

Audit and Governance Committee paper

Strategic delivery	Setting standards	<input type="checkbox"/>	Increasing and informing choice	<input type="checkbox"/>	Demonstrating efficiency, economy and value	<input checked="" type="checkbox"/>
Paper title	Strategic Risk					
Agenda item	6					
Paper number	AGC (10/06/2015) 456					
Meeting date	10 June 2015					
Author	Paula Robinson					
For information or decision?	Information and comment					
Recommendation	AGC is asked to note the latest edition of the risk register, and progress with agreeing our approach to risk assurance mapping, set out in the covering paper.					
Resource implications	In budget.					
Implementation	Strategic Risk Register and operational risk monitoring: ongoing. Risk assurance mapping: implementation approach agreed with CMG. Discussions to take place with DH Internal Audit so as to establish a viable programme of work over the next 2-3 years.					
Communication	CMG reviews risk quarterly in advance of each AGC meeting. AGC reviews the strategic risk register at every meeting. The Authority reviews the strategic risk register periodically.					
Organisational risk	Captured in document.					
Annexes	A: Strategic Risk Register					

1. Strategic Risk Register

1.1. CMG review – May 2015

- 1.2. CMG reviewed the new Strategic Risk Register (SRR) on 20 May. Five of the twelve risks are currently above tolerance, and CMG discussed those risks, and their controls, in particular. Risk scores were also reviewed throughout. CMG's specific comments are contained in the attached SRR at Annex A, which also includes an overview of CMG's general discussions about the risk register.

2. Operational risk and risk assurance mapping

- 2.1. It is important that the existing operational risk system is revitalised, and that the system works hand in hand with the planned approach to risk assurance, as we develop it.

- 2.2. Following initial CMG consideration in February, the operational risk template used by teams was relaunched, with a view to reinvigorating teams' uptake of this process, and to using the same headings we will ultimately use in risk assurance mapping. This will serve the dual purpose of familiarising Heads and others with the broad headings, and of making our operational risk identification process more consistent between different teams. The revised template was relaunched to teams at the end of March, and the Head of Business Planning will now commence a period of working directly with other Heads and their teams to ensure that the new template is being adopted.

- 2.3. For the time being, we have agreed to use the following risk assurance areas:

- Planning
- Performance and risk management
- Quality management
- Financial management, systems and controls
- Information and evidence management
- People management
- Accountability
- Oversight and scrutiny

- 2.4. We consider that the latter will include our regulatory functions; if not, this could prospectively form an additional area of its own.

- 2.5. At the May CMG Risk meeting, we then considered how we could best adopt a proportionate risk assurance approach, given the lack of capacity to deliver this new function. The following was agreed as an outline methodology:

- Each of the listed risk assurance areas should be considered in turn.
- The relevant group to do this will be the CMG Plus group (CMG plus other team managers).
- In preparation for each of the meetings, we will draw on the following elements to identify the range of risks and controls to assure:
 - The HFEA strategy 2014-2017
 - Strategic Risk Register 2015/16
 - Team operational risk logs (transposed into the new template, to

- o assist read-across)
 - o Business plan activities
 - o Current projects / programmes and their associated risk logs
 - We will also consider key questions to ask ourselves about risk assurance in each area.
 - At each meeting we will then examine each risk, drawn out from the above, looking at the completeness and efficacy of the controls. We will:
 - o Categorise the controls into the 'three lines of defence', where the first line of defence is operational management; the second line of defence would be CMG/AGC/Authority, the third line of defence would be internal audit, and the final (least-preferred) option would be external audit or another external agency.
 - o Know how we can be sure each control is effective (ie, not just 'is it in place', but how is it monitored, and how often) – so that we can provide convincing assurance to AGC and the Authority, and to ourselves.
 - o Identify improvements needed in our controls, including gaps.
 - o Rate our controls for each risk area as 'inadequate', 'requires improvement', 'good', or 'outstanding' (against defined criteria for each area).
- 2.6. CMG agreed this outline approach, and concluded that in order to do this exercise successfully with our limited resources, it will be critical to adjust the way in which we use our DH internal audit capacity. It will also be important to define the parameters and rate of progress very carefully, to ensure that staff are able to participate fully and that the exercise is both worthwhile and proportionate.
- 2.7. The next step will be to work closely with DH internal audit to incorporate risk assurance workshops into our existing internal audit programme, so that the relevant arrangements can be put in place. The aim should be to focus on the most relevant areas first, and to draw up a timetable for delivery that fully addresses all the areas listed over (say) the next two to three years.
- 3. Recommendation**
- 3.1. The Audit and Governance Committee is asked to note the above update on recent CMG discussions about strategic risk and risk assurance.
- 3.2. Comments are invited on the latest edition of the risk register, and on the other matters set out in this paper.

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	⊙ ⇄ ⇄ ↓

* This column tracks the four most recent reviews by AGC, CMG, or the Authority (e.g. ↑⇄↓⇄).

Recent review points:

CMG November 2014 (start - ⊙) ⇒ CMG February 2015 ⇒ AGC and Authority March 2015 ⇒ **CMG 20 May 2015 (latest review)**

¹ Strategic objectives 2014-2017:

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

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

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

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

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

CMG overview**20 May CMG risk meeting:**

- CMG updated the controls and the scores throughout.
- Since March AGC approved our revised definition of inherent risk, CMG also reviewed the current inherent risk scores, but the review did not result in any changes.
- CMG noted AGC's discussion in March about the capability risk (C1) and its interaction with capacity (in the context of turnover and induction/probation periods for new staff members). CMG agreed that although the current period of high turnover seems to be coming to an end, this risk could recur, and should therefore be retained.
- AGC specifically requested that the tolerance level for this risk (set low, at 6) should be reviewed by CMG. The reduction in overall staffing numbers over the past few years has left us with little resilience, particularly in specialist and small functions, and so turnover could affect capability more in some instances, with possible impacts on strategic delivery. Therefore, CMG agreed that our tolerance for the capability risk needed to remain low, even though the risk level was now reducing. The tolerance level is therefore unchanged, and the risk is still currently above tolerance (although the residual risk has been reduced slightly), since the reduction in turnover is only just becoming apparent.
- CMG also agreed that there should be an SMT discussion in the near future about how best to instil and maintain good records management practices and learning in the organisation, given that this was not currently explicitly part of anyone's role. Having TRIM training and general guidance and induction in records management, was currently listed as a control under several risks. This was different from the technical issues relating to possibly replacing TRIM, or to previous discussions about implementing the retention schedule.

Criteria for Inclusion of Risks:

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

Rank:

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

Risk Trend:

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

Risk Scoring System:

See last page.

Assessing Inherent Risk:

Inherent risk is usually defined as ‘the exposure arising from a specific risk before any action has been taken to manage it’. This can be taken to mean ‘if no controls at all are in place’. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes does introduce some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, in order for our estimation of inherent risk to be meaningful, CMG 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.’ (Agreed at March 2015 AGC.)

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 for the time being, following recent recruitment and new staffing model.		
		Audit of Epicentre to reveal any data errors.	Due for completion June 2015 – Sam Hartley				
		Inspector training, competency-based recruitment, induction process, SOPs, QMS, and quality assurance all robust.	In place – Debra Bloor				
Monitoring failure.		Outstanding recommendations from inspection reports are tracked and followed up by the team.	In place – Debra Bloor				
Unresponsiveness to or mishandling of non-compliances or grade A incidents.		Update planned to compliance and enforcement policy. Authority workshop took place in March 2015. More work to follow, including input from Committee Chairs and revised policy to September Authority alongside a set of other related Compliance team updates.	Partly complete – revision will go to 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..	Done – Debra Bloor – May 2015				
Insufficient inspectors or licensing staff		Recruitment completed for clinical and scientific inspectors.	In place – Debra Bloor				
		Recruitment completed for licensing team member.	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 have yielded sufficient candidates, although this has required going beyond the initial ALB pool to external recruitment in some cases.	Managed as the situation evolves – Debra Bloor
	NHS Jobs account changed 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.	Done – May 2015 – Rachel Hopkins
	Additional temporary resources available during periods of vacancy and transition.	In place – Rachel Hopkins
	Group induction sessions put in place where possible.	In place – Debra Bloor
Resource strain itself can lead to increased turnover, exacerbating the resource strain.	Operational performance, risk and resourcing oversight through CMG, with deprioritisation of work an option.	In place – Paula Robinson
Unexpected fluctuations in workload (arising from 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).	New staffing model developed, to release an extra inspector post out of existing establishment. This has increased general resilience so as to enable more flex when there is an especially high inspection/report writing/application processing workload.	Done – Debra Bloor – May 2015
	PGD workshop annually with the sector to increase their insight into our PGD application handling processes and decision-making steps; coupled with our increased processing times from efficiency improvements since 2013 (acknowledged by the sector).	In place and annual – Debra Bloor
Some unanticipated event occurs that has a big diversionary impact on key resources, eg, several major Grade A incidents occur at once.	Addressed by new staffing model.	Done – Debra Bloor – May 2015
	Compliance and enforcement policy review (see above) will improve handling processes for incidents and non-compliance.	Partly complete – revision will go to 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.	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 T&S licences delegated to ELP and now in place. Licensing Officer due to become live.	Delegation to be returned to in 2016 review of SOs. Licensing Officer role to take decisions from ELP due end June 2015.				
Failing to demonstrate competence as a regulator		Review of compliance and enforcement policy (in progress).	Partly complete – revision will go to 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 to build resilience in inspection team for such events – dealing with high-impact cases, additional incident inspections, etc.	Done – Debra Bloor – May 2015
	SOPs and protocols with Communications team.	In place – Debra Bloor
	Fairness and transparency in licensing committee information.	In place – Debra Bloor
	Dedicated section on website, so that the public can openly see our activities in the broader context.	In place – Debra Bloor
Administrative or information security failure, eg, document management, risk and incident management, data security.	Staff have annual information security training (and on induction).	In place – Dave Moysen (next round is due in Q1 of 2015/16)
	TRIM training and guidance/induction in records management in place.	Internal ownership of this function will be decided by SMT in the near future – end June 2015
	The IfQ website management project will be reviewing the retention schedule.	By December 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	Syncs in with IT strategy work – 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.
	Review of compliance and enforcement policy (in progress).	Partly complete – revision will go to 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 is in development. Decisions are being made about the degree of reliability required in each data field. For those fields where 100% reliability is needed, inaccurate or missing data will be addressed as part of delivery.	All aspects – detailed project planning in progress – Nick Jones (IfQ business case submitted Dec 2014; decision was delayed to April 2015 but then received)		Above tolerance. Managing these risks forms an intrinsic and essential part of the detailed project planning and tendering. Tendering is currently near completion.		
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.	In place and ongoing – Dec 2014 onwards – Nick Jones		Following a lengthy delay, we received formal approval for both the data and digital elements of IfQ in late April 2015.		
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		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 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).		
Cost of delivering better information becomes too prohibitive.		Costs taken into account as an important factor in consideration of contract tenders.	In place – Dec 2014 - May 2015 – Nick Jones				
Redeveloped website does not meet the needs and expectations of our various user types.		Programme approach and dedicated resources in place to manage the complexities of specifying web needs, clarifying design requirements and costs, managing changeable Government delegation and permissions structures, etc. User research done to properly understand needs. Tendering and selection process includes 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 submitted.	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 – Jan/Feb 2015 (depending on approval) – Juliet Tizzard	
Communications infrastructure incapable of supporting the planned changes.	Needs to be updated as part of IfQ in order to support the changes.	In place – set out in business case – Juliet Tizzard (Dec 2014)	

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 much later).	In place – Nick Jones/Dave Moysen				
Increased reporting needs mean we later discover a problem, or that an unanticipated level of accuracy is required, with data or fields which we do not currently focus on or deem critical for accuracy.		IfQ planning work incorporates consideration of fields and reporting needs are agreed. Decisions about the required data quality for each field were ‘future proofed’ as much as possible through engagement with stakeholders to anticipate future needs and build these into the design.	In place – Nick Jones				
Reliability of existing infrastructure systems – (eg, Register, EDI, network, backups).		Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery.	In place – Dave Moysen				
System interdependencies change / are not recognised		Strong interdependency mapping being done between IfQ and business as usual.	Done – Nick Jones – April 2015				

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
IfQ IfQ 3: Delivery of promised efficiencies	There is a risk that the HFEA's promises of efficiency improvements in Register data collection and submission are not ultimately delivered.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			☉ ↔ ↔ ↔	Nick Jones
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	3	9 Medium					
Tolerance threshold:			9 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations			Effectiveness – commentary	
Poor user acceptance of changes, or expectations not managed.		Stakeholder involvement strategy in place and user testing being incorporated into implementation phase of projects	In place – Nick Jones/Juliet Tizzard			At tolerance.	
Clinics not consulted/involved enough		Working with stakeholders has been central to the development of IfQ, and will continue to be. Advisory Group and expert groups coming to an end, but a new stakeholder group for implementation phase is planned.	In place – Nick Jones/Juliet Tizzard				
Scoping and specification are insufficient for realistic resourcing and on-time delivery of changes.		Scoping and specification were elaborated with stakeholder input, so as to inform the tender. Resourcing and timely delivery are a critical part of the decision in awarding the contract.	In place and contract awards in progress – Nick Jones – May 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 will only be awarded to bidders who make an affordable proposal.	In progress – Nick Jones – May 2015				

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Legal challenge LC 1: Resource diversion	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			☉ ↓ ↔ ↔	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	5	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	5	15 High					
Tolerance threshold:			12 High				
Causes/sources		Mitigations	Timescale and ownership of mitigations			Effectiveness – commentary	
Complex and controversial area.		Panel of legal advisors from various firms at our disposal for advice, as well as in-house Head of Legal.	In place – Peter Thompson			Above tolerance. Two cases are awaiting judgments as at the end of May 2015. We expect a resolution on both shortly.	
		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				
		More work planned on enhancing committee tools to incorporate recent lessons learned.	In progress as at May 2015 – Catherine Drennan / Sam Hartley				

<p>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.</p>	<p>Scenario planning is undertaken at the initiation of likely action.</p>	<p>In place – Peter Thompson</p>	
<p>HFEA could face unexpected high legal costs or damages which it could not fund.</p>	<p>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.</p>	<p>In place – Peter Thompson</p>	
<p>Legal proceedings can be lengthy and resource draining.</p>	<p>Panel in place, as above, enabling us to outsource some elements of the work.</p>	<p>In place – Peter Thompson</p>	
	<p>Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise work should this become necessary.</p>	<p>In place – Peter Thompson</p>	
<p>Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.</p>	<p>Licensing SOPs, committee decision trees in place.</p>	<p>In place – Sam Hartley.</p>	
	<p>Work planned to explore other relevant processes in light of lessons learned following a recent judicial review judgment.</p>	<p>In progress as at May 2015 – Catherine Drennan / Sam Hartley</p>	

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					
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. 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.	Done – 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 (Jan 2015) – Sue Gallone				

Register data becomes corrupted or lost somehow.	Back-ups and warehouse in place to ensure data cannot be lost.	In place – Nick Jones/Dave Moysen	
Other HFEA data (system or paper) is lost or corrupted.	As above. Staff have annual compulsory security training to guard against accidental loss of data or breaches of confidentiality.	In place – Dave Moysen	

Risk area	Description and impact	Strategic objective linkage	Risk scores	Recent trend	Risk owner		
Data D 2: Incorrect data released	There is a risk that incorrect data is released in response to a Parliamentary question (PQ), or a Freedom of Information (FOI) or data protection request.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			☉ ↔ ↔ ↔	Juliet Tizzard
			Likelihood	Impact	Inherent risk		
			5	4	20 Very high		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	4	12 High					
Tolerance threshold:			8 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations	Effectiveness – commentary			
Poor record keeping		Refresher training and reminders about good records management practice.	Ownership of this function will be decided by SMT in the near future – end June 2015	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 information	In progress – for completion June 2015 – Sam Hartley				
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors		PQs, FOIs and OTRs have dedicated expert staff/teams to deal with them. If more time is needed for a complex PQ, attempts are made to take the issue out of the very tightly timed PQ process and replace this with a more detailed and considered letter back to the enquirer so as to provide the necessary level of detail and accuracy in the answer. We also refer back to previous answers so as to give a check, and to ensure consistent presentation of similar data.	In place – Juliet Tizzard / Nick Jones				
		PQ SOP revised and log created, to be maintained by new Committee and Information Officer/Scientific Policy Manager	In place - Sam Hartley				

<p>Answers in Hansard may not always reflect advice from HFEA.</p>	<p>The PQ team attempts to catch any changes to drafted wording that may unwittingly have changed the meaning. This, and ongoing issues with the very high volume being received at present, will be raised with DH when the framework agreement is next reviewed. HFEA's suggested answer and DH's final submission both to be captured in new PQ log.</p>	<p>In place – Sam Hartley / Peter Thompson Date of next review to be confirmed shortly – Peter Thompson</p>	
<p>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.</p>	<p>As above – expert staff with the appropriate knowledge and understanding in place.</p>	<p>In place – Juliet Tizzard / Nick Jones</p>	

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 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					
Causes/ sources		Mitigations	Timescale and ownership of mitigations			Effectiveness – commentary	
Lack of counselling availability for applicants.		Counselling service pilot being established with external contractor.	Set-up in progress – Nick Jones – Jun 2015			At tolerance. The pilot counselling service will be in place from June onwards, and we will make a further assessment shortly based on early uptake and the delivery experience.	
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 being reviewed by Register staff, CMG and PAC-UK, as part of the pilot set-up. Contract signed with PAC-UK for pilot delivery.	Done (May 2015) – In June the management of the Pilot will transfer 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 29-10-14; 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 in place – Sue Gallone				
		Annual budget agreed with DH Finance team alongside draft business plan submission.	December annually – Sue Gallone				
		Budget confirmation for 2015/16 obtained. Capital allocation is outstanding as at 27 May 2015.	In place – Sue Gallone Being actively sought from DH – 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 budget / 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. Cash flow forecast updated.	Ongoing – Wilhelmina Crown					
		Monthly (on-going) – Morounke Akingbola					

Risk area	Description and impact	Strategic objective linkage	Risk scores			Recent trend	Risk owner
Capability C 1: Knowledge and capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	Efficiency, economy and value: ensuring the HFEA remains demonstrably good value for the public, the sector and Government.	Inherent risk level:			☉ ↔ ↔ ↓	Peter Thompson
			Likelihood	Impact	Inherent risk		
			4	4	16 High		
			Residual risk level:				
			Likelihood	Impact	Residual risk		
3	3	9 Medium					
Tolerance threshold:			6 Medium				
Causes/ sources		Mitigations	Timescale and ownership of mitigations			Effectiveness – commentary	
High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps.		People strategy will partially mitigate. Mixed approach of retention, staff development, and effective management of vacancies and recruitment processes.	Done – May 2015 – Rachel Hopkins			Above tolerance. This risk and its controls currently focus on capability, rather than capacity. There are obviously linkages, since managing turnover and churn also means managing fluctuations in capability and ensuring knowledge and skills are successfully nurtured and/or handed over. Now that the period of highest turnover appears to be ending, CMG has reduced the likelihood of this risk, but still decided to retain it, since high turnover could recur.	
		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			CMG also reviewed the tolerance level for this risk, and agreed it 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 set a low tolerance threshold for this risk.	

Poor morale leading to decreased effectiveness and performance failures.	Engagement with the issue by managers. Ensuring managers have team meetings and one-to-one meetings to obtain feedback and identify actions to be taken.	In place – Peter Thompson
	Staff survey and implementation of outcomes, following up on Oct 2014 all staff conference.	Survey done (Jan 2015) – Rachel Hopkins Follow-up communications and implementation in 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
	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

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

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

RISK MANAGEMENT SCORING MATRIX						
IMPACT	5. Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
Risk Score = Impact x Likelihood	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)	
	LIKELIHOOD					

HFEA Internal Audit Plan 2015/16

This plan was finalised at the HFEA Audit and Governance Committee on 18th March 2015. It comprises an assessment of current risks, the audit plan itself, and a summary of review areas covered across the last three years.

Assessment of current risks:

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

Risk Area	Description and impact	Residual risk level	Status	Causes/sources
Legal Challenge	There is a risk that the HFEA is legally challenged in such a way that resources are diverted from strategic delivery.	15 (High)	Above tolerance	<ul style="list-style-type: none"> • Complex and controversial area; • Lack of clarity in Act and Regulations, leading to the possibility of there being differing legal opinions from different legal advisers, that then have to be decided by a court; • Decisions and actions of the HFEA and its Committees may be contested; • Subjectivity of judgments means the HFEA often cannot know in advance which way a ruling will go, and the extent to which costs and other resource demands may result from a case; • HFEA could face unexpected high legal costs or damages which it could not fund; • Legal proceedings can be lengthy and resource draining; and • Adverse judgments requiring us to alter or intensify our processes, sometimes more than once.
Information for Quality	If the information for Quality (IfQ) Programme does not enable us to provide better information and data, and improved engagement channels, patients will not be able to access the improved information they need to assist them in making important choices.	12 (High)	Above tolerance	<ul style="list-style-type: none"> • Inability to extract reliable data from the Register; • Unable to work out how best to improve CAFC, and/or failure to find out what data/information patients really need; • Stakeholders not on board with the changes; • Cost of delivering better information becomes too prohibitive; • Website redevelopment project fails to deliver or new website is inadequately designed; • Government and DH permissions structures are complex, multi-stranded, and sometimes change mid-project; • Resource conflicts between delivery of website and Business as Usual;

Risk Area	Description and impact	Residual risk level	Status	Causes/sources
				<ul style="list-style-type: none"> • New CMS (content management software) is ineffective or unreliable; • Communications infrastructure incapable of supporting the planned changes; and • Contractor failure – delivery is highly contractor dependent.
Data	There is a risk that incorrect data is released in response to a Parliamentary Question (PQ), or a Freedom of Information (FOI) or Data Protection request.	12 (High)	Above tolerance	<ul style="list-style-type: none"> • Poor record keeping; • Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors; • DH altering careful drafting prior to submission, without always checking the response back with us; and • Insufficient understanding of underlying system abilities and limitations, and/or of the topic or question, leading to data being misinterpreted or wrong data being elicited.
Income and Expenditure	There is a risk that the HFEA could significantly overspend (where significantly = 5% of budget, £250k).	12 (High)	Above tolerance	<ul style="list-style-type: none"> • Fee regime makes us dependent on sector activity levels; • GIA funding could be reduced due to changes in Government/policy • Budget setting process is poor due to lack of information from directorates; • Unforeseen increase in costs e.g. legal, or extra in-year work required; and • Upwards scope creep during projects, or emerging during early development of projects e.g. IfQ.
Capability	There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy.	12 (High)	Above tolerance	<ul style="list-style-type: none"> • High turnover, sick leave etc. leading to temporary knowledge loss and capability gaps; • Poor morale leading to decreased effectiveness and performance failures; • Differential impacts of IfQ-related change and other pressures for particular teams could lead to specific areas of knowledge loss and low performance; and • Additional avenues of work open up, or reactive diversions arise, and need to be accommodated alongside the major IfQ programme.

Internal Audit Plan 2015/16:

Based on the assessment of current risks above and discussions with HFEA senior management and the Audit Committee Chair, the table below sets out the reviews included in the final 2015/16 internal audit plan.

Suggested review	Rationale for inclusion	Scope	Estimated Audit days	Review date
Requests for Information	Links to the Data risk area	<p>The HFEA may be required to release information as a result of:</p> <ul style="list-style-type: none"> • Parliamentary Questions (PQs); • Freedom of Information (FOI) requests; and • Data Protection (DP) requests. <p>We will examine current policies and procedures for the release of information under these circumstances and consider whether:</p> <ul style="list-style-type: none"> • Current policies and procedures cover all relevant information held by the HFEA to which PQs, FOI and DP requests might relate; • Authorisation for the release of information is restricted to the appropriate committees and/or individuals; and • Risks in relation to the release of sensitive information have been identified, are regularly monitored, and are aligned to mitigating controls. 	10	Mid August 2015
Incident Handling	Key regulatory activity	<p>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.</p> <p>These incidents must be notified to the HFEA within 24 hours of their taking place. Once these reports are received, the HFEA must investigate and respond in line with its Compliance and Enforcement Policy.</p> <p>In addition, the HFEA has a responsibility to review and respond to complaints made against clinics. Circa 10 complaints are received each year.</p> <p>We will review current policies and procedures relating to incident and</p>	12	September 2015

Agenda item 7(a): AGC (10/06/2015) 457 – DH internal audit

Suggested review	Rationale for inclusion	Scope	Estimated Audit days	Review date
		<p>complaints reporting and responses and consider whether:</p> <ul style="list-style-type: none"> • The HFEA’s responses to reported incidents and complaints in the 12 months to the date of fieldwork have been conducted in line with agreed procedures; • The HFEA produces and retains sufficient documentation to support its response to incident and complaint reports; • Clear and sufficient information is available to all licensed centres to encourage the timely and appropriate reporting of adverse incidents and complaints; and • HFEA has appropriate performance reporting of all incidents and complaints in order to make appropriate management decisions on their relationships with the clinics. 		
Data Migration – Register of Treatments	Links to the IfQ risk area	<p>Building on the 2014/15 ‘Register of Treatments’ review, we will:</p> <ul style="list-style-type: none"> • Provide ‘critical friend’ input into the work performed by the HFEA to migrate data to the new Register of Treatments database; • Test a sample of data between the old and new Registers to verify the accuracy and completeness of data. 	12	January 2016
Audit management		<p>All aspects of audit management to include:</p> <ul style="list-style-type: none"> • Attendance at liaison meetings and HFEA audit committees; • Drafting committee papers/progress reports; • Follow-up work; • Drafting 2016/17 audit plan; • Resourcing and risk management; and • Contingency. 	6	-
Total			40	

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

ANNUAL ASSURANCE REPORT 2014/2015

*Human Fertilisation
and Embryology
Authority*



Background

In order to be able to provide an annual opinion for 2014/15 to the Human Fertilisation and Embryology Authority's Accounting Officer, it is necessary to consider the work undertaken by Internal Audit over the course of that year, the outcomes of that work and feedback from management on improvements to their areas of responsibility as a result of that work. This together with wider intelligence gathered from all sources of assurance (including the NAO and the Major Projects Authority) and performance reporting, inform the Head of Internal Audit's view of controls, governance and risk management. This report provides an overall summary of Internal Audit work delivered in 2014/15 as well as including the formal annual opinion of the Head of Internal Audit.

Executive Summary

Over the last few years, the Human Fertilisation and Embryology Authority has developed its regulatory model and its status within the NHS and beyond. To achieve its objectives, both executive and non-executive management have undertaken significant work to ensure that the organisation's governance structures including internal control and risk management arrangements are fit for purpose. Internal Audit has continuously provided assurance and advice where appropriate to support management's efforts.

Our opinion is based solely on our assessment of whether the controls in place support the achievement of management's objectives as set out in our 2014/15 Internal Audit Plan and Individual Assignment Reports.

We used the following levels of rating (in line with the agreed definitions across all government departments) when providing our internal audit report opinions:

Rating	Definition
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.

2014/15 Performance Summary

Reviews carried over from 2013/14 plan	0
2014/2015 Agreed programme	4
Total reviews deferred to complete in 2015/16	1
Total reviews dropped in 2014/15	0
Total to deliver 2014/15 plus 2013/14 Carried over	4
Total reviews completed including carry over from 2013/14	3
Total remaining on plan to carry forward to complete in 2015/16	1
% of programme completed	75%
% of programme to carry forward to complete in 2015/16	25%

Total Number of Audits completed by rating (excludes follow up of recs)

Total no reviews completed (incl. agreed draft ratings) 2014/15	Substantial	Moderate	Limited	Unsatisfactory	Advisory	Total Rated Work	Advisory Work
3	0	1	1	0	1	2	1
						66%	34%

Internal Audit Plan Delivery 2014/15 - Assurance and Advisory Work Summary

#	Audit Title	Status	Outcome	Recommendations agreed by priority		
				High	Medium	Low
1	Information for Quality (IfQ)	Complete	Moderate	1	6	1
2	Internal Policies	Complete	Limited	2	0	0
3	Standing Financial Instructions	Complete	No rating – advisory review	N/A		
4	Register of Treatments	Partially complete	In process – Agreed with management to continue ‘critical friend’ input into 2015/16	N/A		
			Total	3	6	1

Compliance with Public Sector Internal Audit Standards and Quality Assurance

The audit work delivered during 2014/15 has been governed by the requirements of the UK Public Sector Internal Audit Standards. HGIAS have conducted a self-assessment against the requirements which indicates that the Internal Audit arrangements continue to comply with the standards and are generally satisfactory. We also continue to operate a system of cold reviewing audit documentation to ensure compliance for individual audit reports.

Head of Internal Audit Opinion 2014/15

“In accordance with the requirements of the UK Public Sector Internal Audit Standards, I am required to provide the Accounting Officer with my annual opinion of the overall adequacy and effectiveness of the organisation’s risk management, control and governance processes.

My opinion is based on the outcomes of the work that Internal Audit has conducted throughout the course of the reporting year and on the follow up action from audits conducted in the previous reporting year. There have been no undue limitations on the scope of Internal Audit work and the appropriate level of resource has been in place to enable the function to satisfactorily complete the work planned.

For the three areas on which I must report, I have concluded the following:

- In the case of **risk management**: Substantial
- In the case of **governance**: Moderate
- In the case of **control**: Moderate

Therefore, in summary, my overall opinion is that I can give **MODERATE assurance** to the Accounting Officer that the Human Fertilisation and Embryology Authority has had adequate

and effective systems of control, governance and risk management in place for the reporting year 2014/15.

Lynn Yallop

Head of Internal Audit

Human Fertilisation and Embryology Authority

Audit completion report on the 2014-15 financial statement audit

REPORT TO THOSE CHARGED WITH GOVERNANCE
June 2015

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

Contents

Introduction: status of our audit	3	Follow up to key recommendations we made in the previous year	11
Key audit findings:			
Significant financial statement risks	5	Other matters for communication	14
Key audit findings - audit recommendations	7	Appendix 1 – Proposed letter of representation	15
Key audit findings: other key findings	9	Appendix 2: Draft audit certificate	17
Key audit findings: list of identified unadjusted misstatements	10		

We have prepared this report for HFEA's sole use (although you may also share it with the Department of Health). You must not disclose it to any other third party, quote or refer to it, without our written consent and we assume no responsibility to any other person.

Introduction: status of our audit

Introduction

This report summarises the key matters from our audit of the 2014-15 HFEA financial statements which we must report to those charged with governance before we finalise our audit work and certify the accounts.

What work have we completed?

We have completed our audit of the 2014-15 financial statements in accordance with International Auditing Standards (UK and Ireland) issued by the Financial Reporting Council and with the audit planning report presented to the Audit Committee in October 2014.

We have also read the content of the draft annual report and the governance statement to confirm:

- their consistency with the financial statements and our understanding of the business;
- that the audited part of the remuneration report has been properly prepared; and
- that the governance statement has been prepared in accordance with HM Treasury guidance.

The total audit fee charged for the year is £27,500.

Actions for the Audit and Risk Committee

The Audit and Risk Committee should:

- Review the findings set out in this report, including the draft letters of representation and audit certificates at Appendix 1 and 2 respectively; and
- Consider whether the unadjusted misstatements, set out in the identified misstatements section (page 11) should be corrected. The Audit Committee minutes should provide written endorsement of management's reasons for not adjusting misstatements.

Introduction: status of our audit

What is the status of our audit?

At the time of writing this report, the audit is substantially complete. The following issues are outstanding:

- Review of the final Annual Report and Accounts;
- Director's final review of the audit work;
- Review of Events After the Balance Sheet Date; and
- Review of the final Consolidation Schedule

Substantially complete

The Accounting Officer will sign the annual report and accounts together with a letter of representation which is attached at Appendix 1.

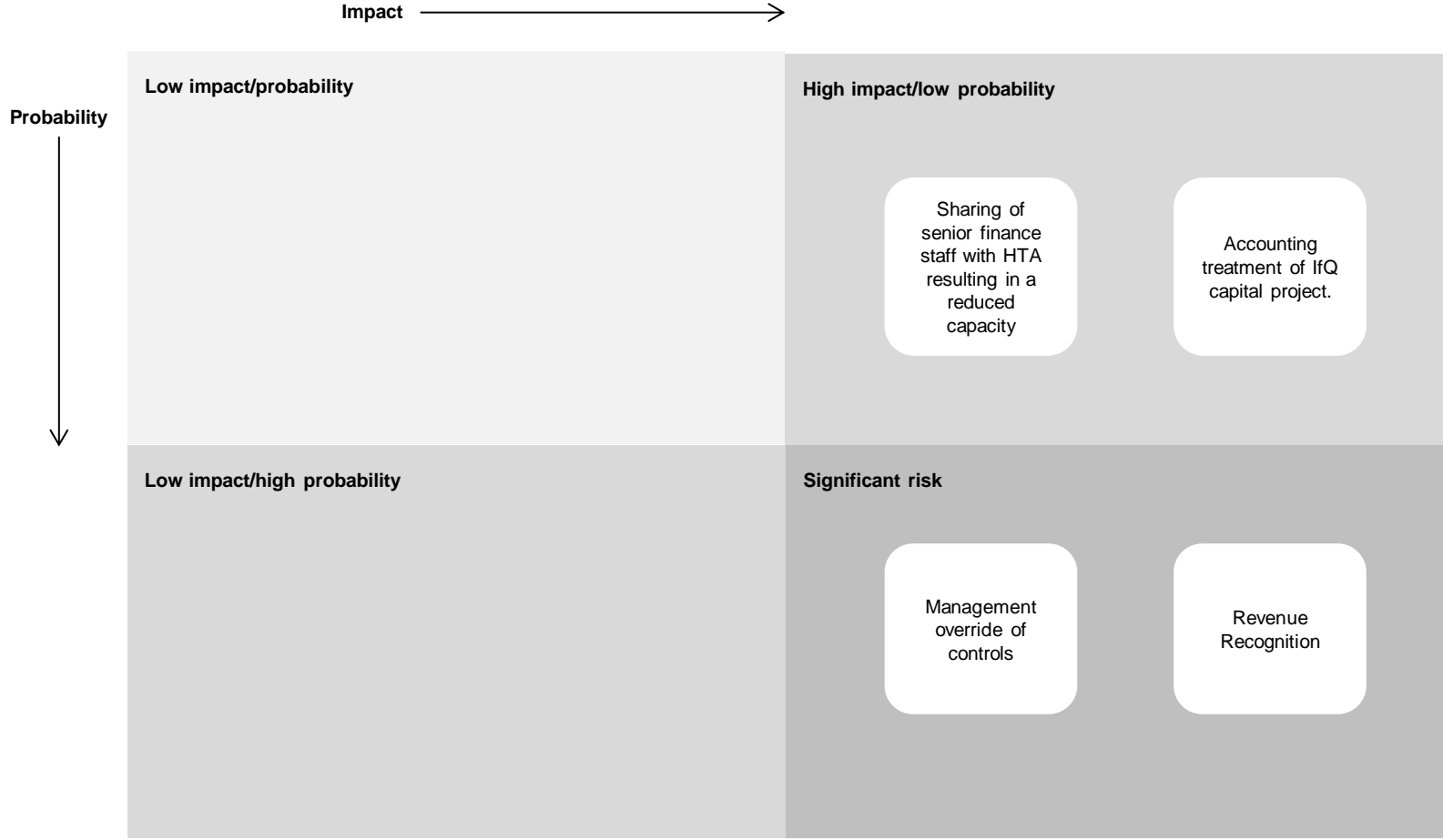
What is our conclusion?

We anticipate recommending to the Comptroller and Auditor General (C&AG) that he should certify the 2014-15 financial statements with an unqualified audit opinion, without modification.

The draft audit certificate is presented in Appendix 2 – Draft audit certificate.

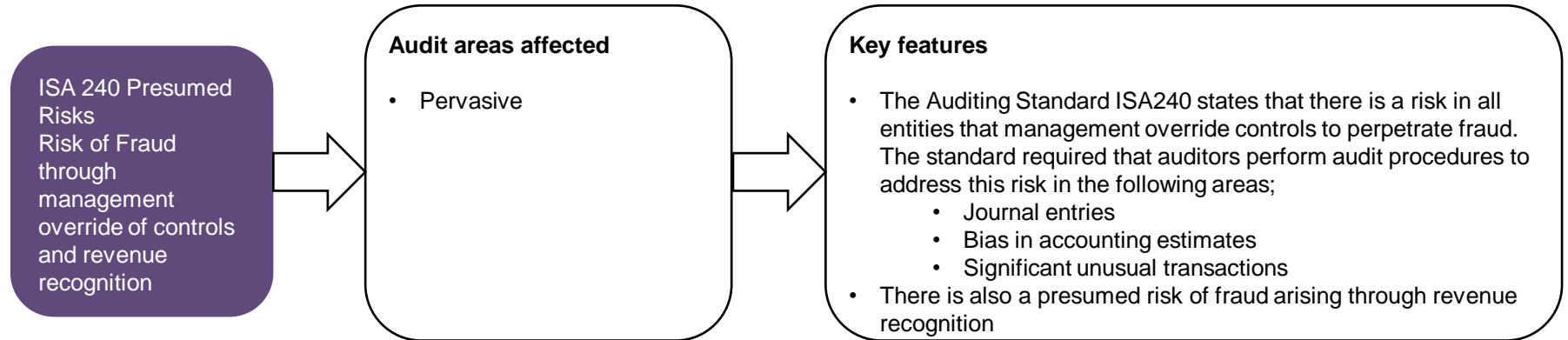
Key audit findings: Significant financial statement risks

We identified the risks below in our audit planning report presented to your Audit and Risk Committee on 1st October 2014. No additional risks have been determined in the course of our audit. Responses and findings against significant risks can be seen in the Key audit findings section of this report.



Key audit findings

Significant financial statement risks



Audit Response

Controls & substantive work over

- Journal entries;
- Accounting estimates; and
- Significant unusual transactions
- Income

Findings

Observations and recommendations

- Controls were assessed to be robust and fully operational: no issues in relation to the above were identified through our audit work. Through our testing we are able to take assurance that there is no material misstatement due to management override of controls.
- We have carried out specific testing to address the risk of fraud through revenue recognition by reviewing the HFEA's audit compliance control and gaining assurance over accuracy and completeness of this revenue. We formed a prediction for licence fee revenue based on information derived from the CRM licence system and confirmed that the revenue recognised in the accounts was in line with this prediction.
- The audit procedures that we performed provided sufficient assurance that there is no material misstatement in the accounts in respect of income recognition.

The risks were addressed and sufficient assurance was obtained

Key audit findings - audit recommendations

Each issue has been given a priority rating to assist in assessing the level of potential risk associated with the finding. The levels are:

1

Major issues for the attention of senior management which may have the potential to result in a material weakness in internal control and/or impact on the ability of the CA&G to certify the accounts.

2

Important issues to be addressed by management in their areas of responsibility.

3

Problems of a more minor nature which provide scope for improvement.

Non-current assets

Review of the expected useful lives of assets

Review of HFEA's Fixed Asset Register demonstrates that assets are often in use for longer than their estimated useful lives. This suggests lack of an appropriate assets replacement policy. In addition assets held beyond their useful lives may not be fit for purpose or may be costly to maintain.

In addition there is a risk that asset valuation in the accounts could be misstated if the volume of nil net book value assets is high. Many of the assets on the Fixed Asset Register have been in use for twice as long as their useful lives. Depreciating these assets over a longer period would have a significant impact on the net book value of the non-current assets and the depreciation charge in year.

We are satisfied that at 31 March 2015 the impact of the nil net book value assets is not material to the accounts. There are however a significant number of assets that are likely to be used beyond this date which suggests the estimated useful lives currently used may not reflect the actual asset management policy and need revising.

2

We recommend 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. This will provide management with clear visibility of when assets need to be replaced and allow them to budget for it accordingly.

We recommend 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.

Agreed.
We are to conduct a detailed review of Useful Economic Lives (UEL) of all our fixed assets in conjunction with our IT team. This will commence in Q2 of 2015-16 business year.

Key audit findings - audit recommendations (continued)

Area	Issue	Priority	Recommendation	Management Response
<p>Management Accounts Insufficient documentation of challenge and review</p>	<p>As part of the planned audit procedures we have evaluated the effectiveness of the high level controls. In doing so we have assessed the robustness of the budget setting process, the quality of the Monthly Management Accounts as well as the review and challenge process.</p> <p>We have found that although the budget setting process is robust and a review of variances and challenge are in place there was no formal documentation of challenge to the variances and directors' responses were not sufficient to enable us to place reliance.</p> <p>By improving the trail of management's review and challenge of the financial performance, HFEA would encourage greater transparency and robustness of the process. It would also give management better visibility of previous decisions and any emerging issues.</p> <p>Robust documentation of management's challenge would also increase the scope for reliance on the high level controls in performing our audit which in turn could lead to efficiencies.</p>	<p>3</p>	<p>HFEA Finance should maintain sufficient documentation to evidence the review and challenge of the Monthly Management Accounts by the Senior Management.</p>	<p>Agreed. We have email exchanges monthly about the management accounts and email summaries of the quarterly meetings, outlining issues by exception. Headlines are discussed at ST and with the Authority. We believe this is proportionate and efficient for our organisation. Advice on the documentation required for NAO's potential reliance on these controls would be welcome.</p>

Key audit findings: other key findings

Identified misstatements

Misstatements that we have identified above our clearly trivial threshold of £1,500 and have not been adjusted are detailed in the identified misstatements section (page 10) .

Uncorrected misstatements would decrease net assets by £11,721.60.

Financial statement disclosures

We have also made a number of other suggestions to improve narrative disclosures and to ensure completeness of the disclosures required under the FReM and other relevant guidance. The most significant of which are:

- Disclosure of the redundancy package received by the previous Director of Finance and Facilities who left in 2014/15.
 - Show the split between Permanent Staff and Other staff in the staff costs note.
 - Amendment to the Related Party note to show clearly the split between expenditure relating to 13/14 and 14/15; accrued expenditure and invoiced expenditure.
-

Accounting policies and financial reporting

As part of our audit, we consider the quality and acceptability of HFEA's accounting policies and financial reporting:

- The quality of financial reporting was good. The draft accounts presented for audit were of a good quality.
 - We considered the appropriateness of the accounting policies to the particular circumstances of the HFEA, judged against the objectives of relevance, reliability, comparability and understandability. We have no issues to raise on this matter.
 - In addition, the Annual Report was considered to be consistent with our understanding of the business, and was in line with the other information provided in the financial statements.
 - We will provide a verbal update on the audit of HFEA's consolidation schedule to the audit committee.
-

Regularity, propriety and losses

We found no items that raised issues in relation to regularity or propriety. There were no significant losses to report and account for.

Key audit findings: list of identified unadjusted misstatements

Unadjusted misstatements					
Area	Issue	SoCNE		SoFP	
		Dr £	Cr £	Dr £	Cr £
Other expenditure	Prior-period cut-off error which should have been accrued for; does not require adjustment.		11,721.60	11,721.60	

Follow up to key recommendations we made in the previous year

Area	What was the recommendation?	Response/Progress	Status
Provisions and contingent liabilities	<p>We recommend that management review of the Accounts for next year is informed by the lessons learnt from this year so that sufficient time and resource can be built in to aid the Accounts production and review process.</p> <p>The completeness of disclosure of Provisions and Contingent Liabilities should be considered and new cases disclosed where there is the possibility of an outflow of resources as per IAS 37.</p>	<p>Accounts production and review took account of lessons learnt from the 2013/14 audit and there were no misstatements identified in the 2014/15 Provisions & Contingent Liabilities notes. Two contingent liabilities were promptly recognised and have been disclosed in the 2014/15 Contingencies note in the financial statements.</p>	Implemented
Asset Valuations	<p>HFEA should ensure their non-current asset register is reviewed on a periodic basis, given that their review in 2013-14 found assets no longer in use at an original cost of c.£200k.</p> <p>However, in applying FREM 6.2.5 and IAS 16, reporting entities should ensure all tangible non-current assets shall be carried at valuation at the reporting period. This is not currently the case at HFEA, and while it is accepted that the impact may be immaterial on the accounts, HFEA need to ensure that this is considered.</p>	<p>A full review of the Fixed Asset Register was conducted in 2014/15 and a list of assets still in use with a nil net book value were identified. HFEA will need to review the useful economic life of different classes of assets to ensure that assets are not depreciated too quickly.</p> <p>HFEA have identified a significant number of assets on the Fixed Asset Register which are at nil net book value and still in use. We expect an exercise to be carried out in Quarter 2 of the 2015/16 financial year to identify the value of these assets in use.</p>	<p>Keep in view</p> <p>Keep in view</p>

Follow up to key recommendations we made in the previous year

Area	What was the recommendation?	Response/Progress	Status
Intra-Government balances	Finance should review categorisation of suppliers and customers to ensure that this corresponds with the information reported in the DH Consolidation return.	No issues were identified in this year's testing of Intra-government balances.	Implemented.
Cash & cash equivalents	<p>HFEA should ensure that in-year bank reconciliations are performed for every month in 2014/15 and that reconciling items are followed up in subsequent months.</p> <p>Credit card balances should not be netted off from cash balances.</p>	<p>Controls around cash reconciliations in 2014/15 did not identify any weaknesses and the year-end cash reconciliation testing was carried out effectively.</p> <p>Credit card balances were correctly not netted off from cash balances in 2014/15.</p>	Implemented.

Follow up to key recommendations we made in the previous year (continued)

Area	What was the recommendation?	Response/Progress	Status
Accruals	HFEA Finance should ensure accruals are supported by evidence that there is an obligation to pay at the end of the reporting period. Where this information is provided by other teams within the organisation, finance should obtain evidence to assure themselves that they are raising accruals for the correct amounts in the right years.	Finance have reviewed accruals raised by other teams in 2014/15 and no errors were found during our accruals testing.	Implemented
Annual Report	HFEA should consider the drafting of their 2014-15 Annual Report to ensure that the headings of Strategic Report and Directors' Report are included and that these sections of the report are fully compliant with Chapter 4A and 5 of Part 15 of the Companies Act 2006 and Schedule 7 of SI 2008 No 410 as required by the FReM.	HFEA implemented the required changes in the 2013/14 Annual Report and no major disclosure issues were identified in the 2014/15 Annual Report.	Implemented
Remuneration Report	As with the Annual Report, whilst the requirements of the Companies Act 2006 as interpreted by the FReM had broadly been addressed, there were a minor number of disclosures missing or that required amendment. Total employer pension contributions for HFEA as a whole were also inaccurate.	HFEA implemented the required changes in the 2013/14 Remuneration Report. No major disclosure issues were identified in the 2014/15 Remuneration Report.	Implemented

Other matters for communication

Independence

We consider that we comply with Auditing Practices Board (APB) ethical standards and that, in our professional judgment, we are independent and our objectivity is not compromised. There are no relationships between us and HFEA that we consider to bear on our objectivity and independence.

International standards on Auditing (UK and Ireland)

We consider that there are no additional matters in respect of items requiring communication to you, per International Standards on Auditing, that have not been raised elsewhere in this report or our audit planning report.

Items requiring communication cover:

- Fraud
- Going concern
- HFEA's compliance with laws and regulations
- Significant difficulties completing the audit
- Disagreements or other significant matters discussed with management

Cooperation with other auditors

Internal Audit

We reviewed the internal audit plan to gain an understanding of the work they performed during the year. This informed our planning and our consideration of the Governance statement.

Treatment of personal data

During the course of our audit we have had access to personal data to support our audit testing.

We have established processes to hold this data securely within encrypted files and destroyed 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 on the NAO website:

http://www.nao.org.uk/publications/0708/statement_personal_data.aspx

Appendix 1 – proposed letter of representation

[Client letterhead]

**The Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
LONDON
SW1W 9SP**

LETTER OF REPRESENTATION: HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY 2014-15

I acknowledge as Accounting Officer of the Human Fertilisation & Embryology Authority my responsibility for preparing accounts that give a true and fair view of the state of affairs, net expenditure changes in tax payers equity and cash flows of the Human Fertilisation & Embryology Authority for the year ended 31 March 2015.

In preparing the accounts, I was required to:

- observe the accounts direction issued by the Secretary of State, including the relevant accounting and disclosure requirements and apply appropriate accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards have been followed and disclosed and explain any material departures in the accounts; and
- make an assessment that the Human Fertilisation & Embryology Authority is a going concern and will continue to be in operation throughout the next year; and ensure that this has been appropriately disclosed in the financial statements.

I confirm that for the financial year ended 31 March 2015:

- neither I nor my staff authorised a course of action, the financial impact of which is that transactions infringe the requirements of regularity as set out in Managing Public Money;
- having considered and enquired as to the Human Fertilisation & Embryology Authority's compliance with law and regulations, I am not aware of any actual or potential non-compliance that could have a material effect on the ability of the Human Fertilisation & Fertilisation Authority to conduct its business or on the results and financial position disclosed in the accounts;
- all accounting records have been provided to you for the purpose of your audit and all transactions undertaken by the Human Fertilisation & Embryology Authority have been properly reflected and recorded in the accounting records. All other records and related information, including minutes of all management meetings which you have requested have been supplied to you; and
- the information provided regarding the identification of related parties is complete; and the related party disclosures in the financial statements are adequate.

All material accounting policies as adopted are detailed in note 1 to the accounts.

INTERNAL CONTROL

I acknowledge as Accounting Officer my responsibility for the design and implementation of internal controls to prevent and detect error and I have disclosed to you the results of my assessment of the risk that the financial statements could be materially misstated.

I confirm that I have reviewed the effectiveness of the system of internal control and that the disclosures I have made are in accordance with HM Treasury guidance on the Governance Statement.

FRAUD

I acknowledge as Accounting Officer my responsibility for the design and implementation of internal controls to prevent and detect fraud and I have disclosed to you the results of my assessment of the risk that the financial statements could be materially misstated as a result of fraud.

I am not aware of any fraud or suspected fraud affecting the Human Fertilisation & Embryology Authority and no allegations of fraud or suspected fraud affecting the financial statements has been communicated to me by employees, former employees, analysts, regulators or others.

ASSETS

General

All assets included in the statement of financial position were in existence at the reporting date and owned by the Human Fertilisation & Embryology Authority, and free from any lien, encumbrance or charge, except as disclosed in the accounts. The statement of financial position includes all tangible assets owned by the Human Fertilisation & Embryology Authority.

Non-Current Assets

Only items, or groups of related items, costing £1,000 or more and with individual values over £250, are capitalised. They are valued at historic cost, as this is not materially different to fair value. Depreciation is calculated to reduce the net book amount of each asset to its estimated residual value by the end of its estimated useful life in the Human Fertilisation & Embryology Authority's operations.

Other Current Assets

On realisation in the ordinary course of the Human Fertilisation & Embryology Authority's operations the other current assets in the statement of financial position are expected to produce at least the amounts at which they are stated. Adequate provision has been made against all amounts owing to the Human Fertilisation & Embryology Authority which are known, or may be expected, to be irrecoverable.

LIABILITIES

General

All liabilities have been recorded in the statement of financial position. There were no significant losses in the year and no provisions for losses were required at the year-end.

Provisions

Provision is made in the financial statements for:

- Costs of early retirement.

Contingent Liabilities

Except as disclosed in the accounts, I am not aware of any pending litigation which may result in significant loss to the Human Fertilisation and Embryology Authority, and I am not aware of any action which is or may be brought against the Human Fertilisation and Embryology Authority under the Insolvency Act 1986.

OTHER DISCLOSURES

Results

Except as disclosed in the accounts, the results for the year were not materially affected by transactions of a sort not usually undertaken by the Human Fertilisation & Embryology Authority, or circumstances of an exceptional or non-recurring nature.

Unadjusted errors

I confirm that I am aware of the unadjusted error that is included on the attached schedule. I do not wish to correct this error as I consider the effect of this unadjusted error to be immaterial to the financial statements as a whole.

Events after the Reporting Period

Except as disclosed in the accounts, there have been no material changes since the reporting date affecting liabilities and commitments, and no events or transactions have occurred which, though properly excluded from the accounts, are of such importance that they should have been brought to notice.

To the best of my knowledge, there are no announcements scheduled to be included in the Chancellor of the Exchequer's Budget, to be given on 8 July, that would impact on the financial statements and disclosures.

Management of Personal Data

Except as disclosed in the Governance Statement, there have been no personal data related incidents in 2014-15 which are required to be reported.

Consolidation Return

The consolidation return is accurate and consistent with the statutory accounts, and is complete in respect of disclosures and the information required by the Department.

Peter Thompson

**Chief Executive and Accounting Officer
Human Fertilisation & Embryology Authority**

Appendix 2 – Draft audit certificate

Proposed audit certificate

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY 2014-15 FINANCIAL STATEMENTS AUDIT CERTIFICATE AND C&AG'S REPORT

THE CERTIFICATE AND REPORT OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSES OF PARLIAMENT

I certify that I have audited the financial statements of the Human Fertilisation & Embryology Authority ("the Authority") for the year ended 31 March 2015 under the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008. The financial statements comprise: the Statement of Comprehensive Net Expenditure, the Statement of Financial Position, the Statement of Cash Flows, the Statement of Changes in Taxpayers' Equity; and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Respective responsibilities of the Accounting Officer and auditor

As explained more fully in the Statement of the Authority and Accounting Officer's Responsibilities, the Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. My responsibility is to audit, certify and report on the financial statements in accordance with the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008. I conducted my audit in accordance with International Standards on Auditing (UK and Ireland). Those standards require me and my staff to comply with the Auditing Practices Board's Ethical Standards for Auditors.

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the Authority's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Authority; and the overall presentation of the financial statements. In addition I read all the financial and non-financial information in the Annual Report to identify material inconsistencies with the audited financial statements. If I become aware of any apparent material misstatements or inconsistencies I consider the implications for my certificate.

I am required to obtain evidence sufficient to give reasonable assurance that the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Opinion on regularity

In my opinion, in all material respects the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Opinion on financial statements

In my opinion:

- the financial statements give a true and fair view of the state of the Authority's affairs as at 31 March 2015 and of its net expenditure, changes in taxpayers' equity and cash flows for the year then ended; and
- the financial statements have been properly prepared in accordance with the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008 and Secretary of State directions issued thereunder.

Opinion on other matters

In my opinion:

- the part of the Remuneration Report to be audited has been properly prepared in accordance with the Secretary of State's directions issued under the Human Fertilisation & Embryology Act 1990 amended to the Human Fertilisation & Embryology Act 2008
- the information given in the Accounting Officer's report, and the management commentary included within the Annual Report, for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the part of the Remuneration Report to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.

Report

I have no observations to make on these financial statements.

Sir Amya C E Morse
Comptroller and Auditor General

Date

National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP