Strategic risks

Strategic delivery:	☐ Setting standards	☐ Increasing and informing choice	☒ Demonstrating efficiency economy and value
Details:			
Meeting	Audit and Governance Committee		
Agenda item	8		
Paper number	AGC (07/10/2015) 468		
Meeting date	7 October 2015		
Author	Paula Robinson, Head of Business Planning		
Output:			
For information or decision?	Information and comment.		
Recommendation	AGC is asked to note the latest edition of the risk register, set out in the covering paper. A verbal update will also be given at the meeting on recent discussions with Department of Health Internal Audit about progressing risk assurance mapping in the HFEA in the context of the internal audit plan.		
Resource implications	In budget.		
Implementation date	Strategic risk register and operational risk monitoring: ongoing. CMG reviews risk quarterly in advance of each AGC meeting. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Strategic risk register

Latest CMG review

1.1. CMG reviewed the risk register on 2 September 2015. SMT also reviewed the legal challenge risk again on 22 September. Five of the 12 risks are currently above tolerance.

1.2. CMG discussed all risks, their controls, and scores. The Strategic risk register is attached at Annex A, and includes an overview of CMG's general discussions about the risk register. The annex also now includes a graphical overview of residual risks plotted against risk tolerances. The Authority found this to be helpful, and we propose to include this as part of the paper (for CMG, AGC and the Authority alike) from now on.

2. Operational risks and risk assurance

Mapping current risks against assurance areas

2.1. As usual, CMG also reviewed a summary of the top operational risks being monitored by teams. The opportunity was taken to map out all our current operational risks against the generic risk assurance areas we have previously identified as potentially relevant (based on the experience of other organisations). This is presented below for interest and information, and was used as the basis for recent discussions with the Department of Health Internal Audit team.

Operational risks mapped against risk assurance areas – all team risk logs

Risk assurance area	No. of risks	Teams
Planning	2	Policy, BP&PMO
Performance and risk management	11	Gov&Lic, HR, Comms, BP&PMO, C&I
Quality management	3	Gov&Lic, Policy, BP&PMO
Financial management, systems and controls	2	Finance
People management & resourcing	13	Gov&Lic, Policy, HR, Comms, BP&PMO, Finance
Information and Evidence Management	0	-
Accountability	2	Gov&Lic, HR
Oversight and scrutiny	1	Policy
General operational delivery (particular activities and projects)	2	HR

2.2. CMG noted the distribution of current operational risks, and agreed that it may be worth focusing our risk assurance first on people management and resourcing risks or else performance and risk management. These are the two main preoccupations in our operational risks, and so would give the greatest value.

2.3. The table below shows more information about what the various team-level risks in each assurance area are about.

Focus of operational risks under each assurance area

Area	Count	What the risks are about
Planning	2	Impact of IfQ on future ways of working; impact of high workloads on planning activities.
Performance and risk management	11	Committee business increase; resource pressures/staff resistance impeding organisational changes; staff changes/competing demands affecting performance; business as usual vs IfQ pressures affecting strategy delivery/failure to learn lessons/failure to identify interdependencies; staff turnover leading to lack of resilience/IT team resource availability risk/re-cabling (business continuity risk)/Information team delivery failure (competing priorities).
Quality management	3	Errors in licensing process; volume of PQs; implementing changes to business planning across multiple fronts, leading to quality decrease or poor acceptance of changes.
Financial management, systems and controls	2	Material errors in accounts; financial information becoming unavailable.
People management & resourcing	13	Key staff absences; tight timescales; IT team availability/dependencies (several mentions); lack of HR and leadership resources; IfQ resource pressures; resources to manage IfQ programme.
Information and evidence management	0	-
Accountability	2	Appeals process; poor implementation of HR policies by managers.
Oversight and scrutiny	1	Mitochondria – exposure to criticism or opposition from those who disagree with the technique becoming legal.
General operational delivery (activities and projects)	2	Failure of SLAs and collaborative provision with CQC; CSL fails to deliver appropriate options and/or gateway process prevents us procuring needed training.

3. Recommendation

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

Annex A

HFEA strategic risk register 2015/16

Risk summary: high to low residual risks

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

[1] Strategic objectives 2014-2017:

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

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

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

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

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

* This column tracks the four most recent reviews by AGC, CMG, or the Authority (e.g. ⇧⇔⇩⇔).

Recent review points:

AGC and Authority March 2015 ⇨ CMG 20 May 2015 ⇨ AGC 10 June 2015 ⇨ CMG review 2 September 2015

The Authority will next receive the risk register at its November meeting. Meanwhile, AGC will review it on 7 October.

CMG overview

CMG reviewed the risk register and discussed each risk in detail at its meeting on 2 September.

In addition, CMG recognised that the office move, which will most likely occur in April 2016, will present certain risks, and may interact with risks and controls already listed. As soon as we have confirmation of the move date and location, the move will be explicitly added to the risk register, either as a separate risk, or as a specific source/cause of risk in relation to several of our existing strategic risks. It is already mentioned in several places, but not yet in any detail.

Since CMG met, the Family Court has passed judgement on several cases where consents to legal parenthood were in doubt. That judgement may have administrative consequences for the HFEA. Further cases can be expected over the coming months, although the HFEA is unlikely to participate in legal proceedings directly. Nonetheless, a decision has been taken that the impact of this work ought to be reflected in the legal challenge risk (LC1), and accordingly the risk score for the likelihood component of the residual risk has been increased to 3 (having been briefly reduced to 2 following the conclusion of another outstanding case). This means that this risk, which briefly dipped within tolerance, is now above tolerance.

Criteria for inclusion of risks:

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

Rank:

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

Risk trend:

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

Risk scoring system:

See last page.

Assessing inherent risk:

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

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

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Regulatory model RM 1: Quality and safety of care	There is a risk of adverse effects on the quality and safety of care if the HFEA were to fail to deliver its duties under the HFE Act (1990) as amended.	Setting standards: improving the quality and safety of care through our regulatory activities.	Inherent risk level:			⇔ ⇩ ⇔ ⇔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			3	5	15 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
			1	**4**	**4 Low**		
			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	Below tolerance.
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Due for completion October 2015 – Sam Hartley (report and recommendations to October CMG)	
	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 of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – Debra Bloor	
	Staffing model changed to increase resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc..	In place – Debra Bloor – May 2015	
Insufficient inspectors or licensing staff	Inspection team up to complement following several recruitments.	In place – Debra Bloor	
	Licensing team up to complement following recruitment.	In place – Sam Hartley	

Recruitment difficulties and/or high turnover/churn in various areas; resource gaps and resource diversion into recruitment and induction, with impacts felt across all teams.	So far recruitment rounds for inspectors and support staff have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as needed – Debra Bloor
	NHS Jobs account changed in May 2015 so that vacancies now appear under an HFEA identity rather than a CQC identity (with CQC continuing to administer), so as to address the cause of misunderstandings by many job candidates.	In place – 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 or rescheduling of work an option.	In place – Paula Robinson
Unexpected fluctuations in workload (arising from eg, very high level of PGD applications received, including complex applications involving multiple types of a condition; high levels of non-compliances either generally or in relation to a particular issue).	Staffing model developed (May 2015), to release an extra inspector post out of the previous establishment. This increased general resilience so as to enable more flex when there is an especially high inspection/report writing/application processing workload (as there is, so far in 2015).	In place – Debra Bloor
	PGD workshop annually (or biannually, as appropriate) 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 made in 2013 (acknowledged by the sector).	In place – Debra Bloor
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, several major Grade A incidents occur at once.	Addressed by revised staffing model.	In place – Debra Bloor
	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – 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 filled earlier in year; 4 new members recruited in September. Ongoing process in place for regular appointments whenever vacancies occur or terms of office end.	In place – 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	
	New (ie, first application) T&S licences delegated to ELP. Delegations to be revisited during 2016 review of Standing Orders. Licensing Officer role to take certain decisions from ELP – implementation due end of 2015.	To be put in place – Sam Hartley Licensing Officer role – December 2015 (postponed from June 2015) Delegations in SOs – April 2016	
Failing to demonstrate competence as a regulator	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – 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 changed (May 2015) to build resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	In place – Debra Bloor
	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, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen
	TRIM training and guidance/induction in records management in place. Head level 6 month contract to be recruited to manage the office move and review records management.	In place – SMT Head post recruitment in progress September 2015 - SMT
	The IfQ website management project has reviewed the retention schedule.	Completed – August 2015 – Juliet Tizzard
	Guidance/induction in handling FOI requests, available to all staff.	In place – Sam Hartley
	Further work to be planned on records management in parallel with IT strategy	Linked to IT strategy work – in progress – Dave Moysen/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. Mitochondria tools in development.	Existing tools in place; mitochondria tools due by October 2015 – Sam Hartley
	Update of compliance and enforcement policy.	Significant progress – revision discussed at September 2015 Authority – 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 developed, and significant work being done to identify all of the data that will require correction before migration can be done. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of project delivery.	All aspects – detailed project planning in place – Nick Jones	Above tolerance. Managing these risks has formed an intrinsic and essential part of the detailed project planning and tendering, throughout. Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015. The digital side of the programme has received only partial approval; full delivery will still require additional approvals after the first phase of work. There is a risk that this could lead to further long delays
Unable to work out how best to improve CaFC, and/or failure to find out what data/information patients really need.	Stakeholder engagement and user research is in place as intrinsic part of programme approach. This was elaborated further during sprint 1, in Aug/Sept 2015.	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 were taken into account as an important factor in consideration of contract tenders and	In place and now completed – Dec 2014 to June 2015 – Nick Jones	

	negotiations.		which would have a further negative impact. This would adversely affect the quality of the final product (rather than the existence of a final product).
Redeveloped website does not meet the needs and expectations of our various user types.	Programme approach and dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done, to properly understand needs and reasons. Tendering and selection process included clear articulation of needs and expectations.	In progress – delivery by end Mar 2016 – Juliet Tizzard	
Government and DH permissions structures are complex, lengthy, multi-stranded, and sometimes change mid-process.	Initial external business cases agreed and user research completed. Final business case for whole IfQ programme was submitted and eventually accepted.	In place (Nov 2014) – Juliet Tizzard In place (Dec 2014) – Nick Jones (decision received April 2015)	
Resource conflicts between delivery of website and business as usual (BAU).	Backfilling to free up the necessary staff time, eg, Websites and Publishing Project Manager post backfilled to free up core staff for IfQ work.	In place – Juliet Tizzard	
Delivery quality will be very supplier dependent. It is also likely to involve multiple different suppliers and could become very resource-intensive for staff, or the work delivered by one or more suppliers could be poor quality and/or overrun, causing knock-on problems for other suppliers.	Programme management resources and quality assurance mechanisms in place for IfQ to manage (among other things) contractor delivery. Agile project approach includes a 'one team' ethos and requires close joint working and communication among all involved contractors during the Sprint Zero start-up phase. Sound project management practices in place to monitor. Previous lessons learned and knowledge exist in the organisation from managing some previous projects where poor supplier delivery was an issue requiring significant hands-on management. Ability to consider deprioritising other work, through CMG, if necessary.	In place – Juliet Tizzard	
New CMS (content management software) is ineffective or unreliable.	CMS options being scrutinised as part of project.	In progress – December 2015 – 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)	

Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place (June 2015) – Nick Jones
Potential risks associated with the HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	For further thought once there is certainty about the timetable for the move (September 2015) – Nick Jones/Sue Gallone

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 migration strategy.	In place – Nick Jones/Dave Moysen	At tolerance. This risk is being intensively managed – a major focus of IfQ detailed planning work, particularly around data migration.
Historic data cleansing is needed prior to migration.	A detailed migration strategy is in place, and a data cleansing step forms part of this (the migration itself will occur later).	In place – Nick Jones/Dave Moysen	
Increased reporting needs mean we later discover a barrier to achieving this, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporates consideration of fields and reporting needs are agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones	
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen	
System interdependencies change / are not recognised	Strong interdependency mapping being done between IfQ and business as usual.	Done (April 2015) – Nick Jones	
Benefits not maximised and internalised into ways of working.	During IfQ delivery, product owners are in place, as is a communications plan. The aim is to ensure that changes are developed involving the right staff expertise (as well as contractors) and to ensure that the changes are culturally embraced and embedding into new ways of working.	In place (June 2015) – Nick Jones	
Potential risks associated with the	Early awareness of the potential for disruption	For further thought once there is	

HFEA's likely office move in April 2016, in that this will coincide with the delivery period for some IfQ milestones.	means that this can be managed through careful planning.	certainty about the timetable for the move (September 2015) – Nick Jones/Sue Gallone

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

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

Potential risks associated with the HFEA's likely office move in April 2015, in that this will coincide with the delivery period for some IfQ milestones.	Early awareness of the potential for disruption means that this can be managed through careful planning.	For further thought once there is certainty about the timetable for the move (July/August 2015) – Nick Jones/Sue Gallone

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	Below tolerance. One case decided in the HFEA's favour at summary judgement. Appeal completed in September (the decision was to award the licence). A recent judgement on consents for parenthood may have administrative consequences for the HFEA. Further court cases are also likely, although the HFEA is unlikely to participate in legal proceedings directly.
	Evidence-based policy decision-making and horizon scanning for new techniques.	In place – Hannah Verdin	
	Robust and transparent processes in place for seeking expert opinion – eg, external expert advisers, transparent process for gathering evidence, meetings minuted, papers available online.	In place – Hannah Verdin/Sam Hartley	
Lack of clarity in HFE Act and regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court.	Panel in place, as above, to get the best possible advice.	In place – Peter Thompson	
Decisions and actions of the HFEA and its committees may be contested.	Panel in place, as above.	In place – Peter Thompson	
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. Standard licensing pack completely refreshed and distributed to members/advisers April 2015.	In place – Sam Hartley	

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 is undertaken at the initiation of any likely action.	In place – 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.

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Confidentiality breach of Register data.	Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality. Secure working arrangements for Register team, including when working at home.	In place – Dave Moysen	At tolerance.
Loss of Register or other data.	As above.	In place – Dave Moysen	
	Robust information security arrangements, in line with the Information Governance Toolkit, including a security policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards.	In place – Dave Moysen	
Cyber-attack and similar external risks.	Secure system in place as above, with regular penetration testing.	In place – Dave Moysen	
Infrastructure turns out to be insecure, or we lose connection and cannot access our data.	IT strategy agreed, including a thorough investigation of the Cloud option, security, and reliability.	In place – Dave Moysen	
	Deliberate internal damage to infrastructure, or data, is controlled for through off-site back-ups and the fact that any malicious tampering would be a criminal act.	In place (March 2015) – Nick Jones	
Business continuity issue.	BCP in place and staff communication procedure tested. A period of embedding the policies is now in progress.	In place (January 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: Likelihood: 5 / Impact: 4 / Inherent risk: 20 Very high Residual risk level: Likelihood: **3** / Impact: **4** / Residual risk: **12 High** Tolerance threshold: 8 Medium	⇔ ⇔ ⇔ ⇔	Juliet Tizzard

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Poor record keeping	Refresher training and reminders about good records management practice. Head level 6 month contract to be recruited to manage the office move and review records management.	In place – SMT Head post recruitment in progress September 2015 - SMT	Above tolerance. Although we have some good controls in place for dealing with PQs and other externally generated requests, it should be noted that we cannot control incoming volumes, which in January 2015 were among the highest we have ever experienced. It is not yet possible to tell if further high volumes will occur during the mitochondria project and the subsequent start-up of applications processing.
	TRIM review and retention policy implementation work – subsumed by IT strategy.	To sync in with IT strategy – Dave Moysen/Sam Hartley	
	Audit of Epicentre to reveal any data errors. All queries being routed through Licensing, who have a definitive list of all licensing details.	Due for completion October 2015 – Sam Hartley (report and recommendations to October CMG)	
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, attempts are made to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones	
	PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific Policy Manager	In place - Sam Hartley	

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

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Data accuracy in Register submissions.	Continuous work with clinics on data quality, including current verification processes, steps in the OTR process, regular audit alongside inspections, and continued emphasis on the importance of life-long support for donors, donor-conceived people and parents.	In place – Nick Jones	At tolerance (which is very low for this risk).
	Audit programme to check information provision and accuracy.	In place – Nick Jones	
	IfQ work will identify data accuracy requirements for different fields as part of the migration process, and will establish more efficient processes.	In progress – June-September 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 established with external contractor in place.	In place (June 2015) – Nick Jones	At tolerance. The pilot counselling service has been in place since 1 June, and we will make further assessments based on early uptake and the delivery experience. Reporting to the Authority will occur annually during the pilot period.
Insufficient Register team resource to deal properly with OTR enquiries and associated conversations.	Additional member of staff dedicated to handling such enquiries.	In place – Nick Jones	
Risk of inadequate handling of a request.	Trained staff, SOPs and quality assurance in place.	In place – Nick Jones	
	SOPs reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract in place with PAC-UK for pilot delivery.	Done (May 2015) – In June the ongoing management of the Pilot transferred to Rosetta Wotton.	

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

Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
Fee regime makes us dependent on sector activity levels.	Activity levels are tracked and change is discussed at CMG, who would consider what work to deprioritise and reduce expenditure.	Monthly (on-going) – Sue Gallone	Above tolerance, but 2014/15 overspend was able to be met from reserves.
	Fees Group created enabling dialogue with sector about fee levels.	In place. First meeting took place on 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 alongside draft business plan submission.	December annually – Sue Gallone	
	Budget confirmation for 2015/16 obtained March 2015. Capital allocation agreed as requested, in June 2015.	In place – Sue Gallone	
Budget setting process is poor due to lack of information from directorates	Quarterly meetings with directorates flags any short-fall or further funding requirements.	Quarterly meetings (on-going) – Morounke Akingbola	
Unforeseen increase in costs eg, legal, IfQ or extra in-year work required	Use of reserves, up to contingency level available. DH kept abreast of current situation and are a final source of additional funding if required. IfQ Programme Board regularly reviews the budget and costs.	Monthly – Sue Gallone Monthly – IfQ Programme Board	

Upwards scope creep during projects, or emerging during early development of projects eg, 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: Likelihood: 4 / Impact: 4 / Inherent risk: 16 High Residual risk level: Likelihood: **3** / Impact: **3** / Residual risk: **9 Medium** Tolerance threshold: 6 Medium	⇔ ⇩ ⇔ ⇔	Peter Thompson

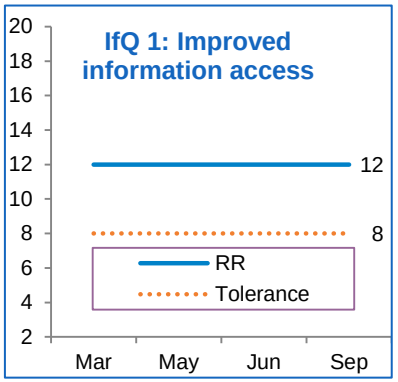
Causes/ sources	Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.	People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins	Above tolerance. This risk and the set of controls remains focused on capability, rather than capacity. There are obviously some linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. CMG reduced (slightly) the likelihood of this risk in May 2015, but still decided to retain it, given that high turnover could recur. CMG agreed the tolerance should remain at 6. Since the HFEA has become a much smaller organisation over the past few years, leaving less intrinsic resilience, it seems prudent to have a low tolerance for this risk.
	A programme of development work is planned to ensure staff have the skills needed, so as to ensure they and the organisation are equipped under any future model, maximising our resilience and flexibility as much as possible. Staff can access civil service learning (CSL); organisational standard is five working days per year of learning and development for each member of staff.	In place – Rachel Hopkins	
	Organisational knowledge captured via records management (TRIM), case manager software, project records, handovers and induction notes, and manager engagement.	In place – Rachel Hopkins	

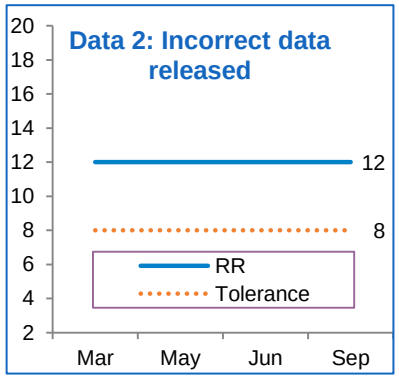
The new UK government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	The HFEA has already been proactive in reducing its headcount and other costs to minimal levels over a number of years. We have also already been reviewed extensively (including the McCracken review). Although turnover is currently reducing to more normal levels, this risk will be retained on the risk register, and will continue to receive ongoing management attention.	In place – Peter Thompson
Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson
	Staff survey and implementation of outcomes, following up on Oct 2014 all staff conference.	Survey done (Jan 2015) – Rachel Hopkins Follow-up communications in place (Staff Bulletin etc.) – Peter Thompson
Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance.	Staff kept informed of likely developments and next steps, and when applicable of personal role impacts and choices.	In place – Nick Jones
	Policies and processes to treat staff fairly and consistently, particularly if people are 'at risk'.	In place – Peter Thompson
Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG.	In place – Paula Robinson
	Early emphasis given to team-level service delivery planning for 2015, with active involvement of team members. Delivery (and resources) in Q1 to date were also considered at monthly CMG in May, and delivery is currently on track. CMG will continue to review this.	In place (Jan 2015) – Paula Robinson

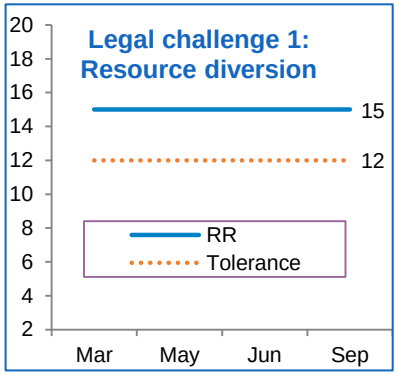
	Moratorium on new project work under consideration in planning for remainder of 2015/16 and for 2016/17, so as to prioritise IfQ delivery and therefore strategy delivery) within our limited resources.	Ongoing dialogue about this in place as part of business planning (August 2015 onwards) – Paula Robinson
	IfQ has some of its own dedicated resources.	In place – Nick Jones
	There is a degree of flexibility within our resources, and increasing resilience is a key consideration whenever a post becomes vacant. Staff are encouraged to identify personal development opportunities with their manager, through the PDP process, making good use of Civil Service Learning.	In place – Peter Thompson
Regarding the current work on licensing mitochondrial replacement techniques, there is a possible future risk, beyond October 2015, that we will need to increase both capability and capacity in this area, depending on uptake (this is not yet certain).	Future needs (capability and capacity) relating to mitochondrial replacement techniques and licensing applications are starting to be considered now, but will not be known for sure until later. No controls can yet be put in place, but the potential issue is on our radar.	New issue for consideration – Juliet Tizzard

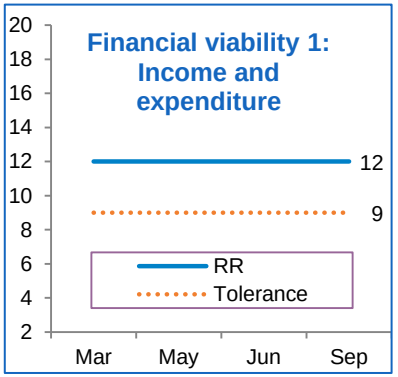
Tolerance vs Residual Risk:

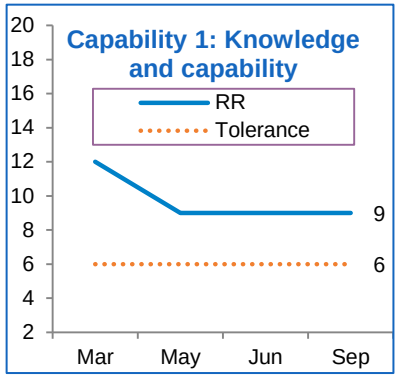
Risks above tolerance



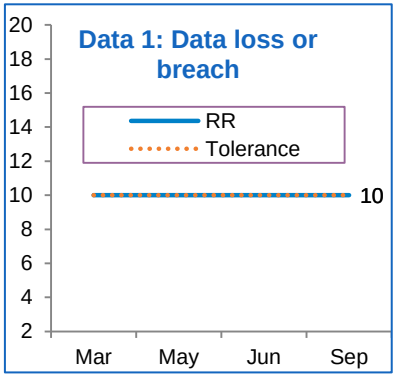


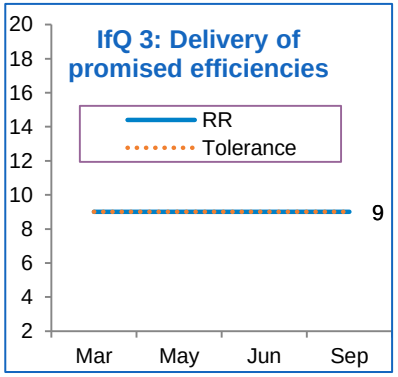


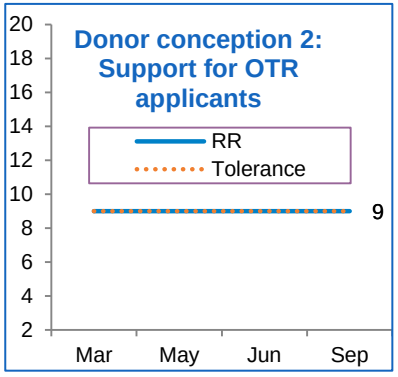


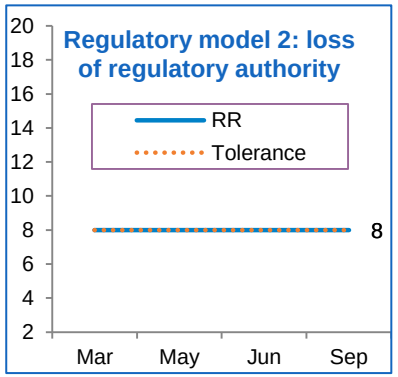


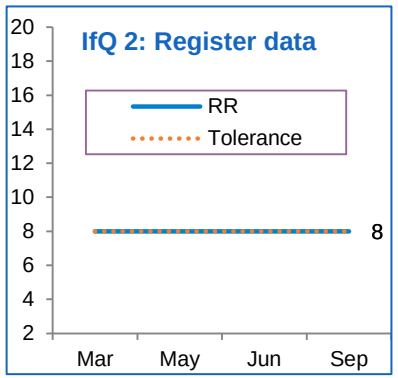
Risks at tolerance

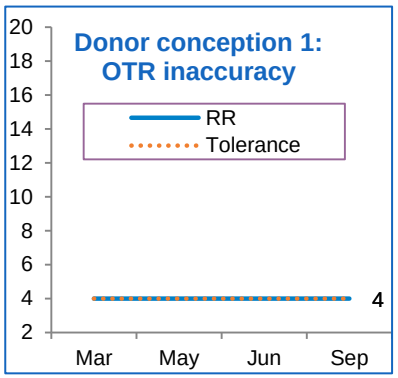




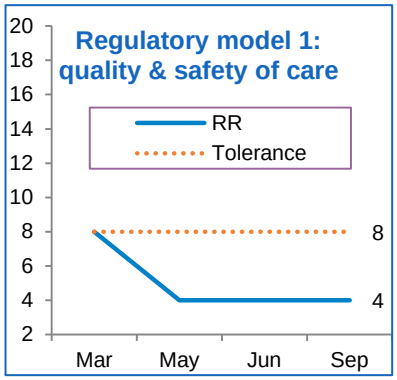








Risk below tolerance



Scoring system

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

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

Risk scoring matrix

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

Risk Score = Impact x Likelihood

Likelihood

HFEA Internal Audit Progress Report

1) Purpose of paper

This paper sets out the following for consideration by the HFEA Audit and Governance Committee on 7th October 2015:

- Progress to date against the 2015/16 Audit Plan; and
- A progress memo in relation to the ongoing Register of Treatment review which is carried forward from the 2014/15 plan.

2) Progress against 2015/16 Internal Audit Plan

2.1 Status of agreed plan:

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

Reviews per 2015/16 IA plan	Audit scope per 2015/16 plan	Status	Findings				Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			Critical	High	Medium	Low				
Requests for Information	The HFEA may be required to release information as a result of: • Parliamentary Questions (PQs); • Freedom of Information (FOI) requests; and • Data Protection (DP) requests. We will examine current policies and procedures for the release of information under these circumstances and consider whether: • Current policies and procedures cover all relevant information held by the HFEA to which PQs, FOI and DP requests might relate; • Authorisation for the release of information is restricted to the appropriate committees and/or individuals; and	Draft report issued 22/09/2015 awaiting response						15	10.5	10

Reviews per 2015/16 IA plan	Audit scope per 2015/16 plan	Status	Findings				Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			Critical	High	Medium	Low				
	• Risks in relation to the release of sensitive information have been identified, are regularly monitored, and are aligned to mitigating controls.									
Incident Handling	It is a requirement of licensed centres to report adverse incidents to the HFEA, where adverse incidents are described as 'any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre.' NOTE: there are circa 500 incidents raised in each year in relation to circa 50,000 activities undertaken by the clinics. These incidents must be notified to the HFEA within 24 hours of their taking place. Once these reports are received, the HFEA must investigate the incident and respond in line with its Compliance and Enforcement Policy. In addition, HFEA has a responsibility to review and respond to complaints made against clinics. Circa 10 complaints are received each year. We will review current policies and procedures relating to incident and complaints reporting and responses and consider whether: • The HFEA's responses to reported incidents and complaints in the 12 months to the date of fieldwork have been conducted in line with agreed procedures; • The HFEA produces and retains sufficient documentation to support its response to	Fieldwork commenced 28/09/15						12	10	1.5

Reviews per 2015/16 IA plan	Audit scope per 2015/16 plan	Status	Findings				Overall report rating	Audit days per plan	Revised audit days	Actual audit days
			Critical	High	Medium	Low				
	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	Building on the 2014/15 'Register of Treatments' review, we will: • Provide 'critical friend' input into the work performed by the HFEA to migrate data to the new Register of Treatments database; • Test a sample of data between the old and new Registers to verify the accuracy and completeness of data.	First update memo issued September 2015	N/A – No ratings provided				N/A	12	10.5	3
Assurance mapping	The focus of assurance mapping of 'capacity and resilience' has been agreed with the Director of Finance and Resources and the Head of Business Planning.	To confirm scope	N/A – No ratings provided				N/A	0	3	0
Audit Management	All aspects of audit management to include: • Attendance at liaison meetings and HFEA Audit and Governance committees; • Drafting committee papers/progress reports; • Follow-up work; • Drafting 2016/17 audit plan; • Resourcing and risk management; and • Contingency.	Ongoing	N/A – No ratings provided				N/A	8.4 (inc. 2.4 days c/f from 14/15)	8.9	6
		Total Findings:	-	-	-	-				
							Total days	**57.4**	**42.9**	**20.5**

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

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

- The final 2015/16 audit plan;
- The draft report for the Requests for Information review; and
- A progress memo in relation to the ongoing Register of Treatment review which is carried forward from the 2014/15 plan.

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.

Three high risk issues were raised as part of the 2015/15 plan as follows:

1. Two related to our review of Internal Policies; and
2. One related to the IFQ programme.

Below is the current status for each of the three high risk issues:

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

Name of Audit	Issue	Management Action	Responsible Officer and Timescale	Current Status
IFQ	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.	Costs will be articulated in the new business case. Earned value will be added to the programme Board reporting.	Mike Arama, 01/04/15	A business case for the project has now been completed and approved. A document detailing the earned value procedure has also been completed; The earned value is calculated monthly

Name of Audit	Issue	Management Action	Responsible Officer and Timescale	Current Status
	The earned value of the programme should be continuously monitored and corrective actions taken.			within the Budget see earned value worksheet The earned value figure has been reported to CMG in the Strategic performance report and was reported to IfQ Programme Board from May.
Internal Policies Review	Completeness of register and allocation of ownership of register and policies. The register is not complete, with policies currently available to staff not being included within the register. We understand that a staff member from the Governance and Licensing team has been allocated from January 2015 with responsibility for keeping the register up to date going forward and liaising with individual departments to ensure that policies are current and reflect best practice.	Complete list to be compiled, to specification outlined in recommendation. Proposals for priority of update/ streamlining of policies to be considered by SMT.	Complete list to be in place by end April 2015. Priorities/streamlining of policies to be considered by SMT by end August 2015 Both actions owned by Head of Governance and Licensing (HoGL)	SMT will consider this week (week of 28th September) proposed SOP for the maintenance of policies, plus the register and timetable for completion of the outstanding policies.
Internal Policies Review	The majority of policies evidenced on the register are past their revision date and are not subject to version control. From review of 46 HFEA policies on the Register, we found that only two were up to date as at the date of this review. 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	SMT to give consideration to process to be used to introduce/ revise/monitor policies, proportionate to size of HFEA and number of functions	Set process for introduction/revision/ monitoring of policies to be in place by end June 2015 Owner: HoGL	SMT will consider this week (week of 28th September) proposed SOP for the maintenance of policies, plus the register and timetable for completion of the outstanding policies.

Name of Audit	Issue	Management Action	Responsible Officer and Timescale	Current Status
	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.			

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, no critical or high risk issues have been raised as a result of work undertaken during 2015/16.

Internal Audit coverage 2013/14 - 15/16:

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

Appendix A – Report Rating Definitions

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

Appendix B - Limitations and responsibilities

Internal control

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

Future periods

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

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

Responsibilities of management and internal auditors

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

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

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

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

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

External File Note to the Human Fertilisation & Embryology Authority (HFEA)

Our work has been conducted and our report prepared solely for the benefit of the Department of Health and its arms-length bodies and in accordance with a defined and agreed terms of reference. In doing so, we have not taken into account the considerations of any third parties. Accordingly, as our report may not consider issues relevant to such third parties, any use they may choose to make of our report is entirely at their own risk and we accept no responsibility whatsoever in relation to such use. Any third parties requiring access to the report may be required to sign 'hold harmless' letters.

To:	From:
Sue Gallone (Director of Finance) **Mike Amara (IfQ Programme Manager)** **Nick Jones (Director of Compliance and Information)** **CC: Audit Committee**	**Lynn Yallop (Head of Internal Audit)**

Date: 22nd September 2015

Subject: Internal Audit Review (HFEA201415004) – Register of Treatments

Background:

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. Internal Audit's approach to this project, as agreed by HFEA management and Audit Committee and outlined in Appendix 1, is to provide ongoing critical friend input at key project meeting milestones.

As a result, the second meeting that Internal Audit attended was a meeting held with the programme board on the 19th August 2015 to discuss the data migration strategy. Key observations are noted below.

Limitations of Scope:
Our review is not a complete review of the data migration strategy and our observations noted below were identified during the programme board meeting held on the 91th August 2015. There could be other elements of the strategy that would require management or the programme board's attention that might be identified by a more detailed review of the strategy.

Observations Noted	Risk Rating
Overall Governance **Programme Board** Based on the limited interaction with the programme board at the meeting on the 19th August 2015, internal audit noted that the programme board activities and agenda items were consistent with the previous meeting, and that there had been no significant changes to the board. Members/representatives of the board continued to consistently demonstrate a good working knowledge of the business and were focused on key risks that would affect the business.	N/A

Observations Noted	Risk Rating
Managing risks The programme board have formally defined a risk register and during the programme board meeting discussed risks within the register. This discussion was broader than just data migration and covered all programme risks. At the time of the meeting the total aggregated risk score was 182. The programme board indicated that there was a need to gain a better understanding of the risk scoring system. The IfQ Programme Manager indicated that this information is captured within the overall risk register and that the reporting of the risks to the programme board would be supported by this information at the next meeting. The IfQ Programme Manager reported to the programme board that risks are currently at an acceptable level. An action was taken to provide the programme board with more detail at the next meeting.	Low
Data Migration Update **Health Check** The programme board have commissioned a health check review of the data that resides within the current database to identify what data is missing and the level of effort that would be required to update all of the data to the following standard/requirement: 1. All registrations, treatments, and outcomes, since 2010 would be expected to meet the same quality standards as that of the new (post ifQ implementation) system; and 2. Any pre 2010 registrations, treatments, and outcomes, which relate to HFEA's ability to comply with minimum document retention requirements should be corrected. The current assessment that was performed was quite detailed and provided the board with a list of all fields that (1) must be corrected to be able to migrate to the new systems, and (2) should be updated to ensure good quality of data. The programme board were advised that they would need to assign resource to this exercise and the estimated time to complete would be approximately six months of at least two dedicated resources. Internal audit noted that there are still some database queries that needed to be run to further identify data gaps, however these were considered by the project team as non-key fields. The programme board needs to review these fields to determine if they need to be evaluated for quality prior to migration to the new system.	Medium
Data Migration Approach The programme board need to determine whether it would be feasible to only correct the "must" fields before migrating the data to the new environment where they would then update the "should" fields. However, taking this approach would result in the risk of the "should" fields not being updated once migrated into the new environment is complete. Alternatively the programme board can decide to perform the complete data cleanse before migration to the new system. However, this would result in a resource intensive exercise that has the potential to delay the go live migration.	Medium

Observations Noted	Risk Rating
The programme board need to assess the risks, with management, of both options and determine an approach that would limit the risk of project delay and cost overrun while ensuring quality, completeness and accuracy of data.	Medium
The programme board needs to further evaluate the fields that have not been checked within the current health check assessment thus far in order to determine if these fields are required to be updated prior to migration. The programme board needs to further develop a plan for ensuring that the remaining data is also cleansed and checked for quality once the migration to the new system is complete. The programme board needs to take into consideration that this would require resource and time once the migration is complete and allocate resource and budget for the completion of this exercise.	Medium

Next Steps:

To note the findings above and ensure the project team address the issues.

In addition, we have subsequently agreed that:

- HFEA will provide future dates of all key meetings so we can ensure internal audit resource is available to attend to observe; and
- HFEA will send all key project documentation through to Internal Audit, i.e. risk registers, project plans, minutes of steering meetings, etc, on a monthly basis. This will ensure we have full oversight of key activities and can provide continuous input into the project. Please note that our formal input conclusions/observations will be documented in a similar file note after each key meeting we attend.

Please do not hesitate to contact me with any queries.

Yours sincerely

Lynn Yallop
Head of Internal Audit

Appendix 1 – Terms of Reference

Health Group Internal Audit

REFERENCE NUMBER: HFEA201415004
FINAL TERMS OF REFERENCE
HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY
FEBRUARY 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 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

01132 54 5515 – 2W12 Quarry House, Quarry Hill, Leeds, LS2 7UE

REGISTER OF TREATMENTS

CONTENTS **PAGE**

Distribution List – Draft Terms of Reference

Nick Jones
Mark Arama

Cc:

Sue Gallone

Distribution List – Final Terms of Reference

Nick Jones
Mark Arama

Cc:

Sue Gallone

1. INTRODUCTION

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

1.2 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.

2. KEY RISKS, OBJECTIVES AND SCOPE

2.1 Key Risks

Through discussion with management and based on our earlier work relating to the IfQ programme (internal audit report HFEA201415001- November 2014) the following risks relating to the programme were identified and considered:

- Key programme risks may not be identified on a timely basis or managed effectively, leading to delays in implementation, additional costs, and an impact on public confidence in the Authority;
- The programme fails to ensure that highly sensitive information is handled, stored and accessed securely, leading to loss or theft of data. This could lead to regulatory penalties and a reputational impact;
- Business continuity arrangements may not be sufficiently robust, leading to significant 'downtime' of key systems after the go-live date and to a consequent poor take-up of new systems by key stakeholders;
- The compatibility of software involved may be poor, leading to inaccurate or incomplete transfer of data between different areas of the system and the need for inefficient workarounds;
- Key staff members do not have the necessary skills to make effective use of the software and deliver programme outcomes;
- Costs fail to be adequately monitored and controlled, leading to overspends against allocated budgets, impacting the HFEA's ability to finance its core regulatory activity; and
- Programme managers do not take into account the views and feedback of all stakeholders, including licensed centre staff, meaning operational risks are not identified and addressed at an early stage and there is poor take-up of the new systems.

Please refer to the table below in section 2.3 for detailed areas and risks.

2.2 Objectives

Our objects will be to provide challenge to the project team in key risk areas.

2.3 Scope

The "critical friend" role will be carried out using a risk-based approach. The role will consider the following potential risks set out in the table below in relation to the programme:

Area	Objectives	Risks
Engaged stakeholders	Programme managers have identified and mapped all key stakeholders. Feedback from stakeholders has been obtained and considered as part of programme planning and continues to be obtained throughout the project.	Stakeholders are not engaged with the programme, leading to poor take-up of systems. Programme managers cannot identify and address potential operational issues where stakeholder feedback is not obtained and meaningfully integrated into programme plans.
Clear scope	Work to be undertaken as part of the programme is clearly defined and phased over the life of the programme. Ownership for all activities within the programme has been allocated to named individuals.	Scope is poorly defined and activities have not been clearly allocated meaning that required activities are not undertaken, or unnecessary activities are undertaken, which leads to inefficiencies and consequent delays.
Managed risks and opportunities	The programme has a live risk register which clearly sets out key risks and agreed actions for mitigating these risks. Programme managers proactively identify risks during the life of the project and monitor the progress of mitigating actions. Key risks for the programme which are set out in section (2.1) above have been identified and their mitigation prioritised at the highest level. This includes the specific risks that: (i) Highly sensitive information is inappropriately handled, stored and accessed, leading to loss or theft of data; and (ii) Business continuity arrangements may not be sufficiently robust, leading to significant downtime of	Risks to the design and implementation of the programme may not be identified and addressed in a timely fashion, leading to operational failures and an impact on public confidence in the HFEA. Highly sensitive information is lost or stolen, leading to financial penalties from regulators and a significant reputational impact. Opportunities to improve delivery of the project may not be identified and realised.

Area	Objectives	Risks
	key systems after the go-live date. It is a formal requirement that all key risks have been sufficiently mitigated prior to programme approval being granted. There is a formal process in place for identifying opportunities (e.g. for improved efficiency) and escalating these to programme managers.	
Delivery-enabled plans	Programme plans are clearly aligned to outputs to ensure that all activity is congruent and goal-oriented. There are clear and credible plans for ongoing programme management after the go-live decision has been made.	Programme plans may not be clearly aligned with outputs, leading to inefficient delivery of the programme. Governance arrangements of the programme after go-live may be unclear, leading to delays in identifying and rectifying emerging operational issues.
Focused benefits management	Key benefits of the programme (such as target savings) are clearly mapped. The realisation of these benefits is/will be measured. Proof of concept for the programme is undertaken and a detailed cost/benefit analysis performed prior to go-ahead for the programme. Projects within the programme are robustly validated through the use of business cases.	Costs of the programme might outweigh benefits for stakeholders where a robust cost/benefit analysis is not performed. Envisaged benefits may not be realised as anticipated if these are not regularly measured and monitored. Projects may fail to contribute to the benefits of the overall programme where they are not robustly validated and aligned to programme outcomes.
High performance teams	Programme teams incorporate the right blend of skills to enable efficient and effective delivery of the overall programme. Teams are supported by clear reporting lines and programme governance structures.	Programme/project teams do not have the necessary capacity and skills to deliver programme outcomes. This causes delays to the programme or poor quality delivery of outcomes.

Area	Objectives	Risks
Smart financing	The programme is supported by a detailed budget, with costs phased over time and all budgeting assumptions robustly analysed. A process is in place for regular financial review of the programme and remedial action is taken where significant variances occur.	Significant variances may occur where budgets are unrealistic or poorly phased. Programme managers will be unable to identify and effectively address budget variances on a timely basis where financial information is not regularly reviewed.
Integrated suppliers	There is a formally approved process for the selection of key suppliers to ensure the Authority achieves compatible software, high quality and value for money for goods and services received. Suppliers are aware of key programme milestones and are incentivised to deliver in a timely fashion.	Goods and services provided by suppliers fail to meet minimum quality and pricing standards, impacting on the quality and timeliness of programme outcomes as well as increasing the risk of overspends.
Active quality management	An effective quality management plan has been developed and communicated to the programme team. Measurable quality indicators are in place and are regularly reviewed.	The programme delivers poor quality outcomes, leading to delays while rectifying actions take place and impacting the take up of the programme by all stakeholders.
Embedded life-cycle assurance and learning	A clear assurance plan has been defined which outlines the nature, timing and extent of quality assurance reviews to measure the effective outcome of the programme. Assurance is gained in key areas both during and after the implementation stages of the programme.	HFEA fails to identify and correct quality shortcomings during the implementation phase and in programme outcomes.
Agile change controls	A formal process is in place for controlling and limiting changes to project scope.	The programme experiences 'scope drift', leading to delays, overspends and poorly quality outcomes.
Governance-enabling decision-making	Effective decision-making is supported through a formally defined governance structure which sets out clear reporting lines, the	Key committees do not receive all relevant information required for effective decision-making.

Area	Objectives	Risks
	responsibilities of key committees and key individuals, and an approved delegation of authority. Formal decisions agreed within key committees are documented and monitored to ensure they have been actioned.	Formal decisions are not enforced where they are not monitored on an ongoing basis.

2.4 Exclusions from scope

This will not be a compliance review; instead internal audit will attend key milestone project management meetings and provide challenge to the project and executive 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 Committee.

3. RELEVANT CONSIDERATIONS FOR THE REVIEW

None noted.

4. GOVERNANCE OF THE REVIEW

The review fieldwork will be overseen by our Internal Audit Specialist, Siven Moodley, and reviewed by the Head of Internal Audit, Lynn Yallop.

5. AUDIT APPROACH

Our approach in undertaking this review will include the following:

- Review of project team meeting documentation, if any; and
- Attending meetings with the project team.

6. DELIVERABLES

The deliverable from this audit will be file notes from the meetings with the project team to the HFEA exec team and audit committee.

7. FEEDBACK

On completion of the audit, we will seek feedback on our performance from the customer in the form of a Client Satisfaction Questionnaire.

8. TIMING & RESPONSIBILITY

Objective	Responsibility	Completed by
Terms of Reference agreed	Nick Jones	06 Feb 2015
Commencement of Fieldwork	Siven Moodley	09 Feb 2015
Completion of Fieldwork	Siven Moodley	31 March 2015 (dependant on meetings)
Discussion of draft findings	Siven Moodley	N/A – external file notes will be shard after meeting
1st Draft Report issued	Siven Moodley /Lynn Yallop	Refer Above
Management Responses received	Sue Gallone	Refer Above
Final Report issued	Lynn Yallop	Refer Above

9. KEY CONTACTS

Audit Team		
Name	Title	Telephone no.
Lynn Yallop	Head of Internal Audit	01603 883308
James Hennessey	Team Leader	07833 680859
Siven Moodley	Internal Audit Specialist	07841 567485

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.

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- ***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 01132 54 5515 – 1N16 Quarry House, Quarry Hill, Leeds, LS2 7UE

HFEA

Audit planning report on the 2015-16 financial statement audit

REPORT TO THOSE CHARGED WITH GOVERNANCE
October 2015

http://www.nao.org.uk/

Contents

Financial statement audit plan

What work will we complete?

Our audit, which will be conducted in accordance with International Standards on Auditing (UK and Ireland) (ISAs (UK and Ireland)), will enable the C&AG to give an opinion on the financial statements.

Further details of the scope of the audit, as well as our respective responsibilities in relation to this engagement, have been set out in our Letter of Understanding issued on the 11th October 2012 which has previously been separately provided to the audit committee.

Members of the Audit Committee are invited to consider and discuss:

- Whether our assessment of the risks of material misstatement to the financial statements is complete;
- Our proposed audit plan to address these risks; and,
- Whether the financial statements could be materially misstated due to fraud, and communicate any areas of concern to management and the audit team.

How are we going to conduct the audit?

Risk based approach

We plan our audit of the financial statements to respond to the risks of material[1]:

- misstatement to transactions and balances; and
- irregular transactions.

The significant financial statement risk which we have identified is:

- Accounting treatment for the IfQ capital expenditure project.

The Auditing Standards ISA 240 states that there is a significant risk in all entities that:

- Management override controls to perpetrate fraud;
- Presumed risk of fraud arising from revenue recognition.

Our team

The details of the key audit staff who will complete this audit are:

- George Smiles; Engagement Director for the audit;
- Sarah Edwards; Engagement Manager for the audit;
- Malini Sampat; Engagement Lead for the audit and will complete the on-site work.

Further details are set out in the following slide.

[1] A matter is material if its omission or misstatement would reasonably influence the decisions of users of the financial statements. The assessment of what is material is a matter of the auditor's professional judgement and includes consideration of both the amount and the nature of the misstatement. Further information on materiality is included on page 9.

Significant financial statement risks

Accounting treatment of IfQ capital expenditure project

Key features

HFEA have budgeted to spend £1.1m on the IfQ capital expenditure project in 2015-16 and it is likely that a large percentage of this amount will be capitalised as intangible assets. There is a risk therefore that capitalised assets do not meet all of the recognition criteria required for capitalisation in IAS 38 *Intangible Assets* resulting in material misstatement in the financial statements.

Change from prior year

Level of risk has increased from 2014-15.

Audit response – We will undertake specific testing to address the risks involved in accounting for intangible assets, paying particular attention to the value and date assets were capitalised, and whether they meet the recognition criteria for capitalisation.

Substantive

- Sample test of additions to intangible assets;
- Completeness testing of intangible assets;
- Perform a substantive analytical procedure on amortisation.

Significant financial statement risks

Management override of controls

Key features

- Under International Standards on Auditing (UK and Ireland) 240 *The auditor's responsibilities relating to fraud in audit of financial statements* there is a presumed risk of management override of controls in all organisations. We are required to assess the risk of material misstatement arising from management override, in particular in relation to significant or unusual transactions, bias in accounting estimates and journals.
- There have been no indications of this risk crystallising in the case of HFEA to date.

Change from prior year

Same approach to meet ISA 240 requirements

Audit response

Substantive

- Review of significant transactions;
- Journal sample testing;
- Consider the assumptions underpinning each of the key estimates in the accounts (i.e. provisions and impairments).

Significant financial statement risks

Revenue recognition

Key features

- Under International Standard on Auditing (UK and Ireland) 240 *The auditor's responsibilities relating to fraud in audit of financial statements* states that there is a presumed risk of fraud in revenue recognition, albeit rebuttable in all entities. As HFEA's main income stream is treatment fees from clinics; there is a risk that not all treatment income is reported to HFEA.
- There have been no indications of this risk crystallising in the case of HFEA to date.

Change from prior year

Same approach to meet ISA 240 requirements

Audit response – We will undertake specific testing to address the risks involved in accounting for fee income, paying particular attention to the completeness of income, and the accounting estimate relating to accrued income. We will also consider any new income streams**.**

Substantive and Controls testing

- Income substantive analytical procedure will be performed by accessing all the invoices sent to clinics and applying the fees per treatment as published on HFEA's website. We will then compare this to the income received by HFEA to ensure it is in line with our expectation.
- We will be assessing the work that the Compliance Audit Team carry out on their visits to clinics. This is the control we will seek to rely on for income, in order to provide us with assurance that the data provided by the clinics to HFEA is complete and accurate.

When do we plan to complete this work?

Timetable

The timetable comprises two interim visits, each one week long, on weeks commencing 08/02/16 and 21/03/16 and a final visit commencing 23/05/16 for two weeks with certification planned for late June. Further details are provided in the table below.

Date	Activity
Sep/Oct 2015	**Planning:** review HFEA's operations, assess risk for our audit and evaluate the control framework.
February 2016	**Interim audit work:** Review of management accounts & disclosures; work on IfQ & income.
March 2016	**Interim audit work:** Detailed testing of account transactions and balances.
May 2016	**Receipt of draft account**
May 2016	**Final audit work:** test expenditure and income and significant balances and disclosures.
June 2016	**ISA 260 Report** comprising Audit Completion Report and Management Letter.
June 2016	**Certification:** seek representations and C&AG issues opinion.

Fees

We aim to hold our fee at £27,500.

Completion of our audit in line with the timetable and fee is dependent upon HFEA:

- delivering a complete Annual Report and Accounts of sufficient quality, subject to appropriate internal review on the date agreed;
- delivering good quality supporting evidence and explanations within the agreed timetable;
- making staff available during the audit.

If significant issues arise and we are required to perform additional work which would result in a change in our fee, we will discuss this with you as soon as possible.

Our audit approach

Our assessment of materiality

Materiality	The concept of materiality recognises that financial statements are rarely absolutely correct, and that an audit is designed to provide reasonable, rather than absolute, assurance that the financial statements are free from material misstatement or irregularity. For the purposes of determining whether the financial statements are free from material misstatement or irregularity we consider whether: 1. the magnitude of misstatement; or 2. the nature and cause of misstatements (e.g. because of the sensitivity of specific disclosure or regularity requirements) would influence the users of the accounts. In line with generally accepted practice, we have set our quantitative materiality threshold for the organisation as approximately 2% of gross expenditure, which equates to £100,000. Other elements of the financial statements that we consider to be more sensitive to users of the accounts will be assessed using a lower qualitative materiality threshold. These elements include the remuneration report disclosures; the losses and special payments note and our audit fee. We apply the concept of materiality in planning and performing our audit and in evaluating the effect of misstatements on our audit and on the financial statements. As the audit progresses our assessment of both quantitative and qualitative materiality may change.
Error reporting threshold	For reporting purposes, we will treat any misstatements below £2000 as “trivial” and therefore will not be reported to the Audit Committee.

Our audit approach

Other matters

Independence	We comply with relevant ethical requirements regarding independence and have developed important safeguards and procedures in order to ensure our independence and objectivity. Information on NAO quality standards and independence can be found on the NAO website: http://www.nao.org.uk/about-us/role-2/what-we-do/audit-quality/audit-quality/ We will reconfirm our independence and objectivity to the Audit Committee following the completion of the audit.
Management of personal data	During the course of our audit we have access to personal data to support our audit testing. We have established processes to hold this data securely within encrypted files and to destroy it where relevant at the conclusion of our audit. We confirm that we have discharged those responsibilities communicated to you in the NAO's Statement on Management of Personal Data at the NAO. The statement on the Management of Personal Data is available on the NAO website: http://www.nao.org.uk/freedom-of-information/publication-scheme/how-we-make-decisions/our-policies-and-procedures/policies-and-procedures-for-conducting-our-business/
Using the work of internal audit	We liaise closely with internal audit through the audit process and seek to take assurance from their work where their objectives cover areas of joint interest. Following our review of internal audit's plans we will consider the outcome of the planned report for the Information for Quality capital expenditure project.

Follow up to recommendations we made in the previous year

Title	Area	What was the recommendation?	Response/Progress	Status
Review of the expected useful lives of assets	Fixed assets	Review of HFEA's Fixed Asset Register demonstrates that assets are often in use for longer than their estimated useful lives. We recommended that at the end of each financial year HFEA Finance assess the impact of the fully depreciated assets on the net book value of the non-current assets and the depreciation charge in year to ensure that balances disclosed are free from material misstatement.	HFEA carried out a review of the impact of fully depreciated assets still in use on the net book value of the non-current assets and have confirmed that they are not material to the accounts.	Complete
Review of the expected useful lives of assets	Fixed assets	Review of HFEA's Fixed Asset Register demonstrates that assets are often in use for longer than their estimated useful lives. We recommended that HFEA Finance performs ongoing review of the estimate of useful lives applied to assets to ensure they are an accurate reflection of their likely use.	HFEA carried out a review of Useful Economic Lives of all their fixed assets by the end of September 2015 and are considering the Useful Economic Lives of assets as they are acquired.	Complete
Management Accounts Insufficient *documentation of challenge and review*	Management accounts	HFEA Finance should maintain sufficient documentation to evidence the review and challenge of the Monthly Management Accounts by the Senior Management.	We agree with HFEA that due to the small size of the organisation the current process of review and challenge of management accounts is both efficient and effective. We will consider whether we can rely on HFEA's management account review process this year.	Cleared

Appendix 1 Sector developments

FReM 2015-16 changes: adoption of IFRS 13 and changes to structure and content of Annual Report and Accounts

The Performance Report, the Accountability Report and the Financial Statements

In 2013-14 the FReM adopted the Companies Act requirements for a Strategic Report and Directors' Report within the Annual Report. As part of the Simplification and Streamlining Project the 2015-16 FReM introduces changes to the structure of the Annual Report and Accounts. There is now a requirement for these to be split into three parts; the Performance Report, the Accountability Report and the Financial Statements.

Main changes – all entities

- Accounting policies or disclosure notes are only required in relation to material items (although where wider commentary would be helpful to the user this may be included);

- The Accountability Report includes a redesigned "Remuneration and staff report". This combines the disclosures for average number of persons employed and related costs and exit packages (previously included in the notes to the financial statements) with the remuneration report disclosures.

Main changes – departments

- The format of the Statement of Parliamentary Supply has been streamlined and will be included within the Accountability Report;

- Removal of the requirement to produce SOPs Note 1 – Statement of accounting policies;

- Reduction of disclosure for SOPs Note 3 – An amendment to only include a reconciliation for resource outturn;

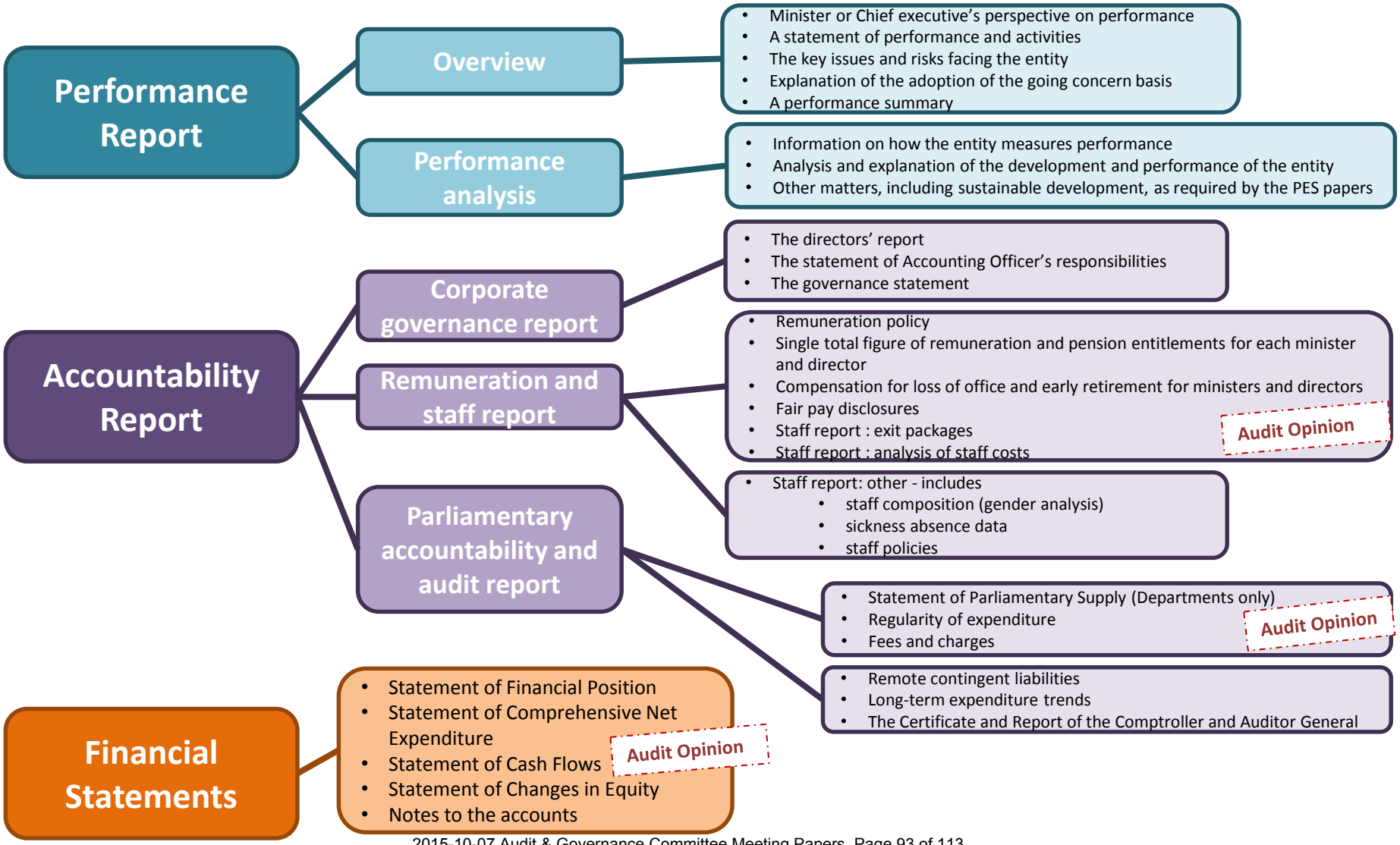
- SOPs Notes 4 and 5 may be published in an annex;

- Core primary financial statements to move to a two column format: "core department & agencies" and "group";

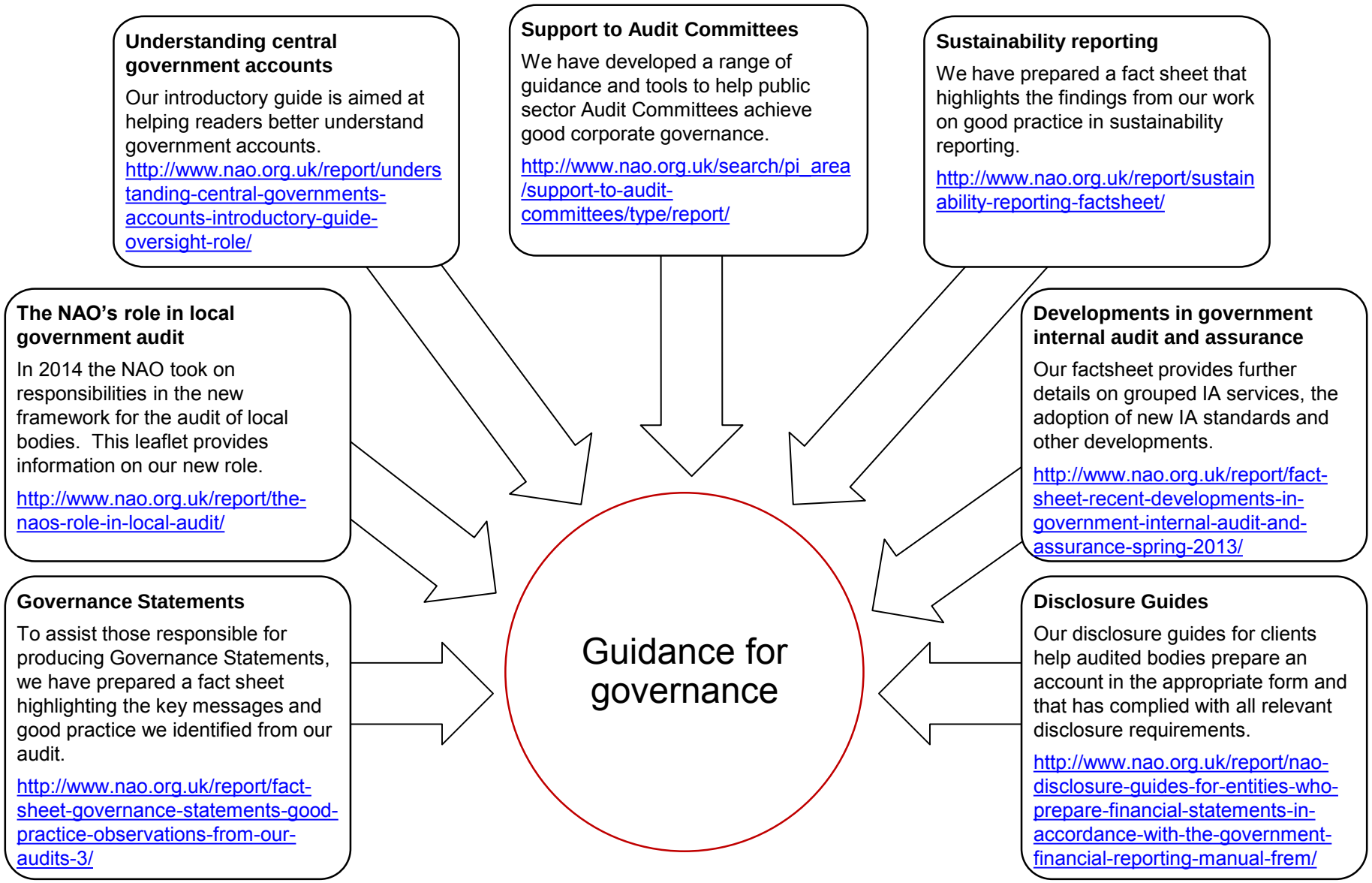
The scope of the external audit has not been reduced and the C&AG will continue to provide the same level of assurance. We will continue to review all other areas of the Annual Report and Accounts and report for consistency with the information obtained during the course of the audit.

Appendix 1 Sector developments

FReM 2015-16 changes: Annual Report and Accounts structure and content



Appendix 1 Sector developments (not all relevant to HFEA)



Appendix 2 - Quality assurance in NAO audits