Audit and Governance Committee meeting

Date: 3 October 2023 – 10.00am to 1.30pm

Venue: HFEA Office, 2nd Floor 2 Redman Place, London E20 1JQ

Agenda item	Time
1. Welcome, apologies and declarations of interest	10.00am
2. Minutes of 27 June 2023 (AM) For decision	10.05am
3. Action log (TS) For information	10.10am
4. Internal Audit (JC) For information	10.20am
5. Progress with current audit recommendations (TS) For information	10.30am
6. External audit report (verbal report) (MP/DG) For information	10.50am
7. Risk Update • Strategic Risk Register (SQ) • Risk Appetite Statement (SQ) • Committee discussion on potential horizon scanning items For discussion	11.00am
8. Deep dive discussion – topic introduced by the Chief Executive (PT) For discussion	11.20am
9. Digital projects/PRISM update (KH) For information	11.35am
10. Resilience, business continuity management & cyber security (MC/NMc) For information	11.50am
11. Counter-fraud Strategy (TS) For decision	12.05pm
12. Fraud Risk Assessment (TS) For decision	12.15pm
13. Reserves Policy (TS) For decision	12.30pm
14. Government functional standards (TS) For discussion	12.45pm

15. AGC forward plan (TS) For decision	1.00pm
16. Items for noting (verbal update) (TS) • Whistle blowing • Gifts and hospitality • Contracts and Procurement For information	1.10pm
17. Any other business • Committee effectiveness review – verbal update from Chair	1.15pm
18. Session for members and auditors only	
19. Close	
Lunch	

Next Meeting: Tuesday 7 December 2023 (including training session after lunch)

Minutes of Audit and Governance Committee meeting 27 June 2023

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	3 October 2023		
Author	Alison Margrave, Board Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Audit and Governance Committee meeting held on 27 June 2023 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

Minutes of the Audit and Governance Committee meeting on 27 June 2023 held in person at HFEA Office, 2nd Floor, 2 Redman Place, London E20 1JQ and via teleconference (Teams)

	In person	Online
Members present	Catharine Seddon, Chair Alex Kafetz, Deputy Chair Mark McLaughlin Geoffrey Podger	
External Advisers	Jo Charlton, Head of Internal Audit (Internal Auditor) – GIAA	Dean Gibbs, KPMG – External Audit lead Mohit Parmar, National Audit Office (NAO) – External Auditor Eric Sibisi, Audit Manager, KPMG
Observers		Amy Parsons, Department of Health and Social Care – (DHSC) Roland Green, DHSC
Staff in attendance	Peter Thompson, Chief Executive Clare Ettinghausen, Director of Strategy and Corporate Affairs Morounke Akingbola, Head of Finance Yvonne Akinmodun, Head of Human Resources Paula Robinson, Head of Planning and Governance Shabbir Qureshi, Risk and Business Planning Manager Debbie Okutubo, Governance Manager	Neil McComb, Head of Information Kevin Hudson, PRISM Programme Manager

1. Welcome, apologies and declaration of interest

1.1. The Chair welcomed everyone present in person and online.

1.2. Apologies of absence were received from Jason Kasraie, Martin Cranfield, Steve Pugh, Rebecca Jones and Rachel Cutting.

1.3. Catharine Seddon declared an interest in item 3, in relation to her first term coming to an end in January 2024.

2. Minutes of the meeting held on 14 March 2023

2.1. The minutes of the meeting held on 14 March 2023 were agreed as a true record and could be signed by the Chair.

3. Action Log

3.1. The Head of Finance presented this item. On actions 4.19, 9.8 and 9.9 – DSPT, the Chief Executive gave a brief synopsis and explained why they were still outstanding. Members were advised that the interim internal audit rating on DSPT was suggesting that we were showing progress even though the requirements remained onerous. It was proposed that all actions be closed and that if required a discussion could be held at a future point.

3.2. Members commented that they agreed with the proposal to close both actions but suggested that it should be raised as an opportunity cost at relevant meetings with the Department of Health and Social Care (DHSC). The Deputy Chair of AGC (Alex Kafetz), commented that NHS Digital England had recently appointed a new Chief Officer, and suggested that the HFEA Chief Executive and himself discuss the DSPT requirements pertaining to HFEA with the new CO.

3.3. On action 11.11, the DHSC representative commented that discussions were taking place and that the Head of Information had been invited to a meeting with the new Head of Cyber Security in National Systems at the Joint Cyber Unit (DHSC/NHSE) to facilitate dialogue, better understand the ALB landscape and collaboratively address any concerns. It was therefore proposed that this action be closed.

3.4. On action 15.4 – goodwill letters, the Executive commented that the completion date was deemed achievable.

3.5. On action 7.32 – second term for members, it was noted that discussions had been held with the DHSC sponsors and therefore proposed that it be closed.

3.6. On action 7.41 – on the appetite and tolerance of risk. It was noted that this was an agenda item. It was therefore proposed that this action be closed.

3.7. On action 10.4, equality, diversity and inclusion and action 10.5, the action on staff survey, both were on the agenda. It was therefore proposed that they be closed.

3.8. It was noted that actions 11.9 and 11.13 were not yet due.

3.9. On action 11.10, the Executive to consider risk management near misses as failures to identify opportunities, it was suggested that this should be a deep dive item at the October meeting. It was therefore proposed that it be closed on the action log and listed on the deep dive topic list.

3.10. On action 11.14, the DHSC representative had received confirmation that the Department's ARC Chair will extend an invite to both the HFEA and HTA to attend a meeting later this year. It was therefore proposed that this action be closed.

3.11. Actions 4.14, 5.6, 5.7, 9.11 had been resolved and could be closed.

3.12. On action 13.5, it was noted that all staff had completed the counter fraud training. However, it took a year for all staff to complete this module. The Head of Finance and Head of Human

Resources were in discussion to put in place measures to ensure that future mandatory training was completed on time. It was proposed that this action be closed.

3.13. On action 16.2, the Head of Finance was taking this forward. It was therefore proposed that it be closed.

Decision

3.14. Members agreed that future versions of the action log should be updated with all actions from AGC meetings, and all completed actions to be tabled at each meeting for removal from the log.

4. Internal audit report and annual opinion

4.1. The Head of Internal Audit – GIAA presented this item. Members were advised that on the annual opinion, a moderate assurance had been given to the organisation's governance arrangements, risk management and systems of internal control.

4.2. It was also noted that three key themes had been identified where the Authority needed to focus their attention on the coming year:

- Training
- Guidance
- Audit trails.

4.3. Members noted that training and guidance had both been identified as themes in previous years, indicating further work was required in these areas.

4.4. In response to a question, the Head of Internal Audit commented that a moderate rating was a good result and that the last three years had been positive. However, the themes drawn out were repetitive over the last couple of years.

4.5. The Chief Executive commented that as a small organisation with limited resources the three themes were related. He also suggested that there were no risks in performance in any of the themes. The trend in auditing towards providing written evidence required an increase in administrative processes which were in themselves an opportunity cost.

4.6. Members commented that internal control frameworks are important and agreed that the burden of the administrative process could be cumbersome. Nonetheless the trend to provide evidence was here to stay as it was a public policy issue. The HFEA was an effective organisation but probably more staff were needed to fulfil the administrative processes demanded by new audit requirements.

4.7. The Head of Internal Audit commented that training and guidance were critical especially because of the size of the organisation and gave the instance of ensuring process resilience when people leave the organisation. She continued that it was important that the organisation was still able to carry on with its functions and achieve its strategic objectives.

4.8. Members noted that the final DSPT would be presented to the next AGC as this report is currently in draft from the 2023/24 plan.

4.9. The Chair commented that there was evidence that significant progress was made in 2022/2023 on accepting and implementing recommendations. Also, that the golden thread was a very useful guidance for management.

4.10. The Head of Internal Audit commented that service standards were very positive but that there was more to achieve. In terms of management responses being delivered on time, the Authority had more work to do as responses ideally need to be delivered within 10 working days. Also, delays in management responses could give rise to misinterpretation of internal audit recommendations.

Decision

4.11. Members noted the annual opinion and themes identified in the internal audit report.

5. Progress with current audit recommendations

5.1. The Head of Finance presented this item. Members were informed that there was progress with recommendation closures. It was also reiterated that the indicated rating on the DSPT was moderate, and this was considered very positive for the HFEA.

5.2. The overdue recommendations were highlighted.

5.3. On staff well-being, this required our stress management policy to be updated, which had been done, but we missed the deadline for submission to the GIAA. It had since been sent to them and we were awaiting feedback.

5.4. On the annual equality, diversity and inclusion training module for Authority members, members were advised that following the closure of the previously used module in Civil Service Learning, the Astute training platform will be used as it was reliable and the trackable feature allowed us to identify who had completed the training, which is an internal audit recommendation.

5.5. It was also noted that the Head of Human Resources, following discussion with the Chair of the Authority, was in the process of writing to one of the members offering them the opportunity to become the equality, diversity and inclusion Board champion.

Action

5.1. The Chair requested that more than a month before the committee papers are to be sent out, the Head of Finance and her team should work on closure dates with the various business areas. This would allow sufficient time to seek GIAA approval for the closure of recommendations before the papers are sent to members so that an accurate, up to date picture is presented at each meeting.

Decision

5.2. Members noted the progress with current audit recommendations.

6. Annual report and accounts

6.1. The Head of Finance presented this item. Members commented that it was a good report with a frank disclosure of challenges.

6.2. The section on risk was discussed. The Director of Strategy and Corporate Affairs commented that a strategic priority was our work on law reform and that there was the risk that we would not have the right skills to implement the identified changes. She commented that this was more of a future risk. Members commented that we need the powers to regulate new and emerging activities arising in the fertility space.

6.3. The Chief Executive commented that this was picked up in the governance risk and even though we are an effective regulator we required more powers.

6.4. The Chair commented that positioning and influencing was still an issue. The Chief Executive agreed to take a further look at how this risk was expressed going forward.

6.5. On Information – PRISM, members suggested that we look further into this and determine at what level PRISM and/or OTR functions would become incapable of issuing accurate information at sufficient pace.

6.6. It was suggested that for staff recruitment, it was noted that blind recruitment can further promote an inclusive and diverse workforce (although it noted that NHS jobs, which the HFEA frequently use, already provided this function).

6.7. Members commented that on the financial statements, they had no issues on the presentation or content. They however suggested that increased expenditure could become an issue and that the Executive should keep this under review.

6.8. The External Auditor commented that they had sent their comments to the Head of Finance and had nothing else to add.

6.9. The Internal Auditor commented that she had nothing else to add.

6.10. Members noted the draft report of the Comptroller and Auditor General to the Houses of Parliament and that there was no separate certificate.

6.11. The External Auditors confirmed that the completion report was an all-encompassing completion report.

Action

6.12. The Chief Executive to take a further look at the positioning and influencing risk area.

Decision

6.13. Members noted the annual report subject to agreed suggestions and updates.

7. External audit work

7.1. The External Audit lead, KPMG presented this item. Members were advised that as at the date of the external audit report, the audit of the financial statements was substantially complete subject to the areas detailed in the report.

7.2. Members were also advised that at this stage the external auditors were planning on issuing an unqualified opinion.

7.3. The Chief Executive extended his gratitude to the external audit team – both KPMG and the NAO teams and to the internal HFEA team including the ex-Director of Finance and Resources, Richard Sydee who recently left the HFEA and to the Head of Finance and her team for the work done to produce the annual accounts and reports.

7.4. In response to a question, the Executive commented that they agreed with the PRISM recommendation contained within the report.

7.5. The Chair also thanked the Finance team and commented that having only three outstanding clinics not yet on the PRISM platform was an achievement and that we had made very good progress.

7.6. The Chair thanked the External Auditors, in particular for the follow up recommendations made in the previous year.

Decision

7.7. Members noted the external audit completion report.

8. Strategic risk

Risk management strategy

8.1. The Risk and Business Planning Manager presented this item to the committee. Members were advised that in May 2023, an update to the Orange Book was released. The risk management strategy was being updated in a proportionate way to adopt those changes that were relevant for the HFEA.

8.2. Members commented that the strategy read well and wanted clarity on what was meant by:

> 'we must be willing to accept a higher level of legal risk, as we have limited control over the number of legal cases that we must deal with'.

8.3. The Chief Executive responded that we operate in a regulatory environment and therefore we need to live with the fact that we can face legal challenge at any time; the key mitigation is to ensure through good governance that such challenges are unlikely to be successful. The Chair commented that as AGC members they were aware that our preparedness for legal risk was always high.

8.4. Members were advised that the risk management strategy will be reviewed on an annual basis.

Strategic risk register

8.5. Members were reminded that the strategic risk register (SRR) was reviewed bi-monthly by SMT and that it was reported to AGC and the Authority at every meeting. Members felt that more detail needed to be added to the in-house work being done.

8.6. Members suggested that the financial risk and governance risk categories should remain on the register.

8.7. On information risk, members suggested that the executive should bear in mind that there are other websites providing and sometimes charging for information on fertility matters from a variety of sources which could lead to the migration of people away from genuine websites. Members believed that this needed to be mitigated. The Director of Strategy and Corporate Affairs commented that we constantly post updates on our website to dissuade patients from using non-authorised webpages and this was done within the resources we have.

8.8. Members asked if the first information risk needs to be re-articulated stating what the HFEA sees as the risk of using such websites and if the resource required is to correct erroneous information.

8.9. On the OTR risk, members sought assurance that donor conceived (DCI) people will be kept safe from fraudulent practices by firms that charge for services that cannot deliver.

8.10. On operational risks, it was noted that limited IT resources remained a risk but there were mitigations in place.

8.11. On people risks, it was noted that re-prioritising was taking place and that resilience remained an issue due to the size of the organisation. The loss of senior leadership risk had also been re-opened due to the Director of Finance and Resources leaving the HFEA. The Chief Executive commented that he was meeting regularly with the Head of Finance and that the new Director of Finance and Resources will start in August. In the meantime, the Chief Executive and the Head of Finance were managing the Finance function.

8.12. In response to a question on loss of senior leadership, the External Audit team confirmed that they were aware of the arrangement and mitigation in place. The Internal Auditor (GIAA) also responded that they were aware of the mitigations and to date there was no adverse impact on their work with the HFEA.

8.13. Members noted the mitigations listed in the reputational risks category. A member commented that if we lost a legal case this could lead to reputational damage. The Chair commented that positioning of the HFEA remained important and the senior management team needed to consider if it was BAU or a risk to be left on the register.

8.14. On security risks, members asked if the risk was underrated in the light of increasing cyber-security risk awareness. The Executive responded that the mitigations in place were updated regularly.

8.15. On strategic risk, members noted that the public body review was still underway.

Deep dive topics

8.16. Topics that had been chosen previously were discussed and some timelines were agreed:

- Increased reporting of corporate governance standards
- The effectiveness of performance management and risk (could be discussed a year after the new system has been embedded)
- Staff retention and recruitment as a resource risk – to be discussed after a full year post covid
- Impact and effectiveness of communication
- HFEA's regulatory effectiveness if some or all our ambition for legislative change is not taken forward by the DHSC and
- OTR - what it means for the organisation.

8.17. For the October 2023 meeting, it was agreed that the deep dive topic should address the kind of legal risks HFEA faces, together with current mitigations, and the resource implications thereof. The Chief Executive would lead on this.

Horizon scanning

8.18. The Chair asked about the patient engagement forum and asked if we were making the best use of lived experience. The Executive responded that even though it was possible we needed to consider how best to deploy our limited resources.

8.19. The Chair also asked if we were currently capturing the risk of not realising any particular opportunity and gave the example of surrogacy. The Chief Executive accepted the challenge but responded that changes to surrogacy regulation was a matter for the Government. The Law

Commission was asking for a reform of the law and until it was clear what was happening, the most sensible course of action was to keep it on our radar.

Decision

8.20. Members commented on the risk strategy update and noted the plan for a further review incorporating changes to the Orange Book, with the aim of presenting a further update to the December 2023 committee meeting.

8.21. Members commented on the revised strategic risk register.

8.22. Members noted the deep dive topics and timelines and provided additional guidance on horizon scanning.

9. Digital projects/PRISM update

9.1. The PRISM Programme Manager presented this item. Members were advised that we were prioritising our work on opening the register (OTR) and that we were making good progress on this. We were confident of hitting the deadline for signed off OTR reports by the end of July 2023.

9.2. In relation to Choose a Fertility Clinic (CaFC), members were reminded that previously it had been advised that we had hoped to have a more detailed timescale for a refresh of the CaFC data by June. However, because of the slower pace of clinic corrections, the detailed assessment had been postponed to September 2023.

9.3. Members were advised that our data analyst has been undertaking a full reconciliation of OTR data held in PRISM and that 3,782 reconciliation issues were identified of which our data analyst has resolved approximately 3,000 issues and was continuing to work through the remaining 800 issues.

9.4. It was noted that OTR required 100% data accuracy so the data analyst was working to fully reconcile this dataset.

9.5. Members were also informed that the data analyst was to move to other CaFC reconciliations and a key planned piece of work was the ‘CaFC verification check’. Members endorsed this action.

9.6. Regarding improving the rate of error correction in clinics, members noted that the PRISM team had not been able to identify any clinic that was not undertaking error correction, and the Register team were in constant contact with clinics regarding individual issues concerning validation errors.

9.7. In response to a question, the PRISM Programme Manager commented that we receive granular data from PRISM, which makes errors obvious, and when errors are identified, information is sent back to clinics.

9.8. The Chief Executive commented that without prompting, some clinics do not send in data, and we therefore continue to engage with them and involve the inspection team when necessary.

9.9. Members requested that the exact timetable for CaFC should be brought to the October meeting.

Action

9.10. Members asked for CaFC to be added as a future deep dive topic.

9.11. The PRISM Programme Manager to include the exact timetable for CaFC to the October report.

Decision

9.12. Members noted the PRISM status update.

10. Resilience, cyber security & business continuity

Infrastructure improvements

10.1. A report detailing the IT infrastructure improvements was presented to members.

Data Security and Protection Toolkit (DSPT)

10.2. The Head of Information presented this part of the report. Members were advised that we were now in the final stages of completing the DSP Toolkit and that we were still likely to have a number of 'not met' items in our final submission. However, alongside this, we would submit an improvement plan.

10.3. Members were reminded that the GIAA internal audit ranking for the DSPT was 'limited' last year, but since then we had improved significantly and the new GIAA internal audit draft plan had categorised us as 'moderate'. Our internal assessment was that the HFEA would still not meet all the requirements of the 2023 mandatory assertions.

10.4. In response to a question on how we compare with similar sized arms-length bodies, the Head of Information suggested that we do not have any comparable analysis data. The Internal Auditor - GIAA commented that the HFEA was on a par with the Human Tissue Authority (HTA). It was also suggested that the high confidence level of the audit should be applauded.

10.5. The Chief Executive thanked everyone involved and commented that it would be easier to maintain our current level in future.

10.6. The Chair commented that it would be more beneficial to focus on our residual risk as standards could change from one year to the next, and she was therefore in support of us maintaining our confidence level.

Decision

10.7. Members noted the infrastructure improvements and the current position on the DSPT.

11. Information assurance and security (SIRO report)

11.1. The Chief Executive presented this item in the absence of a Director of Finance and Resources. It was noted that it followed a framework used in previous years.

11.2. Members noted that throughout the year we undertook scheduled activities to ensure we complied with our policies; this work had been overseen by the HFEA's Information Governance Manager who made periodic reports to the Corporate Management Group (CMG).

11.3. The AGC Deputy Chair, Alex Kafetz commented that he agreed with the conclusion in the SIRO report and that we were doing all we could in terms of information governance and cyber security.

11.4. In response to a question the Chief Executive commented that the issues we were facing were mainly operational in nature and gave the example of connectivity issues. We however had external IT support. There was also a Redman Place building group that the previous Director of Finance and Resources sat on.

11.5. Members were advised that in the interim until the incoming Director of Finance and Resources took up position the Chief Executive would act as SIRO.

Decision

11.6. Members noted the SIRO report.

12. Government Functional Standards

12.1. The Chief Executive presented this item. He commented that we had not made progress due to there not being a Director of Finance and Resources in post.

12.2. It was noted that there are 14 functional standards but we were aware that three were not applicable to us.

12.3. The plan was to get to a point of putting some detail into the work by the next AGC.

Decision

12.4. Members noted the status of our functional standards.

13. Human Resources update 2023

13.1. The Head of Human Resources presented this item. Members were reminded that we had an equality, diversity and inclusion (EDI) audit in November 2022 and a number of areas were highlighted.

13.2. Following the audit, a number of actions and processes had been put in place including:

- the launch of a new EDI page on our intranet
- a refresh of our recruitment page to better highlight our approach in the area of EDI
- the appointment of two members of staff as EDI champions
- arrangements for annual EDI training for Authority members.

13.3. The annual all staff survey took place in the Autumn of 2022 and the action plan was presented to the committee.

13.4. It was noted that a major theme from the survey was the issue of pay and that this would be discussed with the DHSC. The Chair commented that she was happy with the direction of travel.

13.5. Members asked how the celebration of achievement is addressed. The Head of Human Resources responded that it will be promoted through the monthly HR newsletter and at all staff events, as we always had celebration walls.

13.6. In response to a question, it was noted that the vision and strategy of the HFEA was connected with our values and that these were embedded through the personal development plan (PDP) process.

13.7. The Chair suggested that the Head of Human Resources look into lunch time sessions on EDI initiatives.

13.8. In terms of opportunities for fast streamers, it was noted that most of these individuals worked within the Policy team and that to date, it had gone well. They spent six months with us in the HFEA. The Director of Strategy and Corporate Affairs commented that the DHSC sponsor team

put us in touch with the team in charge of fast streamers and that we currently have an Apprentice in the Communication team.

13.9. Members asked about insights that came from the GIAA internal audit paper relating to staff wellbeing. The Head of Human Resources commented that in the staff survey we asked questions on this and we fared well in terms of satisfaction.

13.10. Also, since Covid, we had increased our number of activities including an HR newsletter and for this month there was a section on staff wellbeing.

13.11. The Chair suggested that the Executive look into the introduction of wellbeing days. The Chief Executive responded that he would be interested in knowing how other ALBs have managed this, as it appeared to us to be contrary to Treasury rules. The Chair agreed to put the Chief Executive in touch with another ALB that had introduced wellbeing days.

Actions

13.12. The Chair to put the Chief Executive in touch with another ALBs that has wellbeing days.

Decision

13.13. Members noted the equality, diversity and inclusion report and the staff survey action plan.

14. AGC forward plan

14.1. The Chair commented that the December 2023 meeting should be adjusted so that it ends at 3pm to take into consideration the training on understanding good governance and that the training should be opened up to other Authority members.

14.2. The deep dive topic for the October meeting to be noted but future deep dive topics should be confirmed at each AGC.

14.3. The date of the meeting in October is Tuesday, 3 October 2023.

15. Items for noting

15.1. Whistle-blowing

- Members were advised that there were no whistle-blowing incidents.

15.2. Gifts and Hospitality

- Members noted that there were no changes to the register of gifts and hospitality.

15.3. Contracts and Procurement

- Members noted that there were no contracts or procurements signed off since the last AGC meeting.

15.4. Estate update

- There was no update on our estate.

16. Any other business

16.1. The Chair paid tribute to the outgoing Independent AGC members Geoffrey Podger and Mark McLaughlin and thanked them on behalf of the Authority for their contribution during their two, three-year terms on the committee.

16.2. The Chair also thanked Debbie Okutubo, Governance Manager who had acted as secretary to the Committee over the last four years and was leaving the HFEA at the end of July, and Samuel Akinwonmi, Finance Manager for his workover the last three years. This would be the last meeting for both of them.

16.3. Lastly, the Chair noted that Tom Skrinar would be joining the HFEA on 21 August as the Director of Finance and Resources and would therefore be at the next committee meeting on Tuesday, 3 October 2023.

Chair's signature

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

Signature

Chair: Catharine Seddon

Date: 3 October 2023

AGC Action log

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society		
Meeting	Audit and Governance Committee		
Agenda item	3		
Meeting date	03 October 2023		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For discussion		
Recommendation	To note and comment on the updates shown for each item.		
Resource implications	To be updated and reviewed at each AGC		
Implementation date	2023/24 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from the Audit and Governance Committee – actions from 4 October 2022			
15.4 Update on goodwill letters to be discussed at SMT and brought back to AGC.	Director of Compliance and Information	Oct 2023	**Update** –Progress continuing well and on schedule.
Matters Arising from the Audit and Governance Committee – actions from 8 December 2022			
11.9. Assurance and assurance mapping to be kept under continuous review and form part of training.	Head of Planning and Governance	Oct 2023	**Update:** AGC is aware of the risk review that is in progress as a result of recent changes and additions to the Orange Book. As agreed previously, a paper on this will be brought to the December meeting, and the review is in progress now. Risk assurance and mapping will be taken into account as part of this. As reported previously, training plans are being put in place. For most staff, there is adequate training available on Civil Service Learning. For staff who have direct responsibilities for risk management at team level, we are planning additional in-house training, and we will incorporate relevant aspects about assurance following the review that is in progress. We will continue to include consideration of risk assurance in the deep dive items to AGC, and this is a clear element in internal audits as relevant (for example the internal audit of our project management processes). In light of the changes to the Orange Book, and the impact on this planned work, it is suggested that the due date for this item now be changed to March 2024 so as to allow time for AGC to consider the paper in December, and for us to begin to implement the outcomes.

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
11.13. As part of continual improvement there should be monitoring of trends in the corporate governance sphere.	Head of Planning & Governance	Oct 2023	**Update** – This is for monitoring, which will be done as a matter of routine as part of our annual review of committee effectiveness (commencing now). The outcomes of all of the reviews of effectiveness will be summarised in a Governance paper for Authority in March 2024. It is suggested that this item could be removed from matters arising, since it is part of business as usual.
Matters Arising from the Audit and Governance Committee – actions from 27 June 2023			
9.9 The exact timetable for CaFC should be brought to the October meeting.	PRISM Project Manager	Oct 2023	**Update** – information is presented in agenda item 9 of the October agenda. This action is now completed and can be removed from the action log.
13.12 The Chair to put the Chief Executive in touch with another ALB that has wellbeing days	Chair	Oct 2023	**Update –** per email from the Chair, this was completed after the June meeting. The CEO and Head of HR were introduced to colleagues from CafCas and LSB. This item can now be removed from matters arising.

Deep dive discussion – legal risks

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information/Shaping the future
Meeting:	AGC
Agenda item:	8
Meeting date:	03 October 2023
Author:	Peter Thompson, Chief Executive
Annexes	Annex A – Mitigations

Output from this paper

For information or decision?	For information
Recommendation:	The AGC is invited to consider the mitigations in place to reduce the likelihood of legal challenge or defeat in the courts, focussing in particular on the points for discussion at section 10.
Resource implications:	N/a at this stage
Implementation date:	N/a
Communication(s):	N/a
Organisational risk:	Low

1. Introduction

1.1. At the last AGC meeting on 27 June 2023 it was agreed that a paper be prepared outlining the range of legal challenges the HFEA can face and the mitigations in place to reduce the likelihood of challenge or defeat in the courts.

1.2. The paper does not cover internal legal challenges, on say an HR matter, as such risks are inherent to any organisation.

2. Overview

2.1. All public bodies face the risk of legal challenge. Given the controversial nature of some of the HFEA's responsibilities, the risk of challenge is greater than many other public bodies. While there are mitigations that the HFEA can put in place to reduce the risk of legal challenge, it cannot eliminate that risk. A determined individual or entity with sufficient financial resources will always be able to seek to go to court.

2.2. The key issues therefore are twofold: what can we do to ensure that should our decisions be challenged in the courts (or under the appeal process set out in the HFE Act) we are most likely to win? And what resources do we need to manage any legal action?

2.3. The legal risks that the HFEA faces can be broadly categorised as challenges to:

- our statutory **regulatory decisions** from either a licensed clinic or research centre;
- our statutory decisions relating to **embryo testing** from either the clinic making the application or an individual or campaign group;
- our statutory decisions relating to the **release of information held on our Register**, either in respect an application for:
    - identifiable information from the donor conceived individual; or
    - identifiable register information requests from researcher(s);
- our handling of **statutory information requests** whether under FOI Act or Data Protection laws;
- our **policy decisions** from either a licensed clinic, individual or campaign group.

2.4. This paper considers the risks to each type of challenge and the mitigations available to us (sections 3 – 8 and Annex A). The legal resources are considered in section 9. A number of points for discussion are set out at the end (section 10).

3. Regulatory decisions

3.1. Fertility treatment/research involving human embryos can only take place in the UK under licence from the HFEA. The law requires us to inspect at an interval not exceeding two years and we can issue a treatment licence for up to five years and a licence for embryo research for up to three years. The Act allows us to revoke, suspend or place conditions on a licence. We can also act in response to information about clinic performance coming to light through incident reports or whistleblowing. HFEA licensing decisions are taken by either the Licence Committee (LC) or Executive Licensing Panel (ELP).

3.2. Given the potential seriousness of our powers – we can close down a service / business / research project - there is a very real and constant risk that our regulatory decisions may be challenged, usually by the clinic or research centre that holds the licence. As potentially controversial licensing decisions are reserved to the LC it therefore follows that it is only LC decisions that are likely to be challenged.

3.3. The HFE Act provides a two-stage process through which an HFEA licence decision can be challenged. The first stage involves a reconsideration of the original licence decision at a representations hearing. If that hearing upholds the original decision the clinic/research centre can ask that the case is considered afresh by an independent Appeals Committee. The decision of the Appeal Committee is final, though a judicial review (JR) can be sought on a point of law.

Mitigations

3.4. The principal mitigation to reduce the impact of legal challenge is to take inspection and licensing decisions in a way that is demonstrably reasonable. That is achieved through a combination of policies (most notably the Compliance and Enforcement Policy which improves the consistency of decision making), SOPs, legal training for LC members, peer review, internal management review, legal advice and separation of functions, which are set out at **Annex A**.

3.5. Over the last three years (October 2020 – September 2023) the LC has considered 52 items and only two (linked items) have been appealed. This suggests that the quality of the first-tier decision made by the LC is high and the various mitigations effective. But is also probably a reflection of the fact that few licensing decisions are so severe that a challenge is worth the time and resources required.

3.6. Should a licensed clinic/research establishment seek to contest a decision in the courts before the appeal process in the HFE Act set out above is exhausted, our approach is usually to argue that the JR is premature.

3.7. For the most part the courts are unwilling to challenge the substance of the decisions of statutory public bodies providing they are acting within their powers. This means that most JRs turn on arguments about process and the various mitigations set out at **Annex A** provide good assurance against a successful challenge at JR. We have not lost a JR on process grounds for many years.

4. Embryo testing

4.1. The HFE Act provides for the testing of embryos for serious inherited illnesses under licence by the HFEA. The Authority has delegated the power to consider such applications to the Statutory Approvals Committee (SAC).

4.2. Given that embryo testing is the only reliable means of avoiding the transmission of a considerable and growing number of serious inherited illnesses (as of September 2023, we have authorised 4760 genetic conditions as meeting the criteria in the HFE Act) there is a considerable risk of legal challenge, either from clinics or individuals objecting to a decision to refuse an application or from campaign groups who object to embryo testing, either in principle or in respect of the particular illness in question.

4.3. SAC also makes decisions on the import/export of gametes or embryos in circumstances where the requirements of our General Directions cannot be met. This also entails some risk of legal

challenge, especially if it were felt that our decision affected an individual's human rights in some way. The reasons for such applications are sometimes complex (for example involving post-humous use).

Mitigations

4.4. The principal mitigation to reduce the risk of legal challenge is, once more, to ensure that the decision is demonstrably reasonable. This achieved through a variety of means including legal training for SAC members, SOPs, independent legal advice and expert peer-review, which are set out at **Annex A**. In addition, it is sometimes possible for the centre to submit the same application again with further information. Of course this does not guarantee a different outcome, but it does mean that a legal appeal is not the only recourse available.

4.5. There is no appeal process in the HFE Act for a decision on embryo testing. Should anyone wish to challenge a SAC decision they would have to seek a JR. To date, no SAC decision on embryo testing has ever been challenged in the court, which is in itself an indicator of the quality of the decision-making

5. Register information

5.1. The HFE Act requires us to hold a Register of all licensed treatments in the UK and to make certain information available upon request to donors, donor conceived individuals or the parents of donor conceived children through a process we term Opening the Register (OTR).

5.2. A challenge to OTR would arise if the individual was dissatisfied with the information we requested or, in time, because we released incorrect information. No such challenge has yet occurred. There is also a potential for a challenge on GDPR grounds, particularly from the donor.

5.3. The HFE Act (and subsequent Regulations) also requires us to release identifiable Register information to researchers provided they meet certain requirements and the data is used in ways that ensure it is kept confidential. We have established the Register Research Panel (RRP) to process such requests.

5.4. A challenge to the RRP would arise if the applicant wished to contest a decision to refuse to release all or some of the data requested or that the conditions set on its use were judged unreasonable. Or if identifying information was somehow disclosed. Again, no such challenges have yet occurred.

Mitigations

5.5. Once more, the principal mitigation to reduce the risk of legal challenge, to both the OTR and the RRP, is a combination of policies, staff training, the presence of a legal adviser as appropriate, the detail of which is set out at **Annex A**.

5.6. The fact that the HFE Act requires us to release only certain information also acts as a mitigation.

6. Information requests

6.1. The HFEA, like all public bodies is required to handle the information it holds in a manner which is compliant with the Freedom of Information Act (FOIA) and the laws relating the data protection (DP).

6.2. FOI relates to any information we hold (subject to any of the exemptions in the FOIA) and requests for information can come from a variety of sources: journalists or businesses that sell information, licensed clinics, campaign groups, members of the public. DP only relates to personal information held by us and applications can therefore only be made by the individuals in question.

6.3. The FOIA and DP requires that we respond to applicants within specified timescales. Should an applicant be unhappy with our response they can appeal to the Information Commissioners Office (ICO).

Mitigations

6.4. Once more, the principal mitigation to reduce the risk of legal challenge (reference to the ICO) is a combination of staff training, legal advice (internal and, where necessary, external), SOPs and policies, and the involvement of senior staff in the sign off of individual applications (see **Annex A**).

7. Policy decisions

7.1. Like all public bodies, the various policy decision the HFEA makes are potentially open to JR. However, given the range of policy decisions and their impact, the likelihood and risks of legal challenge are harder to quantify. Given the relatively permissive nature of the regulatory regime in the UK, challenge is more likely to come from individuals or campaign groups who oppose aspects of what the HFEA is required to do in law (e.g. embryo research / testing) or from licensed clinics who might feel that a particular HFEA policy decision impacts on a service they wish to provide or their business model.

Mitigations

7.2. Policy making is not reducible to SOPs in the way that the sort of regulatory decisions set out above are. Nonetheless there are good practice standards which can reduce the likelihood of a successful challenge, in respect of certain issues. There is, for example, government guidance on public consultations; although it would mostly not apply to the type of consultations we carry out. The annual business planning process and the three year strategic planning process provide legitimacy to particular pieces of HFEA policy work, as does public papers to the Board framing options and seeking agreement.

7.3. As noted above, provided the public body is acting within its powers courts do not usually find fault with the substance of any policy decision, and JR tends to focus on process – the adequacy of the consultation, the reasonableness of the decision etc. In recent years our policy decisions we have been challenged just twice in the courts (in respect of the data metrics in CaFC, and on the ratings of certain treatment add-ons) and on both occasions we won decisively.

8. Third party litigation

8.1. It is important to note that the HFEA can be drawn into litigation as a third party (in other words where the challenge is not against a decision of ours). There are few mitigations in such cases, though we can of course choose not to participate. However, there is often an assumption that as the statutory regulatory body in this area the court can expect that we will provide advice on the HFE Act and/or operational matters and were we to choose not to participate we could face public criticism.

8.2. The main issue that arises in such litigation is the demands that it can make on our legal resources and senior staff time.

9. Legal resources

9.1. Legal resources come from several sources. For many years until 2021, in-house legal advice was provided by a single member of staff (Head of Legal) with some administrative support. That brought expertise and continuity, but little resilience. In addition, we used external legal advice to support certain statutory decision making (as noted above, the LC, SAC and RRP) and ad hoc external advice to support legal challenges. For some years now, the DHSC have required us to source external legal advice from a call-off contract held by NHS Resolution. Given the specialist nature of the HFE Act we have tended to source legal advice from a relatively small number of firms.

9.2. When our Head of Legal resigned for personal reasons we moved to a different arrangement on a trial basis, seconding a legal adviser (part-time for up to 12 months) from one of the firms we have used previously. In addition, we currently employ a second in-house lawyer on a part-time basis who sits in the Policy team. This arrangement is now in its second year. It works well, providing high quality legal advice which can be supplemented by specialist expertise from the firm in question as required. It is a resilient model but is more expensive than solely relying on a single in-house lawyer.

9.3. Over the next few months, we will have to make a decision on how we access legal advice in future. Essentially, we have three options:

- **Continue with the current secondment model** - if we want to continue with this model we will have to re-tender the service from next year. It is resilient, meets our needs, provides access to the full range of expertise that a large firm provides, but lacks continuity of personnel and is expensive;
- **Revert to an in-house model** – this can provide continuity of personnel and is relatively inexpensive (but only if we revert to a single member of staff), but it lacks resilience;
- **Share legal advice with another ALB** – this model would involve us sharing legal advisers with another small ALB or paying for advice from a larger ALB. Much would depend on getting the right arrangement, but it could potentially offer a mix of continuity and resilience.

10. Points for discussion

10.1. In thinking about the various legal challenges set out above, the AGC may wish to consider the following questions:

- Are the current mitigations sufficient?
- Is there more we could do?
- Is there sufficient Board level oversight of ongoing legal risks? While recognising the need for separation of functions in respect of ongoing regulatory activity, the sensitivity of some legal action and the speed at which issues can develop.
- Does the available legal resources model seem appropriate?
- Do we fully recognise the opportunity cost impact that significant legal action can have? Even if we have sufficient legal resource, an Appeal under the HFE Act or a JR can divert senior staff time– preparation of witness statements etc. - from other work.

Annex A -Mitigations

Regulatory decisions

Inspection: the quality of the inspection and the reasonableness of the recommendations reduce the likelihood of challenge. To that end:

- inspectors undergo considerable on the job training before they lead an inspection;
- most inspections involve at least two inspectors to counter a single, possibly outlier view;
- the draft report is peer reviewed by one of the senior inspectors;
- regulatory sanctions are decided upon with reference to our Compliance and Enforcement Policy which provides both a public statement against which we are measured and helps ensure consistency from one inspection to another;
- Inspections which uncover a range of serious non-compliances that are likely to result in a recommendation to revoke, suspend or place conditions on a licence are subject to a management review involving the Chief Inspector and/or the Director of Compliance and Information;
- HFEA legal advisers comment on the draft recommendations as necessary to ensure that are securely grounded in the powers in the HFE Act.
- the draft inspection report is shared with the clinic/research centre PR to provide an opportunity to challenge recommendations before they are finalised.

Licensing: the quality and reasonableness of the licensing decision reduces the likelihood of challenge. To that end:

- there is a clear separation of functions between inspection and licensing so there can be no good grounds to argue that the licensing decision was in some way influenced by the inspector. This can be demonstrated with reference to the fact that administrative support is provided by different teams, the inspector is not present at the licensing meeting, the legal adviser to the licence committee is independent of the HFEA;
- members of the LC and ELP receive legal training before taking part in meetings to ensure they understand the HFE Act and any broader legal requirements that underpin good regulatory decision making;
- the LC (and ELP) use a decision tree to guide their deliberations and sit with a legal adviser who also assists with the drafting of the minutes setting out the LC decision and any other documents or notices issued by the committee;
- should a clinic / research centre wish to challenge the first stage decision of the LC, the representations hearing and independent Appeal Committee both follow processes set out in Regulations, with different decision makers and administrative support at each stage to guard against the accusation that either stage is biased.

Embryo testing

Applications: the quality of the clinic application reduces the likelihood of challenge: To that end:

- applications from the clinic are handled by a dedicated member of the HFEA staff who ensures that all of the required information is present;
- they are then considered by an independent expert peer-reviewer, who ensures the relevant scientific evidence has been considered.

Approval: the quality and reasonableness of the approvals decision reduces the likelihood of challenge. To that end:

- the clinic application and the independent peer review is both available to SAC to ensure it has all the necessary evidence to make a sound decision;
- the expert peer reviewer attends the meeting to answer any questions the committee might have;
- the SAC is guided in its deliberation by a decision tree and an independent legal adviser. The legal adviser also assists with the drafting of the minutes setting out the SAC's decision.

Register information

Approvals: the quality and reasonableness of the decision reduces the likelihood of challenge. To that end:

- there is a separation of functions between the Register Research Panel (RRP) who make decisions about requests under the 2010 regulations and members of the research team who liaise with researchers and prepare data for them;
- the legal adviser who attends RRP is independent of the HFEA;
- members of the RRP receive legal training before taking part in meetings to ensure they understand the HFE Act and any broader legal requirements that underpin good decision making;
- the RRP use a decision tree to guide their deliberations and sit with a legal adviser who also assists with any requests for clarification;
- HFEA standing orders set out a process for appeal against any decision of the RRP.

Information requests

The quality and reasonableness of the decision reduces the likelihood of challenge. To that end:

- Requests for information made under the FOIA or GDPR are processed in accordance with established SOPs that are reviewed regularly and updated with any legal changes as required. The SOP includes a process for review if a requester asks for a review of information sent out;
- The in-house Information Governance and Records Manager has access to a dedicated DPO who provides advice and support;
- Reports on FOI performance are submitted to every Authority meeting with a summary of the main subjects covered and the requests and responses are also published on the HFEA website.

Policy decisions

- New policy developments are discussed internally, including with HFEA legal advice and external legal advisers where relevant, particularly, for example in relation to changes to the Code of Practice;
- Board decisions taken in public (and recorded) can be used as evidence of reasonableness in case of challenge.

Digital Projects / PRISM Update September 2023

Details about this paper

Area(s) of strategy this paper relates to:	The right information – to ensure that people can access the right information at the right time.
Meeting:	AGC
Agenda item:	9
Meeting date:	03 October 2023
Author:	Kevin Hudson, PRISM programme manager
Annexes	

Output from this paper

For information or decision?	For information
Recommendation:	To note the plan for delivery of OTR (Opening the Register) and CaFC (Chose a Fertility Clinic) through PRISM, the anticipated delivery dates and the mitigations to be enacted to ensure those delivery dates are met.
Resource implications:	
Implementation date:	To deliver OTR through PRISM by the end of July 2023 and to deliver a first CaFC through PRISM by no later than June 2024.
Communication(s):	
Organisational risk:	Medium

1. Introduction and recap from last meeting

1.1. PRISM went live on 14th September 2021 for 40 direct entry clinics and API deployment was completed by the end of June 2022 for the other 62 clinics. Since then, 483,033 units of activity have been submitted through PRISM.

1.2. At the AGC meeting on 27th June 2023, we advised on the latest progress against the completion plan for OTR and CaFC through PRISM. That plan consists of three distinct planning swim-lanes:

- **Data:** Establish the underlying framework, undertake key reconciliations and correct any arising legacy data issues that will impact either on OTR and CaFC.
- **Developers:** Continue to develop PRISM as required by data and clinics, and to build the OTR and 10 family limit reports according to the stakeholder requirements.
- **Clinics:** To address validation errors in relation to data submitted to HFEA and then, subject to review, to conduct further verification exercises prior to CaFC publication.

1.3. At the June meeting we reported that we were making good progress on the data and developer requirements for delivering the OTR reports through PRISM, but that we had downgraded our programme status on clinics due to a slower pace of correction of cycle errors compared to registration errors.

1.4. As reported to AGC, the PRISM completion programme has two key deadlines:

- To complete the required reports for OTR and 10 Family Limit by the end of July 2023, in advance of the anticipated expansion of OTR requests from September 2023.
- To publish the first CaFC through PRISM between the last quarter of 2023 (starting October 2023) and the first half of 2024 (ending June 2024)

1.5. In this paper we will update AGC on the latest progress on each of the current planning swim-lanes, and how we are now amending that plan:

- To take account of the learning after completing the requirements for OTR reporting.
- To ensure that we can provide additional support to those programme areas proving more challenging.
- To ensure that we can continue to deliver the first CaFC through PRISM by no later than June 2024.

1.6. AGC should note that because of issues with clinics and data (described below), we now no longer think it is achievable to deliver CaFC by its earliest date of the last quarter of 2023.

2. Summary of current position against the PRISM completion plan

2.1. A detailed revised completion plan for PRISM, OTR and CafC is appended to this report.

2.2. The current state of the programme, according to its three planning swim-lanes, is as follows:

- **Developers:** The RAG status remains GREEN. Good progress has been made and PRISM developers delivered OTR reports on plan at the end of July which the OTR team are testing before they can be implemented. Developers have also completed 10 Family Limit reports, and their work will now be replanned to support CaFC, our data workstream, and the final stages of PRISM 'bedding in'.
- **Data:** The RAG status has been downgraded to AMBER: During July and August, OTR has proven complex to reconcile although our analyst has made steady progress on this task. As of the end of August the work was largely complete, with perhaps a few weeks remaining work after our lead analyst returns from leave in late September. Moreover, due to sickness, the analyst team has not been at full strength for some months. We plan to rectify these issues through introducing developer support to assist in some areas relating to PRISM data.
- **Clinics:** The RAG status remains AMBER: As previously reported to AGC, clinic correction of backdated cycle errors, necessary for CaFC and OTR, has proven slower than expected. However as per our plan we released our third and final backdate of CaFC related clinic errors in mid-July and we have been closely monitoring the pace of clinic fixes during August. In addition, clinics have raised concern about their readiness to sign off on CaFC if they still have a small number of records on hold due to technical reasons for which we have developed a response plan.

2.3. In the following sections of this report, we will provide details on each of these topics and then outline how we are revising our completion plan to support those areas which are not progressing as fast as others.

2.4. Lastly, we will update on the impact we believe this has for our anticipated timescales.

3. Progress on development: delivering OTR requirements

Progress on OTR

3.1. Our developers have created new OTR reports using SSRS (SQL Server Reporting Services) which provides all the information requested by the OTR team in a single screen of data, and 'one-click' links to associated detailed information such as the corresponding RITA record and Donor Form Images.

3.2. This report has been passed to the OTR team. Over coming weeks, the OTR team will check the data through testing the report against past OTR cases. We expect to have this work completed during September and we will update AGC verbally at the meeting on the current state of sign off on these reports.

3.3. Once the OTR reports have been checked against historic cases and any adjustments made, then the OTR team will need to undergo a further implementation phase before they can issue a final sign-off. This is when they are using the new reports for new OTR cases. Whilst at this stage

the development work is initially complete and PRISM developers are proceeding to focus on CaFC and 'PRISM bedding in', they will remain on immediate standby to support and carry out any further work which may be required if any queries are raised by the OTR team.

Progress on Person ID and 10 Family Limit

3.4. We have also completed the Person ID matching processes that are important for OTR and 10 Family Limit (10FL) reporting. We have matched 1.4 million records, leaving approximately 3,000 for manual matching of which only 88 are donors. The Head of Information has agreed that in relation to donors, this is not a material level for OTR or 10FL.

3.5. The manual matching programme in RITA has been written and tested has been deployed to live so that the Register team can progress through the manual matches that are required.

3.6. We have also completed a new 10FL limit for the Register team and are working with the register team to understand the best ways in which this can be incorporated into their workflows before moving to a completely new solution for 10FL as described below:

3.7. Completion of new 10FL reports, and the structured data-extract that underpins it, also opens the opportunity to publish this information directly to clinics (and not as a Registration Team enquiry as is the current process) and also to ultimately introduce live 10FL alerts on the system as has been suggested by clinical members of the Authority. This will be incorporated as part of our forward development plan.

Planning future development work after completion of OTR

3.8. In our original programme plan, we stated that after completion of OTR reporting work, our developers would move to '*other development tasks or other developments beyond PRISM*'. However, this work has not been previously specified in detail.

3.9. During the summer we confirmed those remaining tasks that our developers can move on to support both clinics and our work on PRISM data in preparation for CaFC. This is described in detail in section 6 below and the appended revised completion plan.

4. Progress on data: ensuring legacy accuracy for OTR and CaFC

Progress of OTR reconciliation

4.1. Whilst our developers have been working to establish the data feeds and construct the reports for OTR, our data analyst has been working on an OTR data reconciliation.

4.2. The objective of this reconciliation is to identify issues in our PRISM and legacy data that might be resulting in an incomplete or inaccurate elements of reported data, and then to apply fixes to PRISM that corrects these issues.

4.3. This reconciliation has proven complex, and over the past months our data analyst has tackled these challenges from a number of different angles which has necessarily increased the time taken on this process.

4.4. During this process, our analyst has to date identified 599 missing linkages for donor eggs, donor sperm and where he can apply a fix to the database to correct the data. Of these only 333 have so far been processed as the remainder relate to clinics who use API solutions.

4.5. There is a risk that if we deploy the fixes to API clinic data, then unless there are clear protocols with the system suppliers, then these could be mistakenly overwritten by the clinic subsequently accessing the record which could introduce serious errors in any subsequent OTR enquiry.

4.6. Therefore, the programme is in discussion with Mellowood and other suppliers to ensure that PRISM synchronisation processes can be guaranteed in the cases where HFEA make changes to historic data. Once this is established, the remaining data fixes will be applied. Given the 'fixing scripts' are already written, those remaining API fixes will be very quick to push through.

4.7. Our data analyst has also identified historic records ('orphaned embryo thaws') that were submitted incorrectly by clinics through EDI and to which he cannot apply a fix without further clinic advice on missing data. This step has been anticipated in our original plan. (See Appendix 1, Clinic planning swim-lane, task described as 'clinic pre-verification').

4.8. Our analyst has now identified 1733 donor egg thaws, 1258 donor sperm thaws and 1198 donor embryo thaws where we will need to contact clinics. During the autumn, the register team will work with the clinics on these records. There are a small number of clinics where they will need to advise on a large number of fixes, and then a longer 'tail' of clinics with a small number of individual issues.

4.9. Whilst there has been a lot of analytical time spent on reconciling OTR, given the relatively small numbers identified as requiring a fix, the inference made from this work to date is that the quality of PRISM data on which our analyst is working is generally good. This exercise has been important in order to prove that fact.

4.10. When he returns from his leave, our analyst has remaining work to conduct on missing embryo thaw linkages for altruistic stored egg donations and fresh and stored egg-share donations.

Current HFEA data resources

4.11. Currently the organisation has no alternative to expertise of the HFEA data analyst, particularly in relation to the structure and linkages of historic legacy data.

4.12. In addition, since May, the analyst team has also been understrength due to our second data analyst, appointed in October 2022, going on long term sick. They were making reasonable progress in working with our data analyst to understand the complexities of legacy HFEA data. As of the time of writing (early September), we are waiting to hear back about a date for their return to work.

4.13. A key objective for replanning developer work will be to assess how they can support our data analyst, particularly in relation to CaFC.

5. Progress by clinics: readiness for CaFC

Current PRISM activity

5.1. As of 4th September 2023, 483,033 units of activity has been submitted to PRISM. This is shown, split by clinics using PRISM direct entry and API supply, in table 1 below.

Table 1 – Cumulative PRISM activity as of 20th February 2023

		Current Activity		Previously Reported Activity									
Method of data submission		As of 4th September 2023		As of 5th June 2023		As of 20th February 2023		As of 21st November 2022		As of 19th September 2022		As of 6th June 2022	
	No of Clinics	Cumulative PRISM Activity	Cumulative PRISM error rate	Cumulative PRISM Activity	Cumulative PRISM error rate	Cumulative PRISM Activity	Cumulative PRISM error rate	Cumulative PRISM Activity	Cumulative PRISM error rate	Cumulative PRISM Activity	Cumulative PRISM error rate	Cumulative PRISM Activity	Cumulative PRISM error rate
Direct Entry	41	137,572	1.5%	120,076	1.6%	104,017	1.7%	87,205	1.3%	72,126	1.0%	52,705	0.7%
API - IDEAS	38	209,105	3.3%	180,307	3.2%	152,881	4.0%	127,902	2.9%	105,533	3.4%	60,792	6.6%
API - Meditex	10	50,307	4.8%	42,171	5.9%	30,384	4.8%	28,575	5.2%	26,137	5.3%	15,177	22.3%
API - CARE	13	86,049	5.4%	76,860	7.4%	64,971	9.1%	48,206	7.2%	42,537	6.6%	32,371	12.3%
Total	**102**	**483,033**	**3.3%**	**419,414**	**3.8%**	**352,253**	**4.3%**	**291,888**	**3.3%**	**246,333**	**3.4%**	**161,045**	**7.3%**

5.2. PRISM submissions are continuing at a steady state of approximately 5,000 submissions per week, although this decreased by about 15% during August, most likely due to clinic staff leave during the school summer holidays.

Clinic Submission Audits

5.3. In 2023/24, the HFEA are recommencing direct and on-site clinic submission audits to ensure that all submissions are being sent to the HFEA.

5.4. Neil McComb, the HFEA Head of Information is leading this work and 10 clinics have been identified for audit during this financial year.

5.5. As well as creating reports for OTR and 10 family limits, PRISM developers have also created new audit reports for Neil and his team. These reports are final stages of sign off.

Update on ARGC deployment

5.6. After the successful deployment of an API migration for 0067 St Mary's Manchester, Rachel Cutting wrote to the PR of the ARGC clinics to advise that they should now commence deployment.

5.7. The PR has been engaged and Rachel has been communicating with him to find a way forward.

5.8. The PRISM programme team are continuing to closely monitor PRISM readiness preparations by ARGC.

Progress by clinics on correcting backdated validation errors for CaFC and OTR

5.9. As shown in table 1, during the summer there has been good error reductions by both Meditex and CARE clinics.

5.10. In mid-July, we also pushed the last of the validation backdates. This related to registration and validation errors that are relevant to OTR and CaFC for the period of EDI submissions between 1st January 2020 and PRISM launch in September 2021.

5.11. We have encountered no issues where clinics have been unable to edit EDI submitted data in PRISM (which would have been the case had there been serious flaws in our data migration).

5.12. During August we observed a reduction in the rate of error corrections. We believe this may be due to natural clinic staff absences during the school summer holidays.

5.13. We reported to AGC in June that we would make steps to improve the rate of error correction by clinics by using the following steps:

- We will update PRISM with the final set of backdated errors for CaFC in July. This was released to the sector on time.
- Over the following weeks, we will continue to monitor how clinics address that final set of errors. As stated above, there was initial good reduction of errors, but this did slow in August.
- Thereafter, we will start to set targets both for the sector and the individual clinics to ensure we 'close out' error correction for CaFC for all clinics.

5.14. To exclude the impact of summer school holidays we will continue to monitor the rates of error correction until mid-September and then communicate and set targets.

5.15. To support this process, our PRISM developers are building a new validation error report dashboard for the register to help support this 'error close out'.

Clinic concerns on CaFC sign off and PRISM bedding in.

5.16. The PRISM programme team speaks with PRISM users at clinics every fortnight through the PRISM user group call. On that call, clinics queried how they will be able to sign off on an updated CaFC if they still have records on hold due to technical issues that would have otherwise been included in the CaFC calculation.

5.17. Arguably this may not be material. The clinic in question had approximately 100 records on hold out of 11,329 cycles submitted in PRISM since launch. However, we also know that CaFC reports to a very fine level of details which necessarily lowers materiality levels (pregnancy and live birth rates), and we know that this is likely to be a very 'symbolic' issue for clinics when it comes to CaFC sign off.

5.18. Consequently, to head off any potential clinic engagement issues relating to CaFC, it will be important to link the completion of CaFC with the completion of PRISM 'bedding in' as we have communicated to clinics both through the Chair's Letter for GD005 and in Clinic Focus.

5.19. The main outstanding issue for 'bedding in' is to address the (relatively) small number of records on hold that clinics cannot submit for technical reasons. This is currently about 1% of records.

5.20. To rectify this, we will be replanning our developers to support not just our data team but also the clinics directly.

6. Replanned approach for developers to support Data and CaFC

A revised completion plan for CaFC and PRISM 'Bedding In'

6.1. With OTR development nearing completion in relation to our development resource, then given the challenges outlined above in relation to data and clinics, it is a natural step for us to think about how our development resource can be applied to support those challenges.

6.2. We therefore propose commencing directing a **whole team approach** to deliver the first CaFC through PRISM and addressing the current data challenges for PRISM.

6.3. Our development resource can support the HFEA data functions and CaFC particularly in relation to data fixes, addressing issues preventing submission of records, and report writing.

6.4. Developers are less able to help in areas requiring detailed reconciliations and calculations, particularly relating to legacy EDI data. Hence is remains important to keep 'protected' time for our HFEA analyst.

6.5. In mid-August the PRISM programme board reviewed this approach, and it was agreed to for the PRISM developers to commence work on the following topics to support the first CaFC through PRISM and deliver 'PRISM bedding in':

- **Data correction by developers:** Our developers are already correcting data issues identified by the Register team and clinics. We proposed to continue this and expand it.
- **Rationalise Inventory**: 'Inventory issues' are the generally the main reasons that clinics are not able to submit records. This was initially addressed in the Movements upgrade, but we would propose to expand this to remove inventory as a 'submission issue'.
- **Work with pilot clinics to completely eliminate submissions on hold:** As part of our forward plan, our developers would select and then work with nominated pilot clinics to understand their 'on-hold' list in its entirely, eliminate those records on hold, and then share this with the sector.
- **Develop CaFC verification reports:** As described in section 3 above, take our learning from developing OTR reports and apply this to the CaFC verification process.
- **General support as required by the HFEA Data Analyst:** Which may include our developers undertaking validation rule reviews and fixing of ancestor linkages that are essential for CaFC.

6.6. In addition to the points above, there are new PRISM developments, that whilst strictly don't relate to CaFC or 'bedding in', may enhance the usability and value perceived from PRISM. We would propose that we consider these points at the same time as those in 6.5 above, including:

- **Live 10 family limit alerts for PRISM users** if selecting a donor known to be close to, or breaching, the limit.
- **Decoupling movements in and out** so a receiving clinic can post a movement in without having to rely on the sending clinic to first post the movement out, but which also triggers a validation rule that alerts the sender that they have posted the movement.

6.7. The revised PRISM completion plan is shown in Appendix 1 at the end of this report. Key changes that we have made include:

- Our data analyst will now only focus on CaFC reconciliation and not on CaFC report generation and general data fixes as well (as was implicit in the original plan)
- Our developers will use the learning from OTR to generate new verification reports for the sector. This is a critical step given our long-term strategic aim to eliminate verification. We will need to structure the verification reports so that it provides the necessary summary information to allow clinics confidence to sign off CaFC without asking clinics to embark on a deep line-by-line examination of their data which will take clinics an inordinate amount of time to complete, and which many may not complete at all.
- Linking CaFC to 'bedding in', whilst possibly introducing additional work to the CaFC process, means that HFEA are not left with a tail of PRISM fixes after CaFC is published, and avoids the risk on engagement issues with clinics when we come to ask them for CaFC sign off.

Updates on delivery timescales for CaFC

6.8. Given the challenges with clinics and with data, the earliest possible date for CaFC (by last quarter 2023) is now not achievable.

6.9. In discussion with our data analyst, they are still of an opinion that a publication of the first CaFC through PRISM by the end of June 2024 (our latest date as advised to AGC) remains achievable.

6.10. Clinics will remain the critical path for CaFC delivery, and the revised completion plan in Appendix 1 indicates the key 'latest milestones' that must be achieved if we are to deliver CaFC by this date:

- Revised summary verification reports need to be issued to clinics by no later than the end of January 2024.
- Clinics need to have reviewed their summary verifications by the end of April 2024
- Clinics to sign off CaFC by the end of May 2024
- CaFC to be published by the end of June 2024

7. Update on resources on PRISM

Contracted resource

7.1. The full-time contract of the PRISM support office is due to expire at the end of September. We will not be extending that contract any further.

7.2. Our employed developers and tester now have a very good knowledge of PRISM and their ongoing work on supporting clinics to complete PRISM bedding-in will also help support the Register team concerning the detailed aspects of PRISM.

7.3. The two-day per week contract for the PRISM programme manager's contract is due to expire at the end of October 2023 but will be extended for a further six months so that they can oversee the PRISM completion plan and CaFC delivery.

7.4. The three-day per week contract for our longstanding contracted data developer remains to retain them at 3 days per week until March 2024 at the earliest. They remain important both for the PRISM database and also Epicentre replacement.

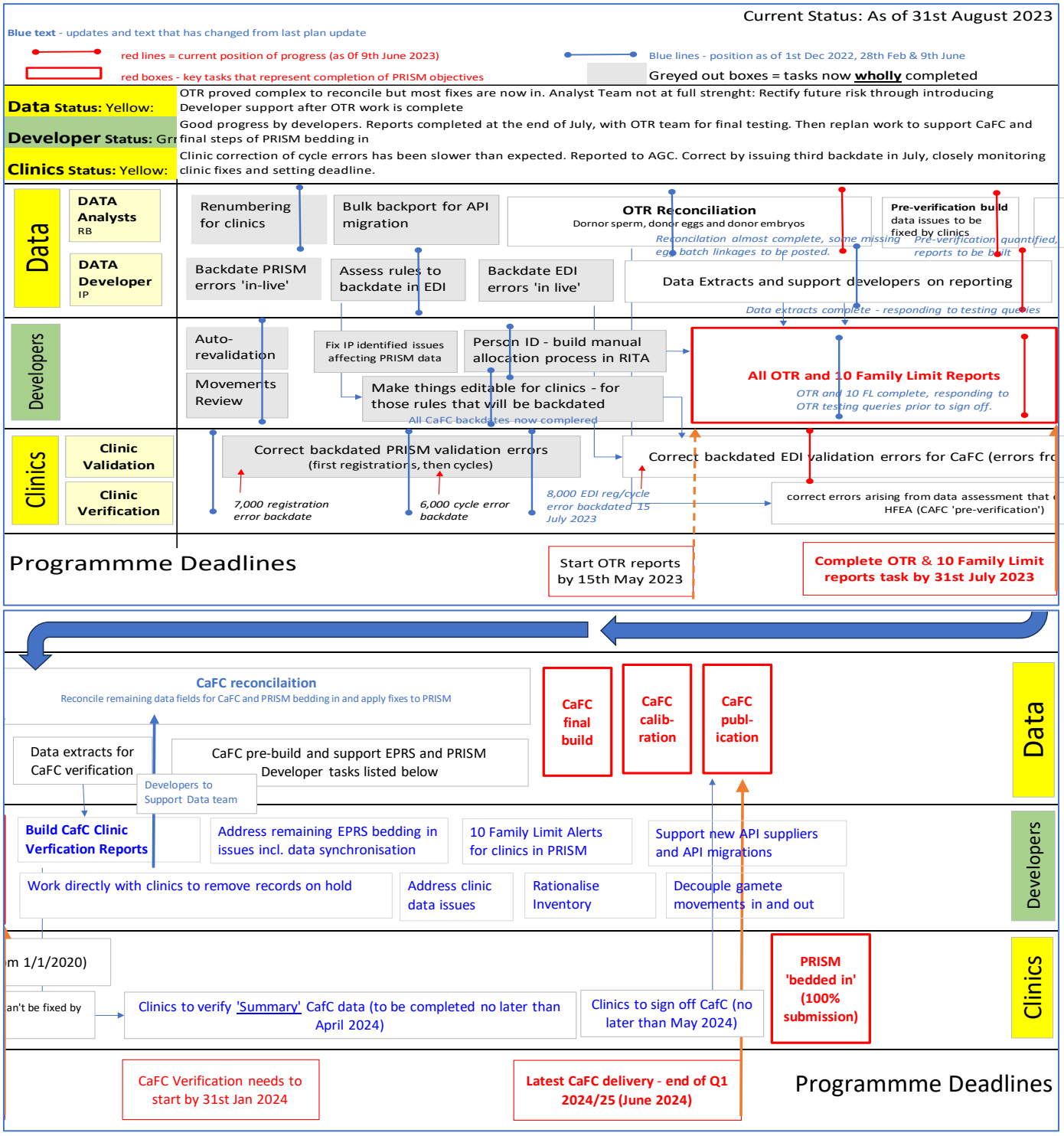
7.5. We are currently seeking the necessary DHSC approval for extension on these two roles.

8. AGC recommendations

8.1. AGC are asked to note:

1. As per plan, PRISM developers have completed the OTR and 10 Family limit reports. The OTR team are testing these reports against historic OTR cases and will feedback any issues which arise to the development team. If required further development work and testing will be undertaken. Once the OTR team are content with the functionality they will move to an implementation phase before these reports are signed-off.
2. That the OTR reconciliation took longer than anticipated but that no major issues were found in the data. A small number of fixes are being processed by our analyst and clinics are being asked to advise further on records where we have insufficient data.
3. As per plan, we have finished the backdate for CaFC errors and some clinic groups have made good progress on fixing errors. However, there is still more work to be done and we will initiate an 'error close out' programme in the coming weeks.
4. We are refocussing our developer resource to support both our data activity for CaFC and direct support for clinics to accelerate PRISM 'bedding-in'.
5. Accordingly, we have issued a revised completion plan which is appended to this report.
6. We still anticipate delivering CaFC before the end of the first half of 2024.

Appendix 1: Revised PRISM Completion Plan



Resilience, Business Continuity Management and Cyber Security

Area(s) of strategy this paper relates to:	The right information – to ensure that people can access the right information at the right time		
Meeting:	AGC		
Agenda item:	10		
Meeting date:	03 October 2023		
Author:	Martin Cranefield, Head of IT and Neil McComb, Head of Information		
For information or decision?	For information		

Recommendation	The Committee is asked to note:
	• Infrastructure improvements
	  • IT security changes
	  • Data backup review
	  • Application & web penetration testing
	• Current position on Data Security and Protection Toolkit		

Implementation date	Ongoing		
Communication(s)	Regular, range of mechanisms		
Annexes	7a –HFEA Risk Strategy, 7b – Operational risk register and Top 3 risks screenshots, 7c – Risk appetite statement, 7d strategic risk register		
Organisational risk	☐ Low	☒ Medium	☐ High

1. Introduction and background

1.1. In recent months, AGC has received regular and detailed updates on Resilience, Business Continuity Management and Cyber Security, in line with the strategic risk register.

1.2. This paper provides an update on IT infrastructure and cyber security in a number of areas.

1.3. It also includes an update on our current approach to submitting evidence for next year's Data Security and Protection Toolkit

2. Infrastructure improvements

IT security changes

2.1. We have successfully rolled out 'Number Matching' in the Microsoft Authenticator app when using multi-factor authentication across most of our services. There are a few remaining services that are using the traditional Approve/Deny prompt via the app and we are looking to move them over to 'Number Matching' soon.

2.2. We are currently in the process of upgrading the Windows server operating systems of all our virtual servers in the Microsoft Azure cloud to later versions of Windows Server, as the version 2012 is soon to stop receiving important Windows security updates. We are approaching the upgrades in a phased approach and are due for completion by end of September.

Recent public cyber attacks

2.3. There have been a number of well-known bodies who have experienced a cyber-attack in recent times which have led to data breaches. In the case of the Electoral Commission, it appears they were the subject of a cyber attack in August 2021, and that it had first identified access to its systems in October 2022. It appears the Electoral Commission was running Microsoft Exchange Server with Outlook Web App (OWA) facing the internet and was vulnerable to an exploit known as ProxyNotShell at the time that suspicious activity was first detected in October 2022. The HFEA does not have an internet-facing Microsoft Exchange Server as we migrated to Microsoft Office365 for email services a few years ago.

Data backup review

We are still working through some outstanding items highlighted in the external backup report to further strengthen our backup resilience.

Application & Web penetration testing

2.4. The pen testing was executed as scheduled and we have received the security reports which covers our key systems that were tested. We are working through the findings of the reports and will provide a more comprehensive update at the next AGC.

3. Data Security and Protection Toolkit (DSPT)

Background

3.1. The new toolkit will be available to us soon. There are no updates since the last meeting of AGC.

Counter-Fraud Strategy

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society
Meeting:	AGC
Agenda item:	11
Paper number:	HFEA (14/03/2023)
Meeting date:	3 October 2023
Author:	Morounke Akingbola, Head of Finance
Annexes	Annex 1: Counter-Fraud Strategy Annex 2: Fraud Risk Assessment (FRA)

Output from this paper

For information or decision?	For information
Recommendation:	AGC are requested to review/comment
Resource implications:	None
Implementation date:	Ongoing
Communication(s):	via the 'Hub'
Organisational risk:	Medium

1. Purpose

1.1. The Counter-fraud Strategy was developed as part of the HFEA's commitment to tackling fraud, bribery and corruption and is a key aspect of the Government Functional Standard GovS 013 Counter Fraud. The strategy was developed in October 2019 when it was first shared with the Committee at the 8 October 2019 meeting. Updates were given with the latest at the March 2023 meeting.

1.2. The strategy has not been materially changed.

1.3. At item 12, is the latest Fraud Risk Assessment (fraud register) which was reviewed by the Corporate Management Group (CMG) at its August 2023 meeting. No new risks have been identified. Additional actions have been identified and it is expected that risk owners will ensure risks assigned to them are added to operational risk registers and managed accordingly.

2. Action

2.1. The Committee are requested to comment on the strategy and the high-level action plan (pages 7 and 8) and the Fraud Risk Assessment at item 12.

Counter-Fraud Strategy 2023-25

Our Vision

Regulating for excellence: shaping the future of fertility care and treatment

Our Values

Together as one

Work Together as One

Make it happen

Make it Happen by reacting positively to change and overcoming challenges

Look forward, stay ahead

Look Forward and Stay Ahead by making decisions that impact the big picture

Know your impact

Know our impact by acting with integrity and compassion in everything we do

Counter Fraud Strategy

1. This document sets out the HFEA's strategy in relation to fraud and corruption. Th HFEA takes its responsibilities for the stewardship of public finances very seriously and is committed to the highest standards of transparency and accountability in order to ensure appropriate use of public funds and assets. It has a duty to prevent fraud and corruption, whether attempted by someone within or outside of the organisation, such as another organisation, an employee, a supplier or a contractor.

2. The Authority is committed to creating and maintaining an effective anti-fraud and corruption culture, by promoting high ethical standards and encouraging prevention and detection of fraudulent activities.

3. In all of its dealings the HFEA will adhere to the seven principles of public life set out in the Nolan Committee's report on Standards in Public Life: Selflessness, Integrity, Objectivity, Accountability, Openness, Honesty and Leadership.

4. Our strategy is based upon three key principles; Acknowledge; Prevent; and Pursue. We will take steps to:

   - assess and understand fraud risks (acknowledge);
   - communicate and promote an effective anti-fraud culture and implement appropriate and robust internal controls and security measures (prevent);
   - take appropriate action in response to suspected fraud, including legal action where appropriate (pursue).

Policies and Procedures

5. The HFEA has in place a number of policies and procedures that are relevant to this strategy and, amongst other things, sets out expected standards of behaviour and how to respond to suspected fraud or irregularities.

6. An overview of the key relevant policies and procedures is as follows:

Culture
Audit and Governance Committee – Terms of Reference
Data Protection Policy
Counter Fraud and Anti-Theft policy, conflicts of interest, gifts and hospitality
Freedom of Information Publication scheme
Recruitment and Retention Policy

Detection

Counter Fraud and Anti-Theft policy

Public Interest Disclosure (whistleblowing) policy

Complaints policy

Prevention

Counter Fraud and Anti-Theft policy

Declaration of interests, gifts and hospitality

Expense policy

Procurement and tendering policy

Investigation and Reporting

Public Interest Disclosure (whistleblowing) policy

Counter Fraud and Anti-Theft policy

Disciplinary policy

Complaints policy

As part of this strategy, the HFEA will ensure the following actions at Annex A are implemented.

Implementation

7. Implementation of this Strategy takes account of the controls that are already in place to mitigate fraud risk. Actions (high-level) to achieve the above objectives are at Annex A.

Accountability

8. The Director of Resources is the SMT member responsible for counter fraud and has delegated responsibility for maintaining, reviewing and implementing this Strategy to the Head of Finance.

9. Additionally, all other Directors and Heads of Directorates are responsible for ensuring that the Strategy is applied within their areas of accountability and for working with the Head of Finance in its implementation. All employees and Authority Members have a responsibility to work in line with this strategy and support its effective implementation. Details of responsibilities are set out in the Counter-Fraud Policy.

10. Progress on implementing this Strategy will be provided to the Audit and Governance Committee (AGC) in addition to the Department of Health and Social Care Anti-Fraud Unit (DHSC AFU).

11. The effectiveness of counter fraud controls is assessed in part by Internal Audit reviews, and an overview of the effectiveness of our mitigating controls are contained in the Internal Audit reports submitted to AGC. Any strategic concerns could be raised in these reports.

Measures of success

12. The successful implementation of this strategy will be measured by:

- successful implementation of the actions contained within the strategy;
- increased awareness of fraud and corruption risks amongst members, managers and employees;
- evidence that fraud risks are being actively managed across the organisation;
- increased fraud risk resilience across the organisation to protect the HFEA's assets and resources;
- an anti-fraud culture where employees feel able to identify and report concerns relating to potential fraud and corruption.

Reporting and review

13. The HFEA's approach to suspected fraud can be demonstrated in its Fraud Response Plan contained in the Counter-fraud and Anti-theft Policy

14. The responsibility for the prevention and detection of fraud rests with all staff, but Directors and Managers have a primary responsibility given their delegated contractual and financial authority. If anyone believes that someone is committing a fraud, or suspects corrupt practices, these concerns should be raised in the first instance directly with line management or a member of SMT then the Chair of the Audit and Governance Committee.

15. The Chief Executive and the Director of Finance and Resources have responsibility for ensuring the HFEA has a robust anti-fraud and corruption response.

16. The Audit and Governance Committee will ensure the continuous review and amendment to this Strategy and the Action Plan contained within it, to ensure that it remains compliant with good practice national public sector standards, primarily Cabinet Office Functional Standards: Counter-fraud.

Document name	Counter fraud strategy
Original release date	August 2019
Author	Head of Finance
Approved by	AGC
Next review date	September 2024
Total pages	5

Version/revision control

Version	Changes	Updated by	Approved by	Release date
1.0	Created	HoF	AGC	Aug 2019
2.0	Updates added	HoF	AGC	Mar 2021
2.1	Cashflow figures amended	HoF	AGC	Oct 2017
2.2	Reviewed	HoF	AGC	Oct 2018
2.3	Reviewed by DoF and amended	HoF	AGC	Dec 2019
2.4	Reviewed unchanged	HoF	AGC	Oct 2020
2.5	Reviewed; min reserves balance amended	HoF	AGC	Oct 2021
2.6	Reviewed: no changes	Hof	AGC	Oct 2022
2.7	Updated key actions	Hof	AGC	Oct 2023

Annex A: Strategic Action plan 2023-25

Aim	Actions	Frequency	Owner	Actionee
Commitment to counter fraud and culture of zero tolerance in relation to fraud and corruption	Review and approval of Counter Fraud Strategy	Every three years	Director of Finance and Resources	Head of Finance
Strategy	Review and update policies and procedures, which are relevant to this strategy	As detailed in each policy and procedure	Director of Finance and Resources	Head of Finance
	Raise awareness of counter fraud strategy through: • Staff induction • Share on the Hub • Email to managers • Training	As required As required Annual Annual	Director of Finance and Resources	Head of Finance
Identify vulnerable areas in relation to fraud, bribery and corruption	Establish and maintain a fraud risk register identifying high risk areas	Bi-annual review		Head of Finance
	Review internal and external audit finding	On publication of internal and external audit reports	Directors	Heads of Service
	Promptly investigate allegations of fraud and irregularities	As required	In line with the relevant policy	
Prevent fraud through the use of appropriate and robust internal controls	Review and update, as appropriate, the finance policies, including procurement and tendering policy and expenses policy	As detailed in each policy	Director of Finance and Resources	Head of Finance
	Approve the internal audit annual plan, which incorporates audits of key	Annually	Senior Management Team	Heads of Service

	areas and the associated internal controls			
Recover losses resulting from fraud	In proven cases apply appropriate sanctions and take steps to recover money or assets	As required	Director of Finance and Resources	Head of Finance

Reserves Policy

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Meeting	AGC		
Agenda item	13		
Paper number	HFEA (16/03/2021) MA		
Meeting date	3 October 2023		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	The Committee are requested to approve the Reserves Policy		
Resource implications			
Implementation date	2023/24 business year		
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High

Background

For several years up to 2016, the HFEA has posted surpluses which have led to a considerable cash reserve. We have tried to reduce our cash reserves by diverting funds towards our development projects and have also maintained licence fees levels.

In 2020/21 during the COVID-19 pandemic, we anticipated that the disruption would impact on our cash reserves where clinic activities were reduced and in turn their ability to pay their licence fees.

We secured funding from the DHSC (£2.4m) to plug any gaps and only drew down £1.3m of grant in aid at the end of the financial year. Our closing cash position at the 31 March 2021 was £3.3m, £0.7m more than a target that was set over four years ago.

In January 2021 we relocated to new offices which resulted in lower accommodation costs. Factoring this into our reserves policy and reviewing the other fixed costs that would need to be paid regardless of unforeseen difficulties has resulted in a small reduction in our minimum reserves from £1.4m to £1.3m.

Our cash balance at the end of 2021/22 was £3.7m and at the end of 2022/23 was £3.4m. This is still higher than our target of £1.52m. The issue of utilisation of our reserves in order to reduce our cash reserves still remains.

There have been increases in some of the fixed costs since the policy was last presented. Where the HFEA has chosen to hold reserves for two months, these costs have increased from £730k to £888k, driven by staff costs. The amount we hold for other commitments has reduced from £119k to £80k.

The amendments to the policy are:

- Para 10 salaries and accommodation costs are 75% increased from 69%
- Para 11 salaries and accommodation costs for two month (£888k)
- Para 12 other commitments (£80k)
- Para 13 contingency (£976k)

We are proposing that the reserves are maintained at a minimum level of £1.38m until the next review.

The Committee are requested to review and approve the enclosed Reserves policy.

Reserves Policy

Introduction

The purpose of this policy is to ensure that both the Executive and Authority of the HFEA are aware of the minimum level at which reserves are maintained and the reasons for doing so. The minimum level of reserves set out in this policy has been agreed with the Department of Health.

Principles

An organisation should maintain enough cash reserves to continue business operations on a day-to-day basis and in the event of unforeseen difficulty and commitments that arise. It is best practice to implement a reserves policy in order to guide key decision-makers.

Reserves Policy

1. The Authority has decided to maintain a reserves policy as this demonstrates:

    - Transparency and accountability to its licence fee payers and the Department of Health and Social Care;
    - Good financial management;
    - Justification of the amount it has decided to keep as reserves.

2. The following factors have been taken into account in setting this reserves policy:

    - Risks associated with its two main income streams - licence fees and Grant-in-aid - differing from the levels budgeted;
    - Likely variations in regulatory and other activity both in the short term and in the future;
    - HFEA's known, likely and potential commitments.

3. The policy requires reserves to be maintained at least at a level that ensures the HFEA's core operational activities continue on a day-to-day basis and, in a period of unforeseen difficulty, for a suitable period. The level should also provide for potential commitments that arise.

Cashflow

4. To enable sufficient cover for day-to-day operations, a cash flow forecast is prepared at the start of the financial year which takes account of when receipts are expected, and payments are to be made. Most receipts come from treatment fees - invoices are raised monthly and on average take 60 days to be paid. Cash reserves are needed to ensure sufficient working capital is available to make payments when they become due throughout the year.

5. The HFEA experiences negative cashflow (more payments than receipts) in some months but overall, there is a net positive position. During 2020/21 and 2021/22, debtor days increased on the back of COVID-19 and PRISM embedding which caused a delay in billing and debt collection. This has impacted on cashflow profile over the last 3 financial years. Based on a review of our cashflows over the last few years till 2021/22, we see on average net cash outflows over the last quarter of c£300k, with the range being between £100k and £400k. In order to ensure that there is always a positive cash balance we would wish to maintain a working capital cash balance of £400k, based on our most unfavourable outflow in the last 4 years.

Contingency

6. The certainty and robustness of HFEA's key income streams, the predictability of fixed costs and the relationship with the Department of Health and Social Care, would suggest that HFEA would be unlikely to enter a prolonged period of financial uncertainty that would result in it being unable to meet its financial liabilities.

7. However, it is clearly prudent for an organisation to retain a sufficient level of reserves to ensure it could meet its immediate liabilities should an extraordinary financial incident occur.

8. In arriving at a reserve requirement for unforeseen difficulty we have considered the likely period that the organisation might need to cover and whilst discussions are undertaken to secure the situation, the immediate non-discretionary spend that would have to be met over that period.

9. We believe that a prudent assumption would be to ensure a minimum of two months of fixed expenditure is maintained as a cash reserve; in terms of the costs that would need to be met we consider the following to be non-discretionary spend that would be required to ensure the HFEA could maintain its operations:

    a. salaries (including employer on-costs);

    b. the cost of accommodation.; and,

c. Sundry costs related to IT contracts, outsourced services, and other essential services.

10. These fixed costs would have to be paid in times of unforeseen difficulty, salaries and accommodation costs alone represent 75% of the HFEA's total annual spend.

11. Based on the HFEA's current revenue budget, the combined monthly cost of salaries and accommodation is £444k, accommodation costs have decreased since the relocation to 2 Redman Place in January 2021, however our wages and salaries have increased. A reserve of two months for these two elements would therefore be £888k.

12. A further reserve for other commitments for two months is estimated to be £80k.

Minimum reserves

13. The HFEA's minimum level of reserves will be maintained at a level that enables positive cashflow (£400k), provides £976k for contingency. The minimum level of cash reserves required is therefore £1.38m (rounded). These reserves will be in a readily realisable form at all times.

14. Each quarter the level of reserves will be reviewed by the Director of Finance and Resources as part of the HFEA's ongoing monitoring of its cash flow.

15. Each autumn as part of the HFEA's business planning and budget setting process, the required level of reserves for the following financial year will be reassessed.

16. In any assessment or reassessment of its reserves policy the following will be borne in mind.

    - The level, reliability, and source of future income streams.
    - Forecasts of future planned expenditure.
    - Any change in future circumstances - needs, opportunities, contingencies, and risks – which are unlikely to be met out of operational income.
    - An identification of the likelihood of such changes in these circumstances and the risk that the HFEA would not be able to meet them.

17. HFEA's reserves policy will be reviewed annually by the Audit and Governance Committee.

Document name	Reserves Policy
Original release date	October 2014
Author	Head of Finance
Approved by	AGC (to be shared with CMG prior to tabling at AGC)
Next review date	September 2024
Total pages	3

Version/revision control

Version	Changes	Updated by	Approved by	Release date
1.0	Created	DoF	AGC	Feb 2015
2.0	Branded/amended	HoF	AGC	Dec 2016
2.1	Cashflow figures amended	HoF	AGC	Oct 2017
2.2	Reviewed	HoF	AGC	Oct 2018
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2.6	Reviewed: no changes	HoF	AGC	Oct 2022
2.7	Reviewed: amends to budget figures	HoF	AGC	Oct 2023

Government Functional Standards

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society
Meeting:	AGC
Agenda item:	14
Meeting date:	03 October 2023
Author:	Tom Skrinar
Annexes	Annex A (enclosed)

Output from this paper

For information or decision?	For information
Recommendation:	AGC is asked to: • note the latest position regarding embedding the use of Functional Standards within HFEA, and • agree the proposed deep dives for Q4
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	
Organisational risk:	Medium

1. Purpose

1.1. To provide an update on HFEA work to embed Government Functional Standards (GFS), and to outline the planned approach for the coming twelve months.

2. Background

2.1. The GFS were created to promote consistent and coherent ways of working across government, and provide a stable and comparable basis for assurance, risk management and capability improvement. The standards serve to help accounting officers fulfil their duties and do not alter the fundamental principles of Managing Public Money (MPM), bringing together and clarifying what should already be happening.

2.2. Fifteen standards have been issued and updated since 2021 and are mandated for use across Government Departments and Arms-Length Bodies, with an expectation that they would begin to be embedded from April 2022. The initial priority is to ensure that all organisations in scope can at least meet the mandatory ('shall') elements of each standard.

2.3. The self-assessment process requires consideration of an organisation's levels of maturity against each standard. In summary these levels are:

- Good – meets all mandatory elements and key advisory elements;
- Better – building on the above, the majority of advisory elements are met;
- Best – meets all mandatory and advisory elements of the standard.
- 'Developing' – does not meet all mandatory requirements.

2.4. Assessments should be undertaken as part of routine assurance, rather than an additional process for accounting officers to engage with, and organisations should set their maturity ambition based on business need.

3. Review

3.1. HFEA teams have undertaken high level reviews against the mandatory "shall" elements of the Functional Standards (see Annex A). As previously, only one of the standards is entirely out of scope for HFEA: GovS 015 Grants, although DHSC has confirmed with HTA that GovS 003 Human Resources is not considered proportionate for organisations such as HTA or HFEA. Other standards may be more or less in scope (eg relating to Property), and we will continue exploring with the Department what their intention is for HFEA regarding Functional Standard Compliance in specific business areas.

3.2. For the most part, teams consider themselves to be broadly compliant with the core requirements and there were no areas where teams felt that they deviated significantly from mandatory elements described in the functional standards, or where urgent attention was required.

3.3. From a continuous improvement perspective, there is clearly more that HFEA can do to compare itself against the Functional Standards but, given the size and scale of the organisation, the intention is to take a proportionate approach in reviewing the

standards, in particular aligning the timing of any detailed reviews with current planning schedules. This has also been outlined in Annex A, with each area including an outline of current levels of risk and/or ambition that might drive a detailed review and plans for next steps (including some planned self-assessments and further discussion with DHSC or Functional Leads who are responsible for individual Standards).

3.4. Centrally prepared self-assessment tools have not yet been prepared for all of the functional standards. The ones that have been prepared are very good and provide a clear and structured approach to self-assessment. HFEA proposes that it does not create its own tools as they would require significant resource to be developed to a sufficiently high standard. Furthermore, standardised assessment will allow meaningful benchmarking between Organisations, and a home-produced assessment tool could reduce comparability with other ALBs. The Director of Finance and Resources has contacted Functional Leads to discuss the assessment and the availability of tools, some of which are in development and will become available over the coming months.

3.5. There is an expectation that future Internal Audits will make specific reference to, and expect to see demonstrable compliance with, functional standards. **[refer to the internal audit plan – where is it? What areas will be reviewed by GIAA against the Functional Standards?]** HFEA also needs to specifically discuss compliance with GovS 009: Internal Audit with GIAA.

3.6. Furthermore, as outlined in Annex A, there are other areas of HFEA business that are planning reviews or policy development that will need to refer to functional standards, including a review of project management and the development of a Business Continuity Plan and Incident Response.

3.7. Having completed an initial review, HFEA proposes the following areas for a deep dive with AGC in Q4:

- **GovS 008: Commercial.** Although HFEA does not regularly carry out significant procurements, the Director of Finance and Resources would like to review procurement practices, in particular considering potential future IT procurement. The intention would be to discuss expectations with DHSC Commercial and consider which elements of the Commercial Continuous Improvement Assessment Framework are most relevant to HFEA and self-assess against those.

- **GovS 014: Debt.** Although HFEA is broadly compliant with sections of the Debt Functional Standard that are relevant, the Director of Finance and Resources would like to consider whether there are opportunities for improvement with the HMT Debt Functional Lead.

4. Recommendation

4.1. The Committee is asked to agree the continuing proportionate approach in conducting the review of functional standards and embedding them in HFEA continuous improvement.

4.2. The Committee is asked to agree the proposed deep dives for Q4 (at 3.7).

Functional Standard	HFEA lead	High level review against mandatory standard	Risk and ambition	Planned next steps
GovS 001:Government functions	HFEA Accounting Officer and Executive	This FS is principally for functional leads in Government departments and is designed to set the FS framework in which ALBs should work. We are already compliant with the long-standing requirements of Managing Public Money, assessed by GIAA and the NAO. We also meet the governance requirements set by DHSC as our sponsor department.	Risk: That assurance within the HFEA is not tailored to the size and complexity of the organisation (see 4.5.4). Ambition: that FS are appropriately embedded and measured via GIAA and DHSC accountability meetings over time.	See each FS below.
GovS 002: Project Delivery	Head of Planning and Governance	We are already broadly compliant with the majority of the standards, however, functional standards in these areas may need more development work where are managing large projects. Many areas of the standards don't apply for smaller projects; however, governance and reporting structures are well established and have been acknowledged as such in recent audits.	The recent audit of our project management function (report issued 21 Apr 23) was rated 'moderate' overall, and the majority of the recommendations have already been put in place. The report did not refer to any functional standards.	A full assessment is to be completed as part of the project management review which is currently in train. We will be assessing our PMO systems in line with the review and are aiming to finish this work by the end of Q4 23-24. Our major programmes fall outside of this review and will be addressed separately.
GovS 003: Human Resources	Head of HR	DHSC HR advised this was not proportionate for organisations such as HTA or HFEA.	HFEA will continue to focus on best practice in its HR service.	Head of HR to review Assessment Tool in considering approach to continuous improvement.
GovS 004:Property	DHSC Estates	HFEA do not own or manage Government property or property leases directly. Will take lead from DHSC Estates.	HFEA do not own or manage Government property or property leases directly. Will take lead from DHSC Estates	Director of Finance and Resources to meet with the DHSC Director of Workspace, Information, Security and Technology.

GovS 005: Digital, Data and Technology	Director Compliance and Information	Broadly Compliant	We commissioned a 3rd party review of data backups and are working to implement the recommendations. Compliance generally maintained via DSPT process.	Will consider more detailed review once Assessment tool available Autumn 2023.
GovS 006:Finance	Director Finance & Resources	Broadly Compliant. Applies to ALBs in the same way as HMT Managing Public Money and agreed Framework agreements between sponsor and ALB.	Director of Finance and Resources is keen to further standardise systems and processes across HFEA and HTA	Director Finance & Resources will refer to Standard Self-Assessment Tool and HMT GFF support in exploring options for shared finance service structure and process.
GovS 007:Security	Director Compliance and Information	Broadly Compliant	We recognise Business Continuity plan and roles & responsibilities need improvement. Compliance generally maintained via DSPT process and NCSC guidance.	Development of Business Continuity plan and Incident Response.
GovS 008: Commercial	Director Finance & Resources	A basic level of compliance. To be reviewed in more detail in discussion with DHSC commercial.	HFEA does not regularly undertake significant procurement, but the new Director of Finance and Resources to review practices, in particular considering the need for IT procurement.	Director of Finance and Resources to meet with DHSC commercial colleagues to discuss in more detail. Possible deep dive for Q3.
GovS 009: Internal Audit	Director of Finance & Resources	To discuss with GIAA	To discuss with GIAA	To discuss with GIAA.
GovS 010: Analysis	Head of Intelligence	Compliant	Risk against data release are reviewed monthly/weekly by team, monthly by CMG and on the strategic risk register by AGC/Authority	SOPs up to date. Lessons learnt after each set of data release. Compliance with other standards e.g. publication of official statistics

GovS 011: Communications	Head of Communications	All compliant where standard is applicable.	Monthly review of risk against principles in standard by team and CMG	Communications strategy reviewed by Authority. New comms strategy developed in parallel with any new organisational strategy. Evaluation of comms plans for each major piece of work/campaign circulated to SMT.
GovS 013:Counter Fraud	Head of Finance	Broadly compliant with standard and in line with broader UK Government counter-fraud standards	Counter-fraud strategy presented to AGC on 2 October 2023, created with reference to the Functional Standard	Established requirement in line with extant Cabinet Office guidance and expectations.
GovS 014: Debt	Director Finance & Resources	Not all of the standard is relevant to HFEA. To discuss further with the HMT debt functional lead.	Will review debt management policy in line with a view to assessment opportunities for improvement.	Director of Finance and Resources to meet with HMT Debt Functional lead to discuss approach. Possible deep dive for Q3.

Audit and Governance Committee Forward Plan

Strategic delivery:	☐The best care – effective and ethical care for everyone	**X**The right information – to ensure that people can access the right information	☐Shaping the future – to embrace and engage with changes in the law, science and society

Details:	
Meeting	Audit & Governance Committee Forward Plan
Agenda item	15
Meeting date	3 October 2023
Author	Morounke Akingbola, Head of Finance
Output:	
For information or decision?	Decision
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the Forward Plan.
Resource implications	None
Implementation date	N/A
Organisational risk	☒ Low ☐ Medium ☐ High Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information
Annexes	N/A

Audit & Governance Committee Forward Plan

AGC items Date:	27 Jun 2023	3 Oct 2023	7 Dec 2023	5 Mar 2024
Following Authority Date:	12 July 2023	15 Nov 2023	24 Jan 2024	20 Mar 2024
Accounting policies				Yes (annually)
Strategic Risk Register	Yes	Yes	Yes	Yes
Horizon scanning				
Deep dives		Legal risk		Impact of onerous corporate governance standards on ability to deliver plans. Functional Standard (Commercial and Debt)
Risk Management Policy[1]	Updated Risk Strategy/ Appetite statement		Risk management strategy	
Digital Programme Update	Yes	Yes	Yes	
Annual Report & Accounts (including Annual Governance Statement)	Yes – For approval			
External audit (NAO) strategy & work	Audit Completion Report		Audit Planning Report	Interim Feedback
Information Assurance & Security	Yes, plus SIRO Report			
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes

[1] Policy will have been reviewed by the Executive, including updated appetite statement for Authority approval.

AGC items Date:	27 Jun 2023	3 Oct 2023	7 Dec 2023	5 Mar 2024
Internal Audit	Results, annual opinion approve draft plan	Update	Update	Update
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Public Interest Disclosure (Whistleblowing) policy				Yes
Anti-Fraud, Bribery and Corruption policy				Yes
Counter-fraud Strategy (CFS), Fraud Risk Assessments (FRA) and progress of Action Plan		Counter-fraud Strategy (CFS) FRA		
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes	Bi-annual HR report		Bi-annual HR report	
Training			Yes- see action from Dec 22	
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Reserves policy		Yes		
Estates	Yes			
Review of AGC effectiveness and terms of reference		Yes – update from 22/23 effectiveness review and table draft questionnaire for AGC members to complete by December.	Yes – standard review	

AGC items Date:	27 Jun 2023	3 Oct 2023	7 Dec 2023	5 Mar 2024
Functional standards	Yes	Yes	Yes	Yes
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes

Suggested training for Committee Members

- Understanding good governance – Dec 23 PR to take forward – meeting arranged with CiPFA (11/09/23).
- Risk Management
- Counter fraud
- External Audit – Knowledge of the role/functions of the external auditor/key reports and assurances.

Suggested deep dive topics as agreed at the 4 October 2022 meeting and not yet listed

- The effectiveness of performance management and risk (as this would be a year after the new system has been embedded).
- Staff retention
- Impact of communication
- HFEA's regulatory effectiveness if some or all of our ambition for legislative change fails.

Suggested deep dive topics as agreed at the 8 December 2022 and revisited at 14 March meeting but yet to be decided when to have them

- OTR - what it means for the organisation
- Retention recruitment- resource risk
- Legal risk and how it will be mitigated
- Public body review – lessons learned?

Suggested deep dive topics as agreed at the 27 June 2023 meeting but yet to be decided when to have them

- CaFC