a projected date for review. We also note in this context that there is no set guidance which specifies that version control should be applied to all HFEA strategies, policies and procedures.	may not reflect organisational objectives and risks where no input is sought from those charged with governance.	for this process with the Head of Governance and Licensing and this is also included within the Appendix of this report. Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.

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	A complete list should be made of all strategies, policies and procedures currently in existence across the HFEA. This would be facilitated through searching the organisation's document management system (TRIM) and liaison with individual department heads. All documents in the Register should clearly state, as a minimum, the following information to facilitate monitoring: • Relevant department, document owner, and TRIM reference; • Approval details, including date and details of approver; and • Future dates of review.	**High**	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)		

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?
	A set process should be introduced to ensure that document owners are contacted with sufficient time prior to expiry of the document for them to coordinate review prior to approval. Once a complete list of policies has been compiled, consideration should be made for the streamlining of policies (including consolidating a number into one policy or removal from the Register). Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.					
2	The HFEA should develop a set process for the production, approval and version control	**High**	SMT to give consideration to process to be used	Set process for introduction/revision/monitoring of policies to be in place by end		

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?
	of its policies which ensures consistency across operational areas in the HFEA. This process should include the requirement that documents are assessed for their alignment to the HFEA's three strategic objectives and how they align with other policies. We have shared examples of best practice for this process with the Head of Governance and Licensing and this is also included within the Appendix of this report. Please see **Appendix A** for good practice guidance that can be used to inform the HFEA's response to this finding.		to introduce/ revise/monitor policies, proportionate to size of HFEA and number of functions.	June 2015 Owner: HoGL		

4 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 A – Good practice guidance

____NHS Trust

An Organisation-wide Document for the Development and Management of Procedural Documents

Version:	
Ratified by:	
Date ratified:	
Name of originator/author:	
Name of responsible committee/individual:	
Name of executive lead:	
Date issued:	
Review date:	
Target audience:	

Contents

Review and Amendment Log

Version No	Type of Change	Date	Description of change
V.5	Annual review	Mar 2011	*Update to section 2 'Purpose'* *Update to section 6.4 'Equality Impact Assessment'* *Update to section 12 'References'*
V.5	Amendment	Mar 2011	*Addition of amendment log* *Addition of example of definition* *Addition of examples of associated documents*
V.6	Annual review	Mar 2012	*Update to section 4 'Duties'* *Update to section 8 'Review and Revision Arrangements'* *Update to section 10 'Document Control Including Archiving Arrangements'*
V.6	Amendment	Mar 2012	*Change to format including automated contents page*

Please Note the Intention of this Document

This document has been developed with the aim of providing a model document template. However, any documentation subsequently produced must follow its own rules and include details of all the requirements set out in sections 1-13, where relevant. The organisation may use this template and adapt it to reflect procedures within the organisation or alternatively use a document already in existence. Whichever approach is used the organisation must ensure it is compliant with the minimum requirements of the relevant National Health Service Litigation Authority (NHSLA) Risk Management Standards.

a To assist the organisation, areas have been identified in the margins where the section within the template document relates to the minimum requirements for the criterion in the relevant NHSLA Risk Management Standards.

1 Introduction

This section should give an overview of the importance and role of all procedural documents.

2 Purpose

Within this section an explanation regarding the intent or aim of the document should be described. This should include the rationale for development of the procedural document and an outline of the objectives and intended outcomes. This may include:

- the organisation's commitment to providing systematic governance arrangements;
- maintaining a corporate image in all documentation used throughout the organisation;
- ensuring agreed practice is followed throughout the organisation with regards to the development of approved documentation; and
- supporting the claims management process by ensuring that applicable documentation can be retrieved to identify organisational practice at the relevant time.

b

3 Explanation of Terms

The document should explain the different types of procedural documents used within the organisation. For example:

- **Strategy**

  Defines the organisation's long term view on a specific subject.

Additionally, list and describe the meaning of any terms used within the context of the document if considered necessary. For example:

- **Stakeholder**

  A party with an interest in an organisation, for example, employees, customers, suppliers or the local community.

The following list is a guide only and is not exhaustive:

- **Approval**
- **Ratification**
- **Consultation**

4 Duties

Give an overview of the duties of individuals, departments and committees, including levels of responsibility for the development of procedural documents.

4.1 Duties within the Organisation

Outline the duties and accountabilities of the chief executive, directors, committees, specialist staff, individuals, and authors with responsibility for document development, and how these duties and accountabilities are allocated. This section should be brief and not provide a detailed explanation of processes.

4.2 Consultation and Communication with Stakeholders

Outline the organisation's expectations in relation to involvement of stakeholders, including patients and staff, in the development of procedural documents.

Include the communication arrangements relating to the development, consultation, approval and implementation of procedural documents.

4.3 Committees Responsible for the Approval of Procedural Documents

Set out the committees responsible for reviewing and approving procedural documents; or include a cross-reference to a document which contains this essential information.

A checklist may be used to ensure a uniform approach to document development and management. See Appendix A - Checklist for the Review and Approval of Procedural Documents.

a

5 Style and Format of Procedural Documents

All procedural documents should be written in a style which is concise and clear using unambiguous terms and language, and where possible keeping to a corporate appearance. Consider producing appropriate documents in languages other than English, dependent on the population groups served by the organisation.

5.1 Style

Identify font type, size, etc. to be used so all procedural documents adhere to a corporate appearance.

5.2 Format

Identify a list of standard headings or a standard template for use with all procedural documents. This should include the type of information listed on the front page of this template document.

6 The Development of Organisation-wide Procedural Documents

This section could be supported by a flowchart. See Appendix B - Flowchart for the Creation and Implementation of Procedural Documents.

6.1 Prioritisation of Work

Procedural documents should not be developed in isolation and their introduction should be balanced against the priorities of the organisation.

Specify how the organisation:

- supports and justifies the development of a new document;
- ensures that new documents link with service priorities;
- ensures that it is not duplicating other work, either nationally or locally (including checking against the local register/library of procedural documents); and
- confirms that implementation is achievable within the resources of the service/organisation.

6.2 Identification of Stakeholders

Specify how the organisation identifies relevant stakeholders and level of involvement, for example, development, consultation, or receipt of final procedures.

6.3 Responsibility for Document Development

For each procedural document under development, the organisation may want to identify an individual, staff group or committee with responsibility for seeing the process through. If so, decisions about how this is agreed should be clearly described.

6.4 Equality Impact Assessment

All public bodies have a statutory duty under The Equality Act 2010 (Statutory Duties) Regulations 2011 to provide, "evidence of analysis it undertook to establish whether its policies and practices would further, or had furthered, the aims set out in section 149(1) of the [Equality Act 2010]"; in effect to undertake equality impact assessments on all procedural documents and practices. See Appendix E - Example Equality Impact Assessment Tool.

The organisation may consider including a standard text such as: *The organisation aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. The Equality Impact Assessment Tool is designed to help you consider the needs and assess the impact of your policy.*

7 Consultation, Approval and Ratification Process

C

7.1 Consultation Process

This section should describe how the organisation undertakes an appropriate review and consultation process, for example, with staff; unions; human resources; finance department; external stakeholders, including patients; for each type of procedural document developed.

The organisation may consider developing a matrix with the type of document on one axis and the individuals, committee(s), department(s) and staff groups to be consulted on the other.

7.2 Document Approval Process

This section should identify the processes for the approval of procedural documents used within the organisation. Following approval at the appropriate committee all procedural documents will require ratification.

d

7.3 Ratification Process

All procedural documents should be ratified by an appropriate committee with designated or delegated board authority. Identify the ratification process used within the organisation.

e

8 Review and Revision Arrangements

8.1 Process for Reviewing a Procedural Document

State the frequency of review for each type of procedural document, and who or which group will be responsible. All reviews and revisions to any procedural document must be approved according to the process described in section 7 of this document and be recorded within the *Review/Amendment Log* table at the beginning of the document.

9 Dissemination and Implementation

9.1 Dissemination

Explain how procedural documents will be circulated, including arrangements to record distribution of the document and thereby aid retrieval. Confirmation of receipt may also be required in some circumstances.

If the document replaces a previous version, also include the process to remove outdated copies and to ensure staff are aware of the new version. See Appendix D - Plan for Dissemination of Procedural Documents.

9.2 Implementation of Procedural Documents

Identify arrangements for training, support, etc.

f

10 Document Control Including Archiving Arrangements

10.1 Register or Library of Procedural Documents

Describe the process and responsibility for recording, storing and controlling the document being developed.

Identify the location of the register or library of procedural documents, such as a shared directory, or the organisation's intranet database of master documents.

Identify who is responsible for maintaining the register/library of procedural documents.

10.2 Version Control

Identify the version control process used in the organisation, including numbering of documents to aid tracking and retrieval. See Appendix C - Version Control Sheet.

10.3 Archiving Arrangements

This section should describe the:

- process for recording archived documents;
- where master copies will be archived;
- how archived documents will be stored;
- responsibility for archiving; and
- when archiving will occur.

10.4 Process for Retrieving Archived Documents

This section should describe:

- where information on archived documents can be found; and
- how copies of archived documents can be obtained.

i

11 Monitoring Compliance with the Document

Outline the organisation's process to monitor compliance of all procedural documents.

11.1 Process for Monitoring Compliance

This section should identify how the organisation plans to monitor compliance with the *Organisation-wide Document for the Development and Management of Procedural Documents*. As a minimum it should include the review or monitoring of all the minimum requirements within the NHSLA Risk Management Standards. The following list is a guide to issues which could be considered within this section and should be added to where appropriate:

- Who will perform the monitoring?
- When will the monitoring be performed?
- How are you going to monitor?
- What will happen if any shortfalls are identified?
- Where will the results of the monitoring be reported?
- How will the resulting action plan be progressed and monitored?
- How will learning take place?

11.2 Standards/Key Performance Indicators

This section could contain auditable standards and/or key performance indicators (KPIs) which may assist the organisation in the process for monitoring compliance.

h

12 References

Provide an evidence base for procedural documents with up to date references. It is recommended that all references are cited in full using an agreed uniform approach to referencing.

This section should contain the details of any reference materials reviewed in the development of the procedural document.

12.1 Legislation

- Human Rights Act 1998
- Health and Social Care Act 2001
- The Equal Pay Act 1970 (Amendment) Regulations 2003
- Civil Partnership Act 2004
- Equality Act 2010
- The Equality Act 2010 (Statutory Duties) Regulations 2011

The Equality and Human Rights Commission website provides further guidance, updates and resources in relation to equality impact assessments and the effect of the Equality Act 2010: www.equalityhumanrights.com

12.2 Guidance from Other Organisations

- Department of Health, NHS Confederation and NHS Appointments Commission (2005) *Promoting equality and human rights in the NHS - a guide for non-executive directors of NHS boards*

g

13 Associated Documentation

This section should provide a cross-reference to any other related organisational procedural documents.

The following is a guide and is not exhaustive:

- Document formatting
- Completing an equality impact assessment

Appendix A - Checklist for the Review and Approval of Procedural Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

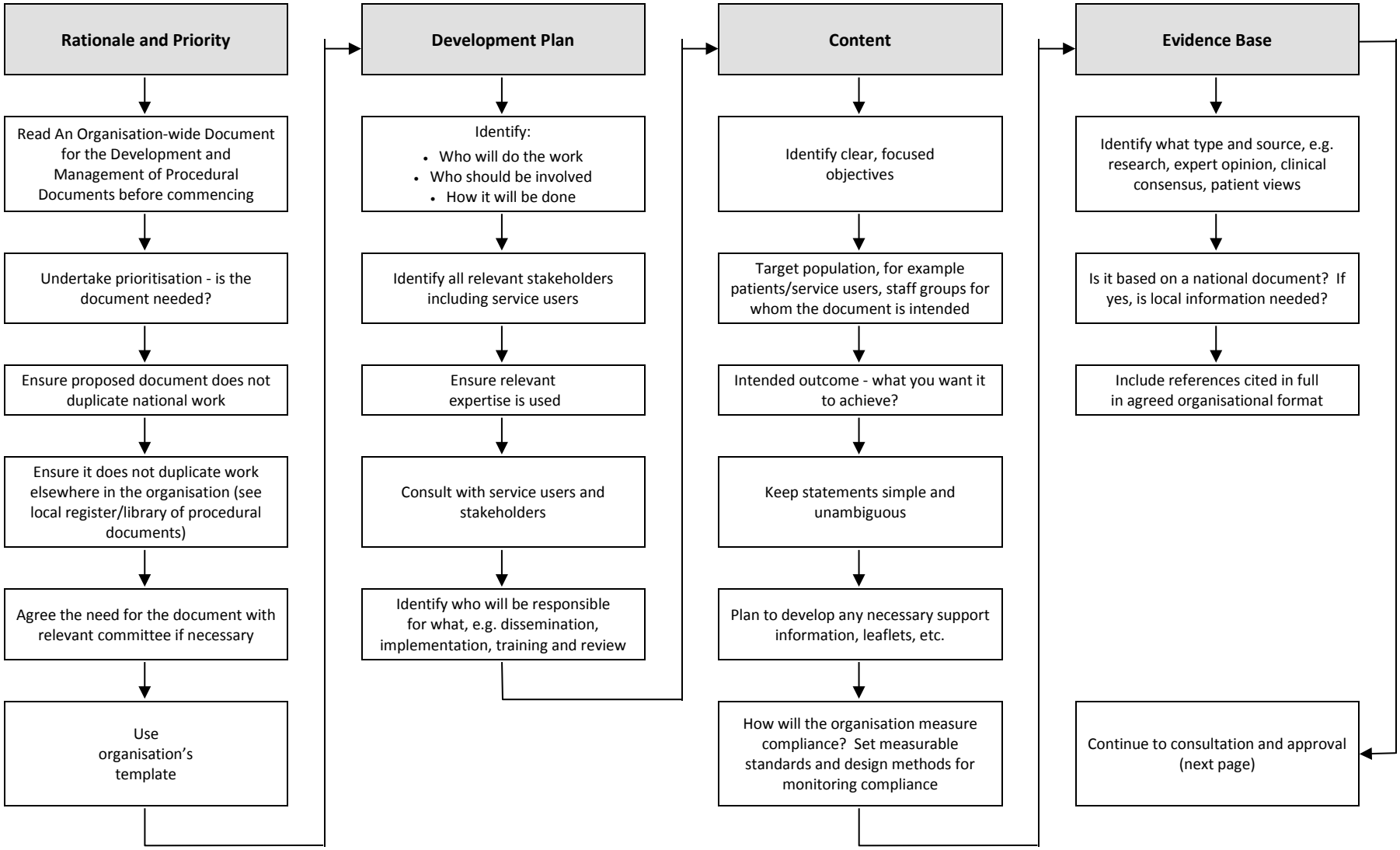
	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?		
	Is it clear whether the document is a guideline, policy, protocol or standard?		
2.	**Rationale**		
	Are reasons for development of the document stated?		
3.	**Development Process**		
	Is the method described in brief?		
	Are individuals involved in the development identified?		
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?		
	Is there evidence of consultation with stakeholders and users?		
4.	**Content**		
	Is the objective of the document clear?		
	Is the target population clear and unambiguous?		
	Are the intended outcomes described?		
	Are the statements clear and unambiguous?		
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?		
	Are key references cited?		
	Are the references cited in full?		
	Are local/organisational supporting documents referenced?		
6.	**Approval**		
	Does the document identify which committee/group will approve it?		
	If appropriate, have the joint Human Resources/staff side committee (or equivalent) approved the document?		

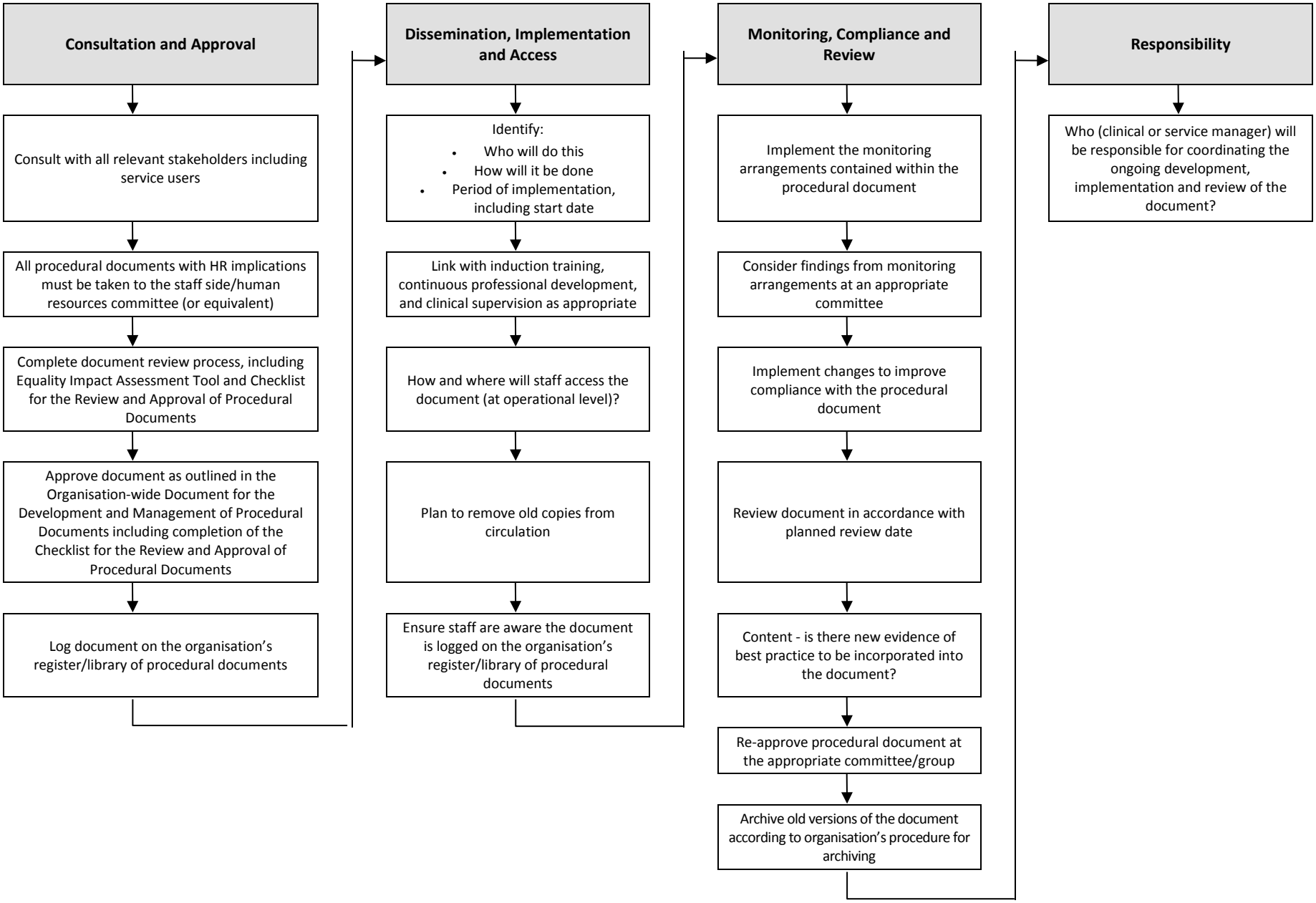
	Title of document being reviewed:	Yes/No/ Unsure	Comments
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?		
	Does the plan include the necessary training/support to ensure compliance?		
8.	**Document Control**		
	Does the document identify where it will be held?		
	Have archiving arrangements for superseded documents been addressed?		
9.	**Process for Monitoring Compliance**		
	Are there measurable standards or KPIs to support monitoring compliance of the document?		
	Is there a plan to review or audit compliance with the document?		
10.	**Review Date**		
	Is the review date identified?		
	Is the frequency of review identified? If so, is it acceptable?		
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?		

Individual Approval			
If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval.			
Name		Date	
Signature			
Committee Approval			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Name		Date	
Signature			

Acknowledgement: Cambridgeshire and Peterborough Mental Health Partnership NHS Trust

Appendix B - Flowchart for the Creation and Implementation of Procedural Documents




Consultation and Approval
Consult with all relevant stakeholders including service users
All procedural documents with HR implications must be taken to the staff side/human resources committee (or equivalent)
Complete document review process, including Equality Impact Assessment Tool and Checklist for the Review and Approval of Procedural Documents
Approve document as outlined in the Organisation-wide Document for the Development and Management of Procedural Documents including completion of the Checklist for the Review and Approval of Procedural Documents
Log document on the organisation's register/library of procedural documents
Dissemination, Implementation and Access
Identify:
Who will do this
How will it be done
Period of implementation, including start date
Link with induction training, continuous professional development, and clinical supervision as appropriate
How and where will staff access the document (at operational level)?
Plan to remove old copies from circulation
Ensure staff are aware the document is logged on the organisation's register/library of procedural documents
Monitoring, Compliance and Review
Implement the monitoring arrangements contained within the procedural document
Consider findings from monitoring arrangements at an appropriate committee
Implement changes to improve compliance with the procedural document
Review document in accordance with planned review date
Content - is there new evidence of best practice to be incorporated into the document?
Re-approve procedural document at the appropriate committee/group
Archive old versions of the document according to organisation's procedure for archiving
Responsibility
Who (clinical or service manager) will be responsible for coordinating the ongoing development, implementation and review of the document?

Appendix C - Version Control Sheet

Version	Date	Author	Status	Comment

Appendix D - Plan for Dissemination of Procedural Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:			
Date finalised:		**Dissemination lead: Print name and contact details**	
Previous document already being used?	**Yes / No** (Please delete as appropriate)		
If yes, in what format and where?			
Proposed action to retrieve out of date copies of the document:			
To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Format (paper or electronic)**	**Comments:**

Dissemination Record - to be used once document is approved

Date put on register / library of procedural documents:		**Date due to be reviewed:**	

Disseminated to: (either directly or via meetings, etc.)	Format (paper or electronic)	Date disseminated:	No. of copies sent:	Contact details / Comments:

Appendix E - Equality Impact Assessment Tool

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the document/guidance affect one group less or more favourably than another on the basis of:**		
	• Race		
	• Ethnic origins (including gypsies and travellers)		
	• Nationality		
	• Gender (including gender reassignment)		
	• Culture		
	• Religion or belief		
	• Sexual orientation		
	• Age		
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems		
2.	**Is there any evidence that some groups are affected differently?**		
3.	**If you have identified potential discrimination, are there any valid exceptions, legal and/or justifiable?**		
4.	**Is the impact of the document/guidance likely to be negative?**		
5.	**If so, can the impact be avoided?**		
6.	**What alternative is there to achieving the document/guidance without the impact?**		
7.	**Can we reduce the impact by taking different action?**		

If you have identified a potential discriminatory impact of this procedural document, please refer it to [*insert name of appropriate person*], together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact [*insert name of appropriate person and contact details*].

Appendix F - Template Document for the Development and Management of Procedural Documents

____NHS Trust

An Organisation-wide Document for the Development and Management of Procedural Documents

Version:	
Ratified by:	
Date ratified:	
Name of originator/author:	
Name of responsible committee/individual:	
Name of executive lead:	
Date issued:	
Review date:	
Target audience:	

Contents

Review and Amendment Log

Version No	Type of Change	Date	Description of change

National Audit Office

Human Fertilisation and Embryology Authority

Interim audit report on the 2014-15 financial statement audit

REPORT TO THOSE CHARGED WITH GOVERNANCE
March 2015

This report summarises the key issues from our audit visits to date. A further completion report will be produced following our final visit in May and issued to those charged with governance before we finalise our audit work and certify the accounts.

Audit testing

Work completed to date	During the first week of a two week interim audit visit in February we: • Carried out payroll testing and income testing for the 9 months from April 2014 to December 2014. • Reviewed provisions & contingent liabilities for the 9 months from April 2014 to December 2014. • Reviewed the interim draft financial statements for the 9 months to December 2014. **There are no major findings from this testing.**
Future work	We have our second week of interim audit planned for March to carry out testing on other expenditure, journals, and a review of the status of the IfQ capital expenditure programme to date. We will complete our testing over a two-week final audit visit in May.

Other matters

These matters have been raised and discussed with HFEA.

Annual accounts & report structure	As part of the NAO role in the Building Public Trust awards which recognise trust and transparency in corporate reporting; we have shared the FReM disclosure checklist for the financial statements and the annual report with HFEA. We have also shared with HFEA the EPN412 issued by the Cabinet Office which provides enhanced guidance for receiving timely information necessary for the pension disclosures in the remuneration report.

Audit and Governance Committee

Paper Title:		**Implementation of Audit Recommendations – Progress Report**
Paper Number :		**[AGC (18/03/2015) 451 MA]**
Agenda Item:		**10**
Meeting Date:		18 March 2015
Author:		Wilhelmina Crown
For information or decision?		Decision
Resource Implications:		As noted in the enclosed summary of outstanding audit recommendations
Communication		CMG
Organisational Risk		As noted in the enclosed summary
Recommendation to the Committee:		AGC is requested to review the enclosed progress update and to comment as appropriate.

Annexes		Summary of Recommendations		
Recommendation Source	Status / Actions	2011/12 to 2013/14	2014/15	Total
Internal – *DH Internal Audit*	*To complete*	*4*	*6*	*10*
	Complete	*2*	*5*	*7*
External Auditor – *NAO*	*To complete*	*1*		*1*
	Complete	*1*		*1*
COUNT		*8*	*11*	*19*

1. Report

1.1. This report presents an update to the audit recommendations paper presented to this committee in December 2014.

1.2. Eleven new recommendations have been added since the last meeting. Recommendations from the Internal Policies review will be added next time as the report is just being finalised.

1.3. Recent updates received from Action Managers are recorded in this document.

1.4. Eight recommendations are noted as completed and the remaining 11 are in hand.

1.5. The remaining outstanding recommendations are classified as (M) or (L) as low. None is classified as high.

1.6. Progress with the implementation of the remaining outstanding audit recommendations will be provided to future meetings of this committee and to CMG on a quarterly basis.

2. Recommendation

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

2011 - 12	Title	Section	Findings	Grade	Risk / Implication	Recommendation	Management Response	Action Manager	Date
2011-12	Review of Supplier Maintenance	1	Guidance for Supplier Maintenance: Documentary guidance exists which sets out the financial authorities and responsibilities over procurement, purchasing and payment for goods and services. However, some of the detailed guidance needs to be updated. The HFEA Ordering and Payment Procedures are based on the Barclays Business Master system, which has been replaced by the Barclays Internet Banking system. The HFEA Financial Reporting Procedures do not reflect the current suite of management accounting reports.	L		HFEA Ordering and Payment Procedures should be updated to reflect the use of the Barclays Internet Banking system. HFEA Financial Reporting Procedures should be updated to reflect the current suite of management accounting reports.	Agreed. The Financial Procedures will be updated to reflect this and other recommendations arising from this audit, and also updates to the Authority's Fraud and Anti-Theft Policy. June 2012 update: The finance procedures have been revised in draft and presented to CMG. Recommendations from the meeting are due to be incorporated and finance training arranged for staff new to their financial responsibilities / who would like a refresher. September 2012 update: The Financial Procedures – the main document setting out procedures and processes for all staff – have been updated and are on the intranet. Revisions include reference to the Fraud and Anti-Theft Policy; changes in staffing; and enhancement of T&S information in line with DH policy. The detailed procedures in use by only the finance team have been substantially updated. The banking procedures refer to Barclays Internet banking. Some detailed procedures remain to be updated, it is anticipated this will be completed by end October. November 2012 update: The finance SOP on the HFEA's Ordering and Payment of goods and services has been updated to reflect the use of Barclays Internet Banking. The imminent delivery of the SAGE 200 project will radical transform the financial system and processes currently in place. It is therefore recommended that all other documents are reviewed after the new system is introduced. March 2013 update: The Sage 200 project is underway. The financial procedures and finance team SOPs will be subject to material revisions to reflect the forthcoming (1 April 2013) introduction of WAP (to facilitate online processing of purchase orders to payment). June 2013 update: Pending resolution of the technical problems with the new WAP system the revisions to the financial procedures were also delayed. The WAP system went live on 3rd June and revised summary financial procedures are to be presented to this meeting. Some of the individual detailed procedures will be completed subsequently. Aug 2013 update: Delayed due to finance team restructuring. In addition, an annual review of the existing suppliers database will be written into the standard operating finance documentations which is planned to be completed by November 2013 Nov 2013 update Now expected in Dec 2013 Feb 2014 update A review of time and availability resources has necessitated moing this piece of work back in Q1 of 2014-15. This rrecommendations relates to the updating of SOP's which are internal to finance staff only. May 2014 update Awaitng completion by Director of Finance and Facilities Internal audit planned in Q1 2014/15 to update this recommendation September 2014 Update Finance policies and SOPs to be updated. November 2014 Update As above. Financial controls audit is to look at existing policies to highlight "gaps" and any identifeid will be incorporated February 2015 update Policies for Procurement and Budgetary Control have been updated and agreed. The Financial Procedures Manual is the final document to be produced and will be drafted	*Head of Finance*	April-12 July-12 October-12 May-13 March / April 2013 July-13 November-13 December-13 April-14 June-14 December-14 February-15 March-15

2011 - 12	Title	Section	Findings	Grade	Risk / Implication	Recommendation	Management Response	Action Manager	Date
	Data Confidentiality	4	Information Asset Register A number of policies are in place that relate to the management of information, including: · Information Classification and Retention; · Records Management; and · Information Access. These policies do not reference HFEA's Information Asset Register (IAR) which is used to apply a security classification to information assets. HFEA use different security classifications to define the controls which are to be	L	Polices related to information management may be applied without consideration of the security classifications documented in the IAR.	Management should review the policies related to information management to consider whether those policies require linking to the IAR.	1. This is a good suggestion which we will progress during 2012. November 2012 update In progress, a meeting has been arranged to initiate changes. March 2013 update: The OGSIRO has recently issued documents relevant to risk appetite and security for information assets. This needs to be taken account of in the review, which has been delayed. June 2013 update: Work delayed Nov 2013 update Now expected in Dec 2013 Feb 14 update - due to workload pressures, this has been delayed again. It is now firmly scheduled to be completed end March 2014 May 14 update Policies to be updated after IfQ changes - discussion to take place by end June 2014 to see if interim update possible September 2014 Update These policies form part of the Information Governance toolkit and are currently being reviewed. It is anticipated that the reviews will be completed by November 2014. November 2014 Update - Work in progress January 2015 Update Policies to be reviewed. The new anticipated completion date end May 2015	*Director of Finance / SIRO* *Head of IT*	November-12 December-12 May-13 September-13 December-13 April-14 December-14 November-14 January-15 May-15
P C W		2	Risks are significantly summarised within the HLRR and the supporting Assurance Framework has yet to be prepared	M					
			We noted that the risks within the HLRR are summarised to a significant degree with a large number of contributory factors. For example: • The risk around decision making quality has a number of causes including decision-making apparatus, representation and appeals processes, workload pressures, governance transition programme and business/admin processes, practices and behaviours. Business/admin processes, practices and behaviours itself then refers to document management, risk and incident management, data security and finance processes.		The HLRR may not provide sufficient detail to ensure that controls to address the broad nature of identified risks are adequate and that there is sufficient assurance over the continued, satisfactory operation of those controls	As intended, an Assurance Framework should be developed showing the alignment of controls, mitigating actions and sources of assurance relating to the risk of breakdown in areas underlying the high level risks.	Accepted in part. We will need to approach this finding in a proportionate and manageable way. Our proposed actions are: 1. To review our operational risk system to ensure it is being used fully and consistently across the organisation – the aim being to ensure operational risk is managed in a coherent and comparable way between all teams. This will help our overall risk assurance. The Head of Business Planning to start on this following Corporate Strategy work. January 2015 update: Following some initial discussion at the CMG Risk meeting on 19 November 2014, a further paper was considered at the next CMG Risk meeting, which took place on 5 February. This set out overall proposals for a revised operational risk approach, and, in tandem, the gradual introduction of risk assurance mapping, with an outline suggested process. The process will now be designed in more detail in line with the discussion at CMG. Although the risk assurance element will take longer to achieve, since we have very limited capacity for extra activities, and staff are unfamiliar with this sort of process, the changes to the existing operational risk system are expected to be implemented in February and March, and will focus on increasing consistency between teams. This will be done in tandem with service delivery planning for 2015/16.	HoBP	February-15 End March 2015; and ongoing gradual implementation of RAM

2011 - 12	Title	Section	Findings	Grade	Risk / Implication	Recommendation	Management Response	Action Manager	Date
			• The statutory and operational systems and delivery risk relates to operational delivery and business continuity being hampered by unreliability in, or excessive demand on, key statutory and infrastructure systems. Whilst we can see how the underlying factors draw together into the overall risk, at this summarised level it becomes more difficult to evidence the alignment of controls and assurances against the overall risk. Each risk has a series of controls identified, but they are not directly aligned to each underlying cause of the overall risk and if every control in the organisation relevant to possible factors impacting the risk were listed the HLRR would be unmanageable. In some organisations, many of these causes and underlying controls would appear as risks within a risk management system in their own right, and of course in HFEA a number will be within the operational risk registers. However, we believe that what this highlights is the need for development of an Assurance Framework, as management have identified, that would sit behind the risk register and provide a more detailed level of information on individual controls, risk mitigations and sources of assurance within the business.				2. Revise the High Level Risk Register template to make more apparent the linkages and lines of sight between causes/sources of risks and the September 2014 Update Most of this work will form part of the post-Strategy review of the whole content and lay-out of the risk register, but efforts have already been made to make the lines of sight more obvious, as indicated above. January 2015 update: Presented at December AGC. A CMG workshop was held in January to review all risks in detail, and we now regard this recommendation as complete. CMG will continue to review the risk register on a quarterly basis, reporting to AGC at every meeting and to the Authority when agenda space permits. 3. Explanation of whole current risk system (all levels) to June AGC, for clarity (particularly for the newer members / attendees who will not be aware of all aspects of our risk management system). Head of Business Planning to work with CMG and members to consider this between 07/14 & 01/15 January 2015 update: This was addressed as above in June 2014. As soon as the work on risk assurance and operational risk has been completed, the risk policy will be reviewed and updated to reflect the newly agreed approach and procedures. At the same time, SOPs will be incorporated that reflect all procedures. We will also schedule regular annual reviews to ensure the policy always remains up to date and reflects current practice. 4. Regarding the composite nature of our strategic risks, we will consider whether to break these down into smaller components when we review the high level risk register following the setting of our new strategy. (However, for the time being we are satisfied that the composite approach is sufficient and effective at the strategic risk level.) Head of Business Planning to work with CMG to assess usefulness and possibilities of RAM, inc resource implications To agree our approach by 12/2014 November 2014 Update A revised version of the high level risk register will be brought to the December AGC meeting for comment. This has been redesigned to take in the audit recommendations, as well as the HFEA's strategy. 5. Risk Assurance Mapping – we will consider what other small organisations do, and review whether it would be worthwhile and feasible for the Authority to adopt a similar approach. Meanwhile, some of our other planned actions, listed in this report, will increase the amount of risk assurance built into our existing risk September 2014 Update Via a useful DH Risk Assurance Network meeting in July (the first one of an ongoing series), we have made a useful contact at the CCQ, who are also considering how to introduce risk assurance in a manageable and proportionate way. It is likely that we will be able to adopt some of their methodology, which they are kindly sharing with us as they continue to develop it. This work will be considered following the more urgent work November 2014 Update Risk assurance mapping will be explored alongside the redevelopment of our operational risk system. The recent development of DH's risk and assurance network has already proved useful in this regard, and the CQC (also new to risk assurance as an activity) have kindly shared their process with us. It is likely that we will be able to adopt a very similar approach. Resource implications will remain an important factor in agreeing the detail of this, and this will be discussed in more detail at CMG (most likely in the new year). January 2015 update: As indicated above, Risk CMG considered a paper and recommendations about operational risk and risk assurance mapping on 5 Feb. Further work will follow. We expect full implementation to be gradual over several years. Development of this activity will require some coaching, training and various group meetings, since we are new to this as a concept and as an activity. We also need ot consider team resources, which are already at full stretch. We will ensure managers understand the difference between		June-14 Complete January-15 June-15 December-14 Complete March-15 May 2015 for an approach and draft

2011 - 12	Title	Section	Findings	Grade	Risk / Implication	Recommendation	Management Response	Action Manager	Date
							operational risk identification/management, and risk assurance. To some extent we can learn useful lessons and borrow processes from the recent introduction of RAM into the HTA, and the CQC, both of whom are in the same position of trying to accommodate this additional new activity in a proportionate and manageable way, such that the process yields useful assurance and is understood by those using it, but does not cause		draft implementation plan over several years

2011 - 12	Title	Section	Findings	Grade	Risk / Implication	Recommendation	Management Response	Action Manager	Date
							more risk than it manages.		
	CORPORATE GOVERNANCE	1	The Authority receives only a verbal update from committee chairs on the business undertaken by committees	L					
			The Authority receives feedback on the activities of committees through verbal updates by the relevant chairs at the next Authority meeting. However, minutes of the meetings of committees are not circulated and whilst the verbal update is helpful in providing context and understanding of the work of committees it does mean that members of the Authority have no opportunity to consider matters discussed in advance of meetings to identify any questions. We also noted that on occasion committees can be dealing with sensitive matters that may subsequently appear in the press, and there is no formal mechanism for communicating such matters prior to the next meeting of the Authority, which could be after external reporting.		Authority members may not have a full understanding of the activities of committees, or may not have time to identify questions. Members may not be aware of key decisions taken in committees before they are reported in the press.	Consider circulating minutes from committee meetings for information as part of Authority papers to members, in addition to the verbal updates. Consider whether there would be any merit in having an additional communication channel for any key decisions likely to have significant external coverage.	Head of Governance and Licensing (HoGL) to feed into annual review of committees, and take members' views on whether they would appreciate this November 2014 Update Annual committee review has begun, including discussions on communications. On target to feed into review of SOs in new year. January 2015 Update Committee review still in progress. Audit and Governance Committtee minutes are now circulated to all members and other Committees may follow suit. March 2015 update Closed - committee reviews complete, minutes circulated after meetings and annual AGC report to Authority instituted. Recommendation completed	HoGL	Autumn 2014, with January-15 March-15 Complete
		2	Some governance information on the website needs updating	M					
			We noted that there are a number of governance items on the HFEA website that appear to require updating: • In the "About HFEA" section the link to provisions of the 1990 Act as amended by the 2008 Act (www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH080211) does not work, that legislation page seemingly having been archived, and the About HFEA section also still refers to having 22 members; • The section on Equality and Diversity refers to new guidance to public bodies due to be issued in 2010 and goes on to say that the Authority intends to overhaul and update its approach to equality issues as part of its preparation for the commencement of the new public sector duty, and makes mention of having considered an initial preliminary assessment at the open public meeting in Cardiff on 8th December 2010; and • On the website the "Our Public Events" sub sections are for the 2008 and 2009 Annual Conferences.		Users of the website may be confused by out of date information. Reputation may be impaired as a result of the perception of lack of attention to the quality of information on the web. There may be a perception that the Authority has not paid sufficient attention to its equality and diversity objectives.	Review the website and update any information that is out of date. In particular, update the equality and diversity section. Implement a mechanism for regular testing for broken links to third party information.	Equality policy being refreshed in summer 2014, with updated documentation to go on website. Other website changes being factored into IfQ programme. November 2014 Update Delayed due to member of staff allocated to project being re-deployed on IFQ01 project. Policy refresh to be conducted Q4. March 2015 update Review of equalities initiated and expected to be considered by Authority at its meeting in May 2015. Website September 2014 Update All sections apart from the Equality and Diversity section of the website have now been fixed. The Equality and Diversity section has been delayed due to IFQ	Equalities – HoGL IfQ Programme Manager transferred to Director of Strategy and Corporate Affairs	Equalities – by October 2014. Now expected March 2015 Now expected May 2015 On implementation March-15

2011 - 12	Title	Section	Findings	Grade	Risk / Implication	Recommendation	Management Response	Action Manager	Date
		3	There is no up to date register of policies and policies on counter-fraud and whistleblowing are overdue for review.	M					
			We noted that per Standing Orders the Authority should maintain a register of policies for the purpose of monitoring the need for review and updating. However, we were unable to obtain such a register. We obtained copies of the policies for Counter-fraud and Whistleblowing and noted that these were respectively dated July 2010 and May 2012 despite containing references to being subject to annual review.		Policies may no longer be appropriate to current operations and/or reflect latest best practice.	A register of policies indicating the owner and scheduled date for review should be maintained and monitored to ensure timely review of all policies. The Counter-Fraud and Whistleblowing policies should be reviewed and updated if necessary.	HoGL to create and maintain register of policies. September 2014 Update Register created and policies that need to be udpated will be prioritised and scheduled, in discussion with policy owners. November 2014 Update Closed - register is created and now work ongoing with IA on Internal Policy review to ensure all policies up to date. Head of Finance to update Counter-fraud policy. September 2014 Update Finance policies and SOPs to be updated. November 2014 Update Have not commenced review of the Fraud Policy. This will be done by the end of Jannuary 2015 January 2015 Update Update of Anti-Fraud policy is in progress, however, work pressures has resulted in the completion date being moved to March. February 2015 update Anti Theft and Counter Fraud Policy has been reviewed and presented to AGC for agreement in March Head of HR to update Whistleblowing policy. Whistleblowing policy updated already by Head of HR and communicated to all staff, awaiting sign-off expected. September 2014 Update SMT agreed have agreed an updated policy. A paper of the updated policy was presented to the Staff Forum and CMG in September and to AGC in December. November 2014 Update The whistleblowing policy was agreed by SMT and CMG and will be presented to AGC in December.	HoGL HoF HoHR	May-14 December-14 Complete July-14 December-14 January-15 March-15 Complete May-14 December-14 Complete
N A O	A n n u a l R e p o r t & A c c o u n t s	5	Remuneration Report	L					
			As with the Annual Report, whilst the requirements of the Companies Act 2006 as interpreted by the FReM had broadly been addressed, there were a minor number of disclosures missing or that required amendment. Total employer pension contributions for HFEA as a whole were also inaccurate			HFEA should obtain up-to- date declarations of interest for the Senior Management Team (who are disclosed in the Remuneration Report) as they do for Non-Executives	September 2014 update Update planned for November 2014, with requirement to notify changes as they occur. November 2014 Update Declarations of interest for SMT will be obtained in January, alongside those for Authority Members January 2015 Update This is in progress and being completed by EA to Chair and Chief Executive.	HoF	November-14 January-15 Complete
		6	Intra-Government balances	L					
			Significant discrepancies were identified in the categorisation of intra-government balances. The disclosures in the latest draft Accounts have now been corrected			Finance should review categorisation of suppliers and customers to ensure that this corresponds with the information reported in the DH Consolidation return	September 2014 update Comparison will take place when DH request future consolidations November 2014 updated This will take effect when Decembers' hard close commences in Jan-15 January 2015 Update As above, however it is at year end that this important point will be embedded. Note will be taken of progress from M9 audit, which will be completed by 20/03/15.	HoF	March-15 April-15

Audit by:	Title	№	RATING / IMPORTANCE	FINDING/OBSERVATION	RISK / IMPLICATION	RECOMMENDATION	AGREED ACTION	ACTION MANAGER	IMPLEMENTATION DATE
DH'S INTERNAL AUDIT	Information for Quality	1	M	The IT strategy needs to be updated and finalised					
				We acknowledge that an overall vision and some business objectives have been set. However, an IT Strategy, aligned with business strategy, has not yet been formally documented. Our review showed that the current IT strategy has not been adequately defined but will be updated based on the programme implementation as well as consideration around infrastructure requirements and the target operating model. The data security and end point security requirements are still being defined as well. We also noted that a clear view of the regulatory requirements for data security is also not in place.	Lack of alignment of the programme to the organisational and IT strategy may lead to directing resources in a manner that is not effective and efficient.	The IT strategy needs to be defined upfront and the programme and changes within the IT environment need to be aligned to the wider IT strategy in order for IT to effectively meet business and regulatory needs.	The strategy and IfQ can be worked up in parallel. An IT strategy is in development to take into account wider infrastructure developments (e.g. cloud hosting), office relocation, and the IfQ programme. CMG and SMT have considered 'first principle' proposals and the strategy will be worked up fully in the new year.	*Director of Compliance & Information*	April - 2015
		2	M	Delays in progress against original plan					
				Under the original plan, a proof of concept (POC) was expected to be delivered at this time. However initial requirements gathered were not detailed sufficiently to progress with the POC to a level that could provide sufficient assurance to the programme board. Subsequently the programme approach, scope and timelines have since been revised to allow further work to be performed to capture detailed requirements. It is unclear at this stage whether a standalone POC will still take place or built into the implementation phase and whether the anticipated programme duration of up to 24 months for 2015 completion is still possible.	Lack of clearly defined plans will impact the progress of the programme against the original plan.	Develop detailed plans in conjunction with the key stakeholders for each phase of the programme, so that keys steps, dependencies and durations are captured earlier on and reduce the risk of scope creep and/or significant extension to timelines.	Yes, this will be defined in the programme definition.	*Information for Quality Programme Manager*	April - 2015
		3	H	Current budget needs to be revisited					
				The exact programme of work, costs and timelines will be confirmed in the business case that will be developed post completion of the 'Requirements gathering and Feasibility' phase. In February 2013, the outline business case anticipated the overall cost to be £0.6m (+/- 20%). By December 2013 the high level costs for the programme were expected circa £1.4m. We understand through discussions that the increase was largely due to the expansion of the programme's scope, following the technical appraisal and inclusion of changes to HFEA website & CaFC. The current budget of £1.4m should be revisited considering that the programme is still in the feasibility stage and that approximately 40% of the budget (£1.4m allocated from internal financial resources by the Director of Finance and approved by the Authority), has been spent to date.	Inadequate budgeting process and lack of reasonable budget assumptions would lead to potential overruns requiring further approval of extra budget resources. This in turn could lead to misdirecting of business resources severely impacting the success of the programme.	The programme budget needs to be revisited and a thorough appraisal of the programme costs must be conducted and this should be reflected in the business case. Furthermore, based on the correct programme costs appraisal, the business can make an informed decision on whether to undertake the programme or not. The earned value of the programme should be continously monitored and corrective actions taken.	1) Yes, costs will be articulated in the new business case. March 2015 update Done 2) Earned value will be added to the programme Board reporting. March 2015 update Done	*Information for Quality Programme Manager*	01/04/2015 Done 2015-03-01 01/04/2015 Done 2015-03-01 Complete
		4	M	Management of risks					
				The current risks that the programme faces such as data migration and data quality issues have been documented. We also noted that risks registers and issue logs are maintained and there is adequate reporting to the CMG. However, the risk register does not formally capture the residual risk or the assurance obtained over those mitigation actions.	Lack of a comprehensive risk management approach may mean the programme may not fully address the identification and mitigation as well as monitoring of programme risks.	We recommend that a risk mitigation process that includes contingency plans and residual risks be documented. The trend of increase / decrease in risk profile over time should also be understood and there should be ongoing independent assurance over the management of program risks.	Yes, Gateway review booked for 26/03/15. March 2015 update Gateway review to be undertaken March 2015	*Director of Compliance & Information*	April - 2015
		5	M	Data Migration					
				Data migration is acknowledged as a key risk and a key requirement to informing the POC and implementation phase. Subsequently on 21st July, 2014 the programme board agreed for IT to commence research on migration of the register data. The data migration strategy will be critical to informing: ● Data quality standards; ● Ensuring the data directory from source to target is mapped in line with requirements and linked to the data dictionary that has been produced via a separate programme. The data migration strategy should also include approach, data mappings, reconciliations and User Acceptance Testing (UAT) at key stages of the programme for all 'in-scope' system environments (circa 30+ systems to be replaced). We understand that the initial data migration strategy will be developed in December 2014.	Lack of a data migration strategy and execution plan/cut over plans to may mean that the programme goes live with erroneous data which would severely impact the business operations and the reputation of the Authority.	A data migration and quality management plan which includes formal controls around data migration and quality needs to be put in place. Independent assurance need to be given over the data migration and reconciliation.	Yes, a third party has been commissioned to produce a data migration strategy and formal controls for the migration and reconciliation. March 2015 update The draft data migration strategy has been submitted for review by the internal team - revised date April 2015	*Information for Quality Programme Manager*	January - 2015 April - 2015

Audit by:	Title	№	RATING / IMPORTANCE	FINDING/OBSERVATION	RISK / IMPLICATION	RECOMMENDATION	AGREED ACTION	ACTION MANAGER	IMPLEMENTATION DATE
		6	M	Engagement with stakeholders					
				We noted that advisory and expert groups are in place and that meetings were held where the needs and interests of different stakeholders' groups were taken into consideration. However engagement with key operating teams such as IT, who would be a key enabler for the programme, should be strengthened and engaged as soon as possible. Some stakeholders were unsure of their role post December 2014 as the programme looks to move into the next phase (implementation phase).	A lack of engagement by key internal stakeholders can lead to staff not buying into what is to be delivered and loss of their support.	Key internal stakeholders should be carefully managed and monitored throughout the lifecycle of the programme to encourage engagement and support.	Yes, internal stakeholders will be part of the new Programme March 2015 update A stakeholder engagement plan is in progress and should be compelted by the end of this month	*Information for Quality Programme Manager*	March - 2015 April - 2015
		7	L	Programme needs to be adequately staffed and team adequately trained.					
				There have been a few changes in key programme team members in recent months. Whilst we acknowledge that the programme is in its early stages we came across some concerns, from staff interviewed, with respect to the recent staff turnover. It was acknowledged by staff that the handover process /knowledge transfer is adequate although there were instances quoted where this could perhaps be improved and formalised further to enhance domain knowledge.	Key knowledge or experience may be lost through changes to personnel and programme may be negatively impacted due to lack of key skills.	Formally consider training and introducing handover and induction arrangements when new employees are boarded on the programme.	Yes, formalised handover in place.	*IfQ Programme Support Officer*	November - 2015 Complete
		8	M	Independent Assurance					
				We noted that there is support and assurance provided by PMO and independent assurance over project management. However, however independent (external) assurance at key stages of the programme has not yet been considered in the plan. At a minimum, areas for consideration should include high risk areas including: • Data Migration and quality • Data Protection, compliance & Information Security • Disaster Recovery • Third parties • Compliance with regulations	Lack of independent assurance over these key areas of the programme may mean significant programme risks are not adequately managed on an ongoing basis.	The scope of work for programme assurance should be defned including assurance activities in relation to the project phases and articulation of programme risks that the piece of external assurance addresses.	Yes, Programme Assurance will be detailed in the Programme Definition Document. March 2015 update Completed	*Information for Quality Programme Manager*	March - 2015 Complete
	Standing Financial Instructions	1	N/A	(i) Use of flowcharts and tables					
				The HFEA's current Procurement and Tendering document is highly detailed, with key processes set out in numbered paragraphs of text. We would suggest that in preparation of the updated SFIs the use of flowcharts, diagrams and tables should be favoured to replace or supplement text. This is considered to be a more effective method to ensure staff obtain a quick and effective understanding of key processes and therefore that SFIs are used in the manner that they are intended. (ii) Business case templates and approach There are no business case templates available to managers. We would suggest the implementation of an adapted version of the five-step business case approach. This approach has been in use across the public sector including NHS and local government. The approach in summary consists of the following areas : 1. Business cases are supported by a robust case for change – the Strategic Case; 2. Optimise Value for Money – the Economic Case; 3. Commercially viable – the Commercial Case; 4. Financially affordable – the Financial Case; and 5. Can be delivered successfully – the Management Case. In addition to the above, the development of business cases over time should also be set out within the SFIs. There are three suggested changes being : • The business case develops over time with three distinct stages : 1. Strategic Outline case - the scoping stage 2. Outline Business case - detailed planning phase 3. Full Business case - detailed final phase. For HFEA there should be a clear distinction between the stages required for more significant projects versus those required for smaller projects, to ensure that these processes are proportionate. (iii) Mapping procurement expenditure across the organisation We would encourage HFEA to state or diagrammatically represent the expenditure incurred by various areas/departments or type of expenditure. This is exemplified by section 13.1.1 of the SFIs of NHS England which divides expenditure into 'clinical services', 'overheads' and 'capital' before breaking this down further into department, 'pay' and 'non-pay' expenditure, contracted and non-contracted expenditure, and recurrent and non-recurrent expenditure. This will illustrate to those charged with overall responsibility for procurement where to focus their attention to optimise value for money through procurement activity. (iv) Contracts approval and invoice approval	(i) N/A (ii) See Ref A1 (iii) N/A (iv) N/A	Consideration should be given for the inclusion of each of the areas (i) – (xii) set out to left in HFEA's updated SFIs.	March 2015 update The areas have been considered and included proprtionately in the HFEA's procurement and tendering policy	*Director of Finance and Resources*	March - 2015 Complete

Audit by:	Title	№	RATING / IMPORTANCE	FINDING/OBSERVATION	RISK / IMPLICATION	RECOMMENDATION	AGREED ACTION	ACTION MANAGER	IMPLEMENTATION DATE
				We have identified in other ALBs' documentation several instances where a simple table specifies which contracts and invoices can be approved by an appropriate level of management. Consideration should also be given to both the value of such items and also the level of risk (e.g. reputational) associated with such approvals. (v) Frameworks and Crown Commercial Services Details of the services provided by the Crown Commercial Services should be summarised within the policy and the key framework agreements expected to be used should also be noted. This will provide a clear indication of the expected approach to be taken for procurement of the key areas of expenditure, limit the time taken for research where a favoured supplier is highlighted and ultimately provide cost savings. (vi) OJEU procurement process The EU Procurement Directives implemented into UK law by The Public Contract Regulations 2006 apply to the award of contracts by public bodies. A brief description of the OJEU process should be included within the policy. This should indicate a brief flowchart of the process and the thresholds at which OJEU procedures must be undertaken. It should also state or link to the processes to be followed where the values fall below the OJEU limits. (vii) Flowchart/Table of procurement process An overall summary showing five key areas of the procurement process should be included within the policy. These five stages are summarised below, but see Appendix A (ref. 7) for further details: ● Define business need; ● Develop procurement strategy; ● Supplier evaluation and selection; ● Negotiation and award; and ● Implementation of contract and monitoring. This will provide an overview and allow quick access to the key information required including templates and intranet links where relevant. (viii) Pre-qualification questionnaires The inclusion of standard pre-qualification questionnaire templates would be useful to allow a standard approach to be followed but also allow managers to adapt them for their particular project. (ix) Evaluation matrix The inclusion of a standard evaluation matrix for tenders and/or a list of common suggested criteria which can be used by managers will allow consistency and state those areas of particular importance which align to the overall HFEA Strategic and Operational objectives. (x) Retention of documentation There is a requirement to hold tender documentation for a period after the process has ended. This is to ensure that any subsequent claims or enquiries can be adequately evidenced and reduce the risk of financial penalties following a successful claim against HFEA. This also allows demonstration that HFEA is meeting the key requirements of the procurement process which includes the requirement to be fair and transparent. Currently the retention period is not documented. (xi) Post-Implementation of Contract reviews Greater detail of the contract management and supplier management process should be stated. We would suggest different processes for those low risk/low value contracts with more robust review process and contractor meetings where the values are higher or they expose HFEA to a greater degree of organisational risk. (We understand that HFEA have fortnightly Programme Meetings and additionally that these programme meetings are included within the Audit and Governance Committee bimonthly meetings which subsequently feed relevant information to the Board). (xii) Contract terms and conditions The availability of standard contract terms and conditions which are available on the intranet would ensure consistency across all contracts entered into with suppliers.	(v) N/A (vi) See Ref A2 (vii) See Ref A3 (viii) See Ref A6 (ix) See Ref A4 (x) See Ref A5 (xi) N/A (xii) N/A				

Audit by:	Title	№	RATING / IMPORTANCE	FINDING/OBSERVATION	RISK / IMPLICATION	RECOMMENDATION	AGREED ACTION	ACTION MANAGER	IMPLEMENTATION DATE
		2	N/A	Budgetary Control					
				From our review of the documentation within four other Arm's Length Bodies we have noted these areas of good practice for consideration for inclusion in HFEA's Standing Financial Instructions: ● A summary one page timetable should be included that sets out sufficient detail of the processes to be followed for the formulation and approval of budgets and the responsibility for these processes allocated to individual employees; ● Draft budgets to be initially set out well in advance of the financial year to allow HFEA to achieve their strategic and operational objectives. There should be sufficient challenge and discussion to allow a reasonable budget to be set. This should allow involvement of key stakeholders and budget holder should be empowered by Finance to feel that a fair compromise has been reached; ● Budgets approved months in advance of the beginning of the financial year and communicated effectively to budget holders and uploaded into the financial management system to allow monitoring; ● Responsibility for managing budgets should be allocated to those staff with the appropriate training and/or appropriate level of seniority; ● Budgets are monitored on a regular basis with the titleholders involved stated in the policy, variances analysed using specified reports and action taken to correct over- or underspend; ● Any changes to budgets or virements are appropriately approved. (We understand that at HFEA all virements, including payroll items, are approved by the Finance team, although this is not stated in the existing SFIs); ● There is oversight and approval of the entire budget cycle by an appropriate senior management group or Committee. (At HFEA we have been advised that Directors, Director of Finance and Resources and the Chief Executive are involved in the approval process although this is not stated in the current SFIs); and ● Clearly specify if any large amount of expenditure outside the budget has to be approved and by whom. (At HFEA we have been advised that this is approved by the Chief Executive or the Director of Finance and Resources although this is not stated in the current SFIs).	N/A	Consideration should be given for the inclusion of each of the areas set out to left in the HFEA's updated SFIs.	March 2015 update The areas have been considered and included proprtionately in the HFEA's budgetary control policy	*Director of Finance and Resources*	March - 2015 Complete
		3	N/A	Additional Sections					
				Our review of the SFIs for four other Arm's Length Bodies identified the following sections which are commonly included but which are not currently detailed in HFEA's existing SFIs: ● Income, fees and charges and security of cash, cheques, banking arrangements, cash limit control and petty cash; ● Capital expenditure including disposals; ● Non-pay expenditure; ● Payroll expenditure; and ● Stores and receipt of goods.	N/A	Consideration should be given for the inclusion of each of the areas set out to left in the HFEA's updated SFIs.	March 2015 update These areas will be described in the HFEA's financial procedures	*Head of Finance*	March - 2015

Audit and Governance Committee Paper

Paper Title:	**AGC Forward Plan**
Paper Number:	[AGC (18/03/2015) 452]
Meeting Date:	18 March 2015
Agenda Item:	**12**
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. The Committee is asked to consider the ongoing need for four meetings per year.
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**	**10 June 2015**	**7 October 2015**	**9 December 2015**
Following Authority Date:	**May 2016**	**16 July 2015**	**11 November 2015**	**14 January 2015**
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	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	Audit Planning Report
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	
Regulatory &				Yes

Item↓ Date:	**Mar 2016**	**10 June 2015**	**7 October 2015**	**9 December 2015**
Register management				
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		Representations hearing – lessons learned		