

HTA Board meeting, 7 March 2024

Agenda item	2.4 / 24 HTA Performance Report
Purpose: for information or decision?	Assurance / reporting
Decision making to date?	N/A
Recommendation	The HTA Board is asked to note and comment on the performance recorded and the context provided.
Which strategic risks are relevant?	All
Strategic objective	Strategic direction
Core operations / Change activity	Core operations and Change activity
Business Plan item	Senior Management Team – strategic direction and leadership of operational delivery across the organisation (including risk management)
Committee oversight?	Board only
Finance and resource implications	Various due to the range of items covered
Timescales	Various due to the range of items covered
Communication(s) (internal/external)	N/A

stakeholders)	
Identified legislative implications	N/A

HTA Performance Report

by CEO and Senior Management Team

Purpose

1. To inform the HTA Board of the HTA's performance in Quarter 3 (Q3) against our objectives and operational delivery targets
2. In addition, it provides an early indication of the initial performance in Quarter 4 (Q4).
3. Core operations areas from our Business Plan with formal Key Performance Indicators (KPIs) have been included as topics within this paper. These appear in the same order as that document, to allow Board members easy read across. Annex A provides the KPI and Project Data Overview for Q3 (final) and Annex B gives the KPI and Project Data Overview for Q4 (latest).

Regulation

4. KPIs for Regulation were all on track at the end of Quarter 3 with one exception: *100% of panel cases actioned within 10 working days*, which was marginally off-track at 99% as one case was slightly late (by one day and this had no clinical impact). The causes of the delay have been identified and remedial steps taken to mitigate the risk of recurrence.
5. The HTA undertook a mandatory Data Collection Exercise across all licensed establishments in the first half of the year, building on the pre-Covid 'Compliance Updates' process. Sector specific surveys were issued focused on specific areas of risk or concern in each sector. Following a break over the summer and early autumn, further activity was initiated during Quarter 3 (running into Quarter 4) to continue the collection and analysis of the data received. This work is now completed, and a report will be considered by SMT in March with an update on the outcomes provided to the next Board meeting.

6. Evaluated self-assessment (ESA) is one of our “new” regulatory tools as we seek to take more proportionate and bespoke approaches according to the risk presenting. We have continued to undertake these for lower risk establishments in the Research sector and are on-target to deliver 30 of these new assessments by the end of this business year. SMT considered the proof of concept completion report in Quarter 4 and noted the pilot this year had confirmed the usefulness of this tool and the benefits it provided of ‘Engagement, Screening and Awareness-raising’. The report highlighted the effective use made of digital tools (MS Forms), the overwhelmingly positive feedback on the process (from establishments and staff) and that this was a helpful addition to our broadening range of compliance assessment methodologies, that would feed into the next steps following our Review of Inspections project.
7. Active work on the Review of Inspections Phase 1 project was completed in Quarter 2 and we have reviewed the outcomes. The review provided a high-level mapping of the end-to-end inspection process in the HTA and gave an outline of the time spent on each element. This indicated that post-inspection activity amounted to up to 60% of the time; that time spent on VRAs (Virtual Regulatory Assessments) and hybrid approaches could be significantly greater than time spent on more traditional on-site only inspections; and highlighted the clunkiness of the technology systems available to support inspection-related work. Having assessed the indicative findings, SMT agreed to close this project during Q4 and that priority changes would be progressed within the ongoing Innovation in Inspection work in 2024/25. Workstreams identified for prioritisation in 2024/25 included evidence-based assurance activities, initially focusing:
 - on security in the Post Mortem sector,
 - redesigning (within core business constraints) our post-inspection Corrective and Preventative Action (CAPA) processes, and
 - expanding the use of Evaluated Self-Assessment into another low-risk sector.

Communications (including stakeholder engagement)

8. In line with the communications KPI, the Comms Team handled the majority of media enquiries across the quarter within set deadlines. In December, one enquiry about the historical use of material was answered to an extended deadline, and one on the management of the deceased was partially answered with a follow up later.

9. The team prepared a Comms Plan in response to publication of the phase one report of the Fuller Independent Inquiry. The work included: lines to take, a coordinated a statement from the CEO published on the HTA website, monitoring of social and broadcast media and responding to media enquiries. Staff engagement ensured colleagues were aware of updates and how to access support. The overall coverage on the HTA was limited.
10. The Comms Team also provided handling advice and support to the HTA team around the sentencing of Circle Health Group for offences under the Human Tissue Act in October relating to the unlicensed storage of human tissue. Their work included writing to private providers, the General Medical Council and the Royal College of Surgeons to highlight compliance with the HT Act and help reduce the risk of this type of activity reoccurring.
11. Internally, the team routinely share a daily news-round up, a staff newsletter and support events such as, Ask the CEO (which was focussed on the Independent Fuller Inquiry), so that colleagues remain informed about news across the sectors and HTA business. Using the Crown Commercial framework, the team identified a provider to support and maintain the HTA website. A contract was agreed in late December and the site will be transitioned in Quarter Four. This will bring the website hosting and maintenance contract into full commercial compliance and provide an opportunity to make incremental improvements over the duration of the contract.
12. In addition, the team has delivered a programme of engagement events with stakeholders holding forums with representative groups for each sector throughout quarter three and facilitating a webinar with DIs (Designated Individuals) in the post-mortem sector on winter pressures. The webinar had 81 attendees, and feedback was very positive, with many reassured they were taking the necessary action. Some suggested that a session for licence-holders would be beneficial and this is being explored. The most recent Stakeholder Newsletter was issued in December.

Policy

13. The development of the new HTA Strategy 2024-27 is progressing and will be discussed later in the meeting. There has been extensive engagement with the Board, the SMT and HTA colleagues to develop the draft strategy. Engagement sessions aligned to the Strategy themes – Approach to Regulation, Trust and Confidence, Use of Information and Efficient and Effective were conducted in December 23 and January 24. Attendance has been high, and interaction has been very positive. The final staff engagement session was held on 16 February to provide an overview of the draft strategy. The draft strategy will continue to be refined during March in consultation with key stakeholders.

14. In Q3, the Policy function successfully completed a project to assess the HTA's impact by understanding how the HTA's activities have a marked effect or influence on the delivery of its vision and mission, and to help equip the HTA with tools to carry out further work in relation to assessing impact. The assessment is an internal resource to assist and inform planning and resource deployment in coming years, as well as the new corporate strategy. The work involved engaging with a sample of stakeholders (including HTA staff, licensed establishments, arm's length bodies and devolved administrations) and explored the counterfactual that the HTA did not exist. The key findings were presented to the Board in December 2023, alongside how they would be used by the HTA going forward.
15. The last quarter the Policy team led for HTA on engagement with the Department on their proposed policy change to introduce a duty on clinicians to report any reasonable suspicions that an organ donation and transplant-related offence has or may have been committed, and organ transplants that take place outside the UK. The Policy team has worked collaboratively across the organisation and with DHSC and NHS Blood & Transplant to prepare for the regulations, support planning for a 'minimum viable product' and lead on submissions to DHSC and is leading this work for HTA.
16. The Policy team has prioritised essential work in Q3 against a backdrop of stretched resources – one Policy Manager and a Head of Policy & Development. However, after successful recruitment campaigns, two further Policy Managers were appointed and will join the team in Q4 and the team will be at full complement by the end of the business year.

Information Technology (including data and digital)

17. Whilst IT continued to be stretched in Q3, IT Service delivery was consistent throughout the period regarding performance against the Key Performance Indicators. Our IT support agent has actively responded to any RTANCA (Respond to an NHS Cyber Alert) updates during the period and the IT service remained stable with zero downtime during the quarter. Midway through Q4, the IT service is now back to full-strength.
18. There has been a trend of a steady 1% reduction in our KPI against the Microsoft Secure Score. This is a metric used by Microsoft to highlight our security posture. Our IT support partner have identified some suggested improvements from Microsoft to increase this by around 8%, bringing our

security posture to 87% against our KPI of 90%. These remedial works commenced in February 2024.

19. Within Q4, Phase 1 of our CRM (Customer Relationship Management IT system) work has commenced, which is an initial workstream to add some necessary improvements to allow for future phases throughout the next couple of financial years.
20. A new draft IT Strategy for 2024-27 is progressing, formulated through the information and knowledge gathered throughout a stock take exercise. The purpose behind this strategy is to outline the strategic direction of IT, including, investment, improvements and roadmaps through the 2024-27 period.
21. The Regulatory Insight Model & Index (RIMI) project is progressing with the development of core risk indicators to underpin the RIMI engine. These have been widely discussed with staff at a number of events which have provided great opportunities to discuss how the indicators can add value to our regulatory risk profiling and our decision making going forward. In February 2024, we appointed a contractor to undertake a data-mapping exercise to establish the “as is”, gap analysis and identify opportunities to improve data connectivity. They are also developing the RIMI design and development tender document for the next phase of the project. This work is to be completed before the end of March 2024.

Finance

22. The table below is the summary position as at the 31 December 2023 (quarter three of the 2023/24 business year). Year to date we have a deficit against budget of £15k.

23. Table 1: Summary income and Expenditure: year to date

	Actuals £000s	Budget £000s	Variance £	Variance %
Income				
Grant-in-aid	673	473	200	42.3
Non-cash	80	80	-	-
Licence Fees	4,378	4,457	(79)	(1.8)
Other Income	205	172	33	19.3
Total Income	5,336	5,182	154	2.97
Salaries and Wages	3,041	3,104	(63)	(2.0)
Travel and Subsistence	121	101	20	19.8
Other staff costs ¹	138	111	27	24.1
Other operating costs ¹	34	5	29	550.3
IT & Telecommunications	264	314	(50)	(16.0)
Legal / Professional	113	103	10	9.7
Accommodation	159	74	85	114.9
Project costs	198	101	97	96.0
Non-cash	99	85	14	16.5
Total costs	4,167	3,998	169	4.2
Net income	1,169	1,184	(15)	(1.3)

Income

24. Income is over budget by £154k (2.97%). This is mainly due to profile of the budget where the final GIA is shown in March. There are variances within our licence fees; the Human Application sector which is down 8.7% (£165k), Research sector is under budget by 1.43% (£12k). These are offset by increases in the other sectors.

25. At month six (September) was the last period in which we issued licence fee invoices for the year. The focus continues to be on debt collection to ensure these fees are recovered by the end of the year.

¹ These were originally reported together at Q2. Other staff costs includes Shared Services.

Expenditure

26. Explanation of significant variances (>£10k) are as follows:

- **Salaries and wages** – are under budget by £63k due to vacancies being carried for a few months.
- **Travel and Subsistence** – is over budget by £11k. The majority of the overspend relates to home to office travel, spend year to date is £42k versus budget of £27k.
- **Other staff costs** – are overspent by £27k which is represented by overspends within Staff benefits, staff welfare, Staff Away Days totalling £75k and offset by underspends within; recruitment (£25k), staff training and subscriptions totalling £48k.
- **Other operating costs** – are over budget (£29k) represented by an overspend within consultancy (Fuller costs) and printing costs which were high due to changes made within the annual accounts production.
- **IT & Telecommunications** – an underspend of £50k mainly represented by underspends within consumables costs of £6k; Software Licence Subscriptions £2k; IT development and consultancy £31k and maintenance costs £7k.
- **Legal and Professional** – are overspent by £10k of which we are overspending on both internal and external audit fees. This is offset by small underspend within Legal.
- **Accommodation** – is overspending year to date against budget (£85k) due to increased Building and service charges being passed on by DHSC as part of our lease. However, due to profiling of the budget, these costs should come into line by year end.
- **Project costs** – these include costs for the Review of Inspection project (£90k) which will be adjusted in Q4 due to renegotiation of the contract and an overspend against website costs of £8k which again will come down during Q4 as adjustments are processed.
- **Non-cash costs** – these are the cost of depreciation of our fixed assets (laptops) and our lease. Depreciation is running over budget by £14k due to purchases of additional equipment.

Forecast outturn

27. Below is a summary of our forecast outturn for the year.

	Forecast £000s	Budget £000s	Variance £	Variance %
Income				
Grant-in-aid	673	763	(90)	(11.8)
Non-cash	107	107	-	-
Licence Fees	4,396	4,481	(85)	(1.9)
Other Income	210	185	25	13.5
Total Income	5,386	5,536	(150)	2.7
Expenditure				
Salaries and Wages	4,050	4,144	(94)	(2.9)
Travel and	159	136	23	(13.0)
Other staff costs	185	141	44	(22.1)
Other operating costs	38	8	30	341.6
IT Telecommunications	380	406	(26)	(0.9)
Legal / Professional	152	138	14	7.9
Accommodation	152	171	(19)	(11.1)
Non-cash	134	113	21	20.4
Project costs	225	285	(60)	18.9
Total costs	5,475	5,542	67	0.8
Net expenditure	(89)	(6)	(83)	

28. The above forecast deficit of £89k reflects the deferment of some projects to the new financial year. The Project Costs line includes pieces of work on our website including accessibility, work on RIMI commenced early in Q4 following business case approval, assessing our impact for which the final report has been received. In addition, projects relating to the review of inspections costing of £90k (Phase 1), has been reduced to £63k after renegotiation of the contract price.

29. The overall outturn for the full year is not expected to change significantly.

Other key performance indicators

Debtors

30. Outstanding debt from licensing activities as at end of December is £497k represented by 75 establishments. Below is a breakdown of debtors by sector.

Sector	No. of establishments	Value of debt £	%
NHS	36	£266,183	56%
Government bodies	4	£38,190	2%
Local Authorities	1	£7,060	7%
Non-Government bodies	34	£185,146	35%
Total	75	£496,579	

31. Within the NHS debtors there is one account outstanding that relates to the 2022/23 financial year. We have been in regular contact with them, and they are awaiting additional funding before they can clear their outstanding account. Incidentally, they have been licensed in 2023/24 also. The remaining accounts all relate to the current business year and are being actively chased.

32. Within Government bodies, one relates to a Devolved Government totalling £9k which is the balance of a part payment, and three to an ALB £30k. The ALB as of February 23rd has paid £22k leaving a balance of £8k which we expect to receive shortly.

33. The non-government establishments are either private companies or universities. Of the 34, eight relate to financial years 2020/21(1), 2021/22 (3), 2022/23 (4) and the balance were all billed in April 2023. We continue to pursue these.

Financial risks and mitigations

34. Whilst we are posting a small overspend, it is possible that this will increase slightly. Although our reserves are sufficient to cover our deficit, we will be outside of the budget position agreed with DHSC. This is being monitored and has been shared with the DHSC finance team who have not asked us to undertake any further mitigating action

35. The key risk is uncertainty, particularly around unexpected costs. The HTA finance team works closely with the business to reduce the risk of surprises (of

both new costs arising or work being delayed) and monitors price rises as closely as possible.

Audit and Risk

36. The risk register was reviewed by SMT on the 19 December where it was agreed that the RAG status for all but risk 8 had not changed. Risk 8 – failure to deliver the agreed Business Plan was down-rated from 12 (high) to 8 (medium) which reflected removal of some activities from the plan to ensure it was achievable. A proposal to introduce a new format of risk register was discussed with a view to presenting the new format at the ARAC meeting in February. This was agreed in ARAC in January, with some amendments recommended by the chair. , This format will be used in conjunction with the risk identification and review that would take place as part of the strategic planning process.

37. The risk summary can be found at **Annex C** below.

Human Resources

38. Transition to the new HR shared service provider is progressing well but, without an internal HR team, it is taking longer than originally envisaged. This means that our ability to prepare and analyse Management Information is reduced until we have fully transitioned. Our access to core HR transactional functions, including recruitment, and advice and guidance is going well, and we have been supported in navigating some difficult HR issues. Currently available performance information is as follows:

Sickness absence

- Sickness absence rate as at the end of Q3 December 2023 is 0.43% compared to the same period last year of 0.57%.
- There have been 147 days of sickness related absence in Q3 to 31 December with most of these days being unspecified causes of absence. These are distributed across 21 members of staff throughout this period.

Attrition

- At the end of Q3 the yearly rolling rate of staff attrition was 26.9%, however, updated leaver figures have pushed this figure to 34.0% in January but with a likely small improvement in February; fixed term contractors employed for over 12 months are included.

- Oct-23 27.1%

- Nov-23 26.9%
 - Dec-23 34.0%
 - Jan-24 34.0%
- For context, the attrition rate reported for 2022/23 in the HTA Annual Report and Accounts was 30.5%. The figure rose in December due to four concurrent departures. Overall in 2022/23 there were 16 departures. With one month to go, the projected year end figure for 2023/24 is also 16, against a slightly increased headcount.

Training

- The Q3 quarterly mandatory training programme which included Work-life balance, Whistleblowing Essentials, Promoting Diversity and Inclusion and Business Continuity Training with a deadline of end of 31 December 2023, was completed by 62% but that has since improved to 86%. A report to SMT provided details of those yet to complete this training and this has been followed up by line managers. In Q4, with one month remaining, c75% of modules have been completed.

Correction

39. Since the last Board report, we have identified that we previously misreported one KPI (the median age of open major CAPAs) in the period July to October 2023.

40. July and October data were incorrectly reported as being within target, whilst the corrected quarter-end figure at 30 September remained within target. This issue did not arise for November onwards.

41. **Table 1** shows the original and corrected data for the period this issue arose.

Month	Jul '23	Aug '23	Sept '23	Oct '23
Original	80	106	46	76
Corrected	111	137	76	107

Table 1: Original and corrected data for the KPI on median age of open CAPAs on major shortfalls for July to October 2023, target median being not exceeding 90 days

42. A couple of factors contributed to this issue, namely the handover of reporting responsibilities within the Directorate and a calculation error arising from the reference date used to calculate median ages. Steps have been taken to address both issues which should prevent a reoccurrence of the reporting errors.

Quarter 4 early insights

43. During the first half of Q4, the delivery of our core operations remains positive, with our Key Performance Indicators (KPIs) prioritised and on track for successful achievement at year end.
44. Our originally intended programme of change activity for 23/24 was scaled back in agreement with the Board at the December meeting, and we are broadly on track to deliver the more realistic subset of our projects.
45. As part of drafting the Business Plan for 24/25 we are proposing an explicit MoSCoW (must do, should do, could do, won't do) prioritisation approach for the various change activities, which demonstrates to the Board the areas which we think are most important should capacity or resource constraints impact our project work across the year.

Recommendation

46. The HTA Board is asked to note and comment on the performance recorded and the context provided.

Annex A – Quarterly Board Data Overview, 23/24 Quarter 3 Final Position

Core Operations

Business Plan KPIs		<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid green; padding: 2px 5px; text-align: center;">7 On track</div> <div style="border: 1px solid orange; padding: 2px 5px; text-align: center;">2 Amber</div> <div style="border: 1px solid red; padding: 2px 5px; text-align: center;">1 Off track</div> </div>					23/24 YTD
		Aug	Sep	Oct	Nov	Dec	
Operational Delivery							
R e g	222 inspections covering all sectors [measured quarterly against projection for the quarter]	20	24	19	26	13	185
	100% of panel cases actioned within 10 working days	100% (27/27)	100% (34/34)	100% (27/27)	100% (24/24)	96.7% (30/31)	99% (230/232)
	100% of required HA inspections are undertaken during the business year	N/A	N/A	N/A	N/A	N/A	N/A
	Median age of open Corrective and Preventative Actions (CAPAs) for major shortfalls should not exceed 90 days	137	76	107	84	93	N/A
D T & D	90% media responses provided to deadlines	83% (5/6)	100% (4/4)	100% (5/5)	100% (5/5)	50% (2/4)	88% (23/26)
	Server downtime less than 3% (within working hours and excluding planned testing)	0%	0%	0%	0%	0%	0%
	100% of RTANCA (NHS cyber security alert) notifications actioned / replied to within 48 hours	100%	100%	100%	100%	100%	100%
P & C G	100% of FOIs responded to within 20 working days	100% (3/3)	100% (3/3)	100% (3/3)	100% (1/1)	100% (1/1)	100% (22/22)

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Draft policies may be subject to revision following the HTA Board meeting

	Aug	Sep	Oct	Nov	Dec	23/24 YTD	
People & Capability							
Resources	Surplus of income / expenditure no more than 5% of budget	-5.48%	2.14%	-1.00%	2.00%	4.00%	N/A
	Debt no more than 3% of income at year end	N/A	N/A	N/A	N/A	N/A	2%
	Unqualified external audit opinion received	Received	N/A	N/A	N/A	N/A	Received
	Attrition rate no more than 15%	29.20%	29.00%	28.90%	28.80%	26.90%	28.80%
	Staff sickness no more than 3%	1.01%	0.70%	1.82%	8.00%	2.82%	2.41%

Change Activities

Project		Sponsor	Oct 23	Nov 23	Dec 23	Commentary for Board Review
Activities	Create a new HTA strategy	Louise Dineley	A	A	A	Overall status expected to be green following the completion of the themed staff engagement sessions
	Public Bodies review	Louise Dineley	W	W	W	Confirmation of an assessment date for the public bodies review assessment is not expected until 24/25. Preliminary work to assess HTA readiness has been paused until Q4 due to other priorities
	Assessment of our impact	Louise Dineley	G	G	G	Project is completed. Project Close Report submitted for Sponsor's approval
	Establish an insight network	Louise Dineley	R	W	W	A change request has been sought to postpone the Project until 2024-25 once a new Policy Manager is in post
	Data collection exercise	Nicolette Harrison	A	G	G	Additional part-time resource in place. Establishment data (across sectors) received with a few outstanding ODT; risk scoring underway
	Review of inspections	Nicolette Harrison	R	A	A	Finalising Phase 1 supplier contract. To review analysis and recommendations as set out in report, for potential implementation; present options to SMT (Feb 24)
	Independent Inquiry (Fuller)	Nicolette Harrison	A	R	A	Discussions held across the business (Board, SMT, BDT, FII WG) following publication of Phase 1 report. 1st Feb SMT discussion paper tabled: consider activities and potential impact across the business, reflecting report criticisms and recommendations and anticipating Phase 2 activities
	Living Organ Donation approvals	Nicolette Harrison	W	W	W	There is no resource at the moment to re-scope the Project to the initial (more limited) scope agreed for year 23/24. Internal Audit recommendations have been absorbed
	Retained EU Law Bill	Louise Dineley	W	W	W	Work may not be required – Project put back to pipeline
	Windsor Framework	Louise Dineley	W	W	W	Work may not be required – Project put back to pipeline

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Project		Sponsor	Oct 23	Nov 23	Dec 23	Commentary for Board Review
Activities	Guidance on pregnancy loss	Louise Dineley	W	W	W	Work may not be required – Project put back to pipeline
	Respond to external reviews	Louise Dineley	W	W	W	Work may not be required – Project put back to pipeline
	Duty to report	Louise Dineley	W	W	R	Project proceeding at risk, without DHSC resource or funding provision in readiness for Duty to Report commencement on 01 April 2024. The HTA is continuing to follow the same procedures used now to manage DtR enquiries
	IT strategy requirements	Louise Dineley	W	W	W	Escalation raised for Project to provide retrospective Business Case Document or monthly updates
	Records management review	Louise Dineley	W	W	W	Change Request raised January 24 to defer the start date to project start date until March 24 whilst the recruitment campaign for the Records Management & Information Governance Lead post is underway.
	Finance system review	Tom Skrinar	W	W	W	Work may not be required until 24/25 – Project put back to pipeline
	People strategy development	Tom Skrinar	W	W	W	Work may not be required until 24/25 – Project put back to pipeline
	Performance management review	Tom Skrinar	W	W	W	Work to be progressed through BAU
	Data & Security Protection Toolkit	Louise Dineley	C	C	C	Project completed
	Develop RIMI (Regulatory Insight Model & Index)	Louise Dineley	R	A	R	Project paused by SMT due to the concerns over availability of funding. £50K funding allocation was considered for diversion to cover reduced provision of Grant In Aid funding
	Start the outsource of IT	Louise Dineley	W	W	W	Work cannot be progressed due to costs – Project put back to pipeline
	Outsource HR	Tom Skrinar	R	R	A	CQC to provide the HTA with Human Resources support in accordance with the provisions of the SLA: Transactional HR services to transition to CQC. Other HR services (Organisational Development and Academy (L&D)) are due to come on-line from 1 April 2024
All	Portfolio	All SMT	A	A	A	Overall RAG status remains at Amber. However, ambitions have had to be scaled back in-year

Annex B – Quarterly Board Data Overview, 23/24 Quarter 4 Latest Position

Core Operations

Business Plan KPIs

7 On track	2 Amber	1 Off track
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	Sep	Oct	Nov	Dec	Jan	23/24 YTD	
Operational Delivery							
R e g	222 inspections covering all sectors [measured quarterly against projection for the quarter]	24	19	26	13	11	196
	100% of panel cases actioned within 10 working days	100% (34/34)	100% (27/27)	100% (24/24)	96.7% (30/31)	100% (24/24)	99% (254/256)
	100% of required HA inspections are undertaken during the business year	N/A	N/A	N/A	N/A	N/A	N/A
	Median age of open Corrective and Preventative Actions (CAPAs) for major shortfalls should not exceed 90 days	76	107	84	93	85	N/A
D T & D	90% media responses provided to deadlines	100% (4/4)	100% (5/5)	100% (5/5)	50% (2/4)	100% (4/4)	90% (27/30)
	Server downtime less than 3% (within working hours and excluding planned testing)	0%	0%	0%	0%	0%	0%
	100% of RTANCA (NHS cyber security alert) notifications actioned / replied to within 48 hours	100%	100%	100%	100%	100%	100%
P & C G	100% of FOIs responded to within 20 working days	100% (3/3)	100% (3/3)	100% (3/3)	100% (1/1)		100% (22/22)

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	Sep	Oct	Nov	Dec	Jan	23/24 YTD	
People & Capability							
Resources	Surplus of income / expenditure no more than 5% of budget	2.14%	-1.00%	2.00%	4.00%	4.00%	N/A
	Debt no more than 3% of income at year end	N/A	N/A	N/A	N/A	N/A	2%
	Unqualified external audit opinion received	Received	N/A	N/A	N/A	N/A	Received
	Attrition rate no more than 15%	29.00%	28.90%	28.80%	35.80%	35.80%	30.39%
	Staff sickness no more than 3%	0.70%	1.82%	8.00%	2.82%	0.43%	1.83%

Change Activities

		Nov 23	Dec 24	Jan 24	Commentary for Board Review	
Activities	Create a new HTA strategy	Louise Dineley	A	A	A	Status improved from Amber to Green following completion of the themed workshops. The new strategy is now under development and is being quality assured by the DTD Team. Progress is being shared with the SMT and the Board
	Public Bodies review	Louise Dineley	W	W	W	Confirmation of an assessment date for the public bodies review assessment is not expected until 2024-25. Preliminary work to assess HTA readiness has been paused until Q4 due to other priorities
	Assessment of our impact	Louise Dineley	G	G	G	Project closure report has been submitted. PSMT is asked to formally close the Project
	Establish an insight network	Louise Dineley	W	W	W	Project postponed to 2024-25 business year (as agreed at the January PSMT)
	Data collection exercise	Nicolette Harrison	G	G	G	Final report expected to SMT, February 2024
	Review of inspections	Nicolette Harrison	A	A	A	A review of analysis and recommendations as set out in the Phase 1 report; paper to SMT expected February 2024
	Independent Inquiry (Fuller)	Nicolette Harrison	R	A	A	FII Project: next Steps paper to SMT (01/02). Steering Group meeting scheduled for 28/02 to agree ToR, receive cross-organisation updates on current workstreams and discuss progressing future workstreams (as set out in SMT paper)
	Living Organ Donation approvals	Nicolette Harrison	W	W	W	There is no resource at the moment to re-scope the Project to the initial (more limited) scope agreed for year 2023-24. Internal Audit recommendations have been absorbed
	Retained EU Law Bill	Louise Dineley	W	W	W	Work may not be required – Project put back to pipeline
	Windsor Framework	Louise Dineley	W	W	W	Work may not be required – Project put back to pipeline

HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the HTA Board meeting

Project		Sponsor	Nov 23	Dec 23	Jan 24	Commentary for Board Review
Activities	Guidance on pregnancy loss	Louise Dineley	W	W	W	Work may not be required – Project put back to pipeline
	Respond to external reviews	Louise Dineley	W	W	W	Work may not be required – Project put back to pipeline
	Duty to report	Louise Dineley	W	R	R	The project group is preparing for the regulations to go live in Spring 2024 and continues to proceed at risk (given the lack of resources – in terms of staff and budget)
	IT strategy requirements	Louise Dineley	W	W	W	Engage with the business to understand key business priorities and collate information about improvements and requirements. Review existing IT processes and deliverables to determine the journey and roadmap of dependencies and issues in delivery of the Strategy
	Records management review	Louise Dineley	W	W	W	Work cannot be progressed due to resourcing – Project put back to pipeline
	Finance system review	Tom Skrinar	W	W	W	Work may not be required until 2024-25 – Project put back to pipeline
	People strategy development	Tom Skrinar	W	W	W	Work may not be required until 2024-25 – Project put back to pipeline
	Performance management review	Tom Skrinar	W	W	W	Work to be progressed through BAU
	Data & Security Protection Toolkit	Louise Dineley	C	C	C	Project complete for 2022-23 submission. Work in progress for 2023-24 DSPT self –assessment. Baseline assessment deadline is 29 Feb
	Develop RIMI (Regulatory Insight Model & Index)	Louise Dineley	A	R	A	Project delayed by several weeks due to concerns about funding. It was recommended to a revised scope and reduced budget in February with a contract awarded to commence data mapping & production of a RIMI design and development tender document for the next Project phase
	Start the outsource of IT	Louise Dineley	W	W	W	Work cannot be progressed due to costs – Project put back to pipeline
	Outsource HR	Tom Skrinar	R	A	A	CQC to provide the HTA with Human Resources support in accordance with the provisions of the SLA: Transactional HR services to transition to CQC. Other HR services (Organisational Development and Academy (L&D)) are due to come on-line from 1 April 2024
All	Portfolio	All SMT	A	A	A	Overall RAG status remains at Amber. However, ambitions have had to be scaled back in-year

Red	Amber	Green	Blue	White
<p>There is significant risk that the overall Activity will be delivered late or will fail to deliver everything within scope against the agreed baseline plan.</p>	<p>There is a risk that one or more milestones may be late, or that the full scope will not be delivered. However, there is a good possibility of implementing mitigations to bring the plan back on track to meet the schedule and delivery as planned.</p>	<p>Overall Activity is on track to be delivered against the baseline plan and there is no or minimal risk of milestones being delivered late.</p>	<p>Activity is complete having delivered all deliverables within scope, time, quality, cost and met benefits targets.</p>	<p><i>Activity not live.</i></p>

Annex C

Strategic risk register 2023/24

Risk summary: residual risks

Risk area	Strategy link*	Residual risk	Risk owner	Status	Tolerance	Trend**
R1: Failure to regulate appropriately	Delivery (a-d & f) and Development (a-d) objectives	9 – Medium	Director of Regulation	Below tolerance	10	↓ ↔ ↔ ↔
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	6 - Medium	Director of Regulation	At tolerance	6	↔ ↔ ↔ ↔
R3: Failure to manage expectations of regulation	Delivery e) and Development c)	9 - Medium	Director of Data, Technology & Development	At tolerance	9	↔ ↔ ↔ ↑
R4: Failure to utilise our staff capabilities effectively	Delivery, Development and Deployment (a, c, and d)	16 - High	Director of Resources	Above tolerance	9	↔ ↓ ↔ ↔
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	9 - Medium	Director of Resources	Above tolerance	3	↔ ↔ ↑ ↔
R6: Failure to take advantage of opportunities that allow the HTA to be an efficient regulator responsive to change and aware of the impact that it has on the sectors and activities that it regulates to ensure	Development (a-d) objectives	9 - Medium	Director of Data, Technology and Development	At tolerance	9	↔ ↔ ↔ ↓

Risk area	Strategy link*	Residual risk	Risk owner	Status	Tolerance	Trend**
public trust and confidence is maintained						
R7 Failure to optimise the safe use of existing and emerging digital data and technology	Delivery (a-e), Development (a-d) Deployment (a, c and d)	12 - High	Director of Data, Technology and Development	Above tolerance	9	↔↑↔↔
R8: Failure to deliver the agreed Business Plan	Delivery, Development and Deployment objectives	9 - Medium	Deputy Director of Performance and Corporate Governance	Above tolerance	6	↔↑↔↔

* Strategic objectives 2021-2024:

** This column tracks the four most recent reviews by SMT (Senior Management Team) (e.g., ↑↔↓↔).

R1: There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	5	15 - High	3	3	9 - Medium
Tolerance threshold:					10 - Medium

Commentary

Below tolerance.

We believe we have a sound regulatory framework, which we continue to evolve in response to emerging risks and our own desire to continue to be risk-based, proportionate and data-driven.

Recent internal audits gave moderate assurance on Living Organ Donation approvals (March 2023) and the Effectiveness of the Inspection Process (April 2022).

Inspection is only part of our regulatory toolkit, and we continue to manage and respond to incident reports, whistleblowing / informant information and provide advice and guidance to our sectors and the public. We also have an active programme of engagement with our regulated sectors and other relevant stakeholders. We have also recently undertaken a risk-focused data collection exercise across all licensed establishments.

We continue to be transparent about our regulatory activities and outcomes through various means, including publication of inspection reports, performance data and other data, such as the quarterly summaries of closed incidents reported to us. These provide public assurance on our delivery of core regulatory functions. We also provide suitable public comment on matters within our remit where relevant, including on our website and through engagement with media.

We continue to support Sir Jonathan Michael's Independent Investigation into offending at a hospital mortuary and are pursuing a programme of related activity, including with wider sector stakeholders, as set out in our published advice to the Secretary of State in December 2021.

The recent sentencing of Circle Health Group to a £100,000 fine for a breach of the Human Tissue Act licensing requirements is the first such successful prosecution following an initial investigation and referral to the police by the HTA. This outcome should reassure the public and practitioners that the HTA will take strong action when made aware of potential offences.

SMT believes this risk is just below tolerance.

Actions to address risk:

Actions to strengthen or extend our approaches to our regulatory activity and increase transparency, to maintain public confidence in our approach to regulation, are noted below.

The HTA is continuing to evolve our approach to inspection, one of our core regulatory tools, introducing Evaluated Self-Assessments (EVAs) this year. We are on track for a further increased target for inspection coverage of 222 inspections for 2023/24 on existing licences, in addition to full assessment of all new licence applications.

The HTA has further refined its approach to living organ donation assessment in recognition of emerging risk and continues to play a significant role in multi-agency efforts to address risks related to some overseas travel for organ transplantation following the introduction of new offences under the Human Tissue Act in July 2022. An update was provided to the Board in June 2023, who approved our updated Living Organ Donation approvals policy.

During 2023/24, the HTA has extended our approach to transparency by publishing, as open data, further details about licences and regulatory activity in addition to our long-standing publication scheme, under which we publish summary details of closed incidents reported to us and all inspection reports.

Phase 2 of the Data Collection Exercise should restart during Quarter 3, through which we will aim to analyse and make use of the sector-specific risk data collected from all licensed establishments.

Following the completion of Phase 1 of the Review of Inspections in Quarter 2, the HTA will consider options for next steps during Quarter 3.

HTA's SMT continues to consider police referrals for all cases of potential offences under the Human Tissue Act and has referred a significantly increased number of cases to the police during 2023/24, principally in the Organ Donation and Transplantation (ODT) sphere.

The HTA has recognised that further revisions to its Police Referral and Warrants Policy would be beneficial, to better reflect the types of issues that arise in the ODT sphere, and that it would like to further develop a Compliance and Enforcement Strategy. These are activities to be considered for future years, given current resource constraints.

R2: There is a risk that we will be unable to manage the lifecycle of a significant incident, event or issue impacting on the delivery of HTA objectives.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	2	3	6 – Medium
Tolerance threshold:					6 – Medium

Commentary

At tolerance.

This risk concerns our ability to respond to and manage incidents, irrespective of their nature or cause whilst maintaining delivery of core business objectives. It is not confined to incidents relating to our regulatory remit.

In addition, those plans have also been deployed and found effective in several different circumstances over the past few years, including managing the impact of the pandemic and related restrictions, managing the potential impacts of EU Exit following the end of the Transition Period and in our mobilisation planning in preparation for the trial of Fuller.

We have rewritten our Critical Incident Response Plan and tested it during 22/23 with a specialist consultant and also completed a similar exercise for our Business Continuity Plan in Q1 23/24. These have provided assurance on the effectiveness of our plans and our ability to use them.

Having increased the risk scoring in July 2021, in anticipation of the prospective Fuller trial, and its potential to lead to a critical incident for the HTA, we now believe that the likelihood of this risk materialising has reduced. Sir Jonathan Michael's Independent Inquiry into the circumstances of Fuller's offending and any related wider concerns about settings in which the deceased are managed is still continuing. The Phase 1 report, focusing on how Fuller came to undertake his offending at Maidstone and Tunbridge Wells Hospital NHS Trust, apparently undetected, for many years is anticipated to be published during 2023. Phase 2, considering wider settings involved in managing the deceased, is expected to report in 2024.

Given there are currently police referrals being progressed on other unrelated matters within our broader remit, we believe there is still the potential for significant impact of an incident on our corporate objectives, either from those causes or others of which we may still be unaware.

Hence SMT considers the residual risk remains at the tolerance level.

Actions to address risk:

We will review both the Critical Incident Response Plan and the Business Continuity Plan annually.

We intend to undertake an annual test with all staff to ensure we are sufficiently prepared to manage incidents as they arise.

R3: There is a risk that we will fail to manage public and professional expectations of human tissue regulation stemming from limitations in current legislation, misperception of HTA regulatory reach and innovations in the use of human tissues and cells.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	4	12 - High	3	3	9 – Medium
Tolerance threshold:					9 – Medium

Commentary– to be updated based on agreement of the risk

At tolerance.

The HTA has successfully completed year 1 of the delivery of its revised Communications & Engagement Strategy. Progress on embedding the strategy and new channels and tools that have been adopted was reported to the Board at the end of June.

The strategy is underpinned by a commitment for being more proactive and open in our communication and engagement with professionals and the public. In the last quarter we have continued to embed sector-based forums and roundtables, strengthen social media presence, and proactively respond to media enquiries. The work of the Comms & Engagement Team has contributed to the generation of positive headlines in relation to stories such as the first uterine transplant, press statements on successful prosecutions and strengthened partnerships with DHSC, ALBs and license holders.

In addition to the strategy there has been a significant focus in Q1 & 2 to ensure any published material including the experience of using the HTA website meets accessibility standards. The HTA's website has been independently audited and identified some further opportunities to improve accessibility. A revised accessibility statement has been approved and published.

The HTA remains committed to improving the accessibility of all published information.

The HTA acknowledges that to continue to regulate effectively it is important that it understand the impact of its activities whilst at the same time continuing to be responsive to innovation and growth across Life Sciences. The HTA is progressing work that seeks to assess the impact of the HTA as a regulator and its activities. This will culminate in a publication the aim of which will be to share insight and feedback on the regulated activities and sectors and promote public confidence in the safe use of tissues and cells.

Looking ahead at 2023/24 the HTA will be reviewing its Strategy. This will set the direction of travel for the next 3 years and potentially beyond as well as showcasing the ongoing importance of regulating the use of human tissues and cells.

The additional attention to which the HTA might be subject following the anticipated publication of Phase 1 of Sir Jonathan Michael's Independent Inquiry into Fuller's offending may increase the risk of misperception of the HTA's role in the public domain. The HTA Fuller Inquiry Working Group is preparing communications and media products, either for publication or to enable us to respond promptly, accurately and constructively to enquiries as well as ensuring HTA staff are suitably prepared to provide clarity on the HTA's role where required

SMT consider this risk to at tolerance.

R4: Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	3	12 - High	4	4	16 - Medium
Tolerance threshold:					9 – Medium

Commentary

Above tolerance.

As we reach the end of Q2, staff turn-over is 29.2%. This is based on a twelve-month period (Oct-Sept) using our HR system IRIS. We continue to have vacancies in key areas from time to time that can put pressure on the business, in particular in professional corporate roles with limited cover, though we do not feel that we have a significant issue with staff retention currently.

Additional work has arisen in year that has created further pressures on staff, in particular responding to the Fuller Inquiry, in Live Organ Donation work and the proposed Duty to Report. This has put significant pressure on some staff to deliver alongside BAU tasks (see also Risk 5 on resourcing), with risk of burnout and lower Health and Well-being (H&WB)

We have historic/enduring problems with recruitment, in particular to more specialist professional roles (it has taken a significant period of time to fill the Head of IT role). In some cases this is probably due to our pay offer being below market expectations.

The current transition to an HR shared service and lack of internal HR expertise within HTA means that we have not been able to fully maintain our HR offer to staff. This has put some pressure on managers to manage basic HR tasks themselves and created uncertainty around HR transactions for staff. It has also made the organisational focus on things like L&D and H&WB harder to deliver. The shared HR service has now commenced (except L&D and organisational development in April 2024), with detailed procedures in development by CQC over the coming months, meaning that it will take some time to bed in fully. Available resource for projects (e.g. the People Strategy) to be agreed and planned with CQC (see actions below).

HR policies have not been updated for some time creating risk, in particular ensuring compliance with legislation appropriate to protect staff working remotely (at home or with clients).

Actions to address risk:

- Retention. Ensure we are supporting staff, focussing on development, Health and Wellbeing (and reasonable workloads) and performance management, responding to feedback from the Staff Survey. We will restart the Staff Forum to ensure there is safe space for staff to raise and discuss issues. We will develop a People Strategy in 2024/25

working with CQC-HR (depending on HR plan/resource), ensuring our offer to staff supports resilience and a positive culture.

- Recruitment. Work with CQC to review the HTA approach. Continue flexing pay where necessary, and review HTA pay and Job Descriptions (depending on HR plan/resource).
- Review of HTA HR policies with CQC, in particular those that manage Health and Safety risks.
- Work with CQC to ensure smooth transition and HR service meets HTA needs. SLA meetings and KPIs.
- Explore further resource-sharing options with other bodies where appropriate.

R5: There is a risk that the HTA has insufficient or ineffective management of its financial resources

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	3	3	9 – Medium
Tolerance threshold:					3 – Low

Commentary

Above tolerance.

C. 80% of our **2023/24 income** comes from fees and is variable and difficult to budget for, meaning we can be in a deficit position even when our spend is within budget. Currently (at Q2), our forecast fee income is just over 1% below budget; we are monitoring this situation closely. Our GIA and other income is generally reliable.

2023/24 spend is broadly as expected to deliver our agreed business plan within budget, but a number of additional pressures have arisen in year (including the one-off cost of living payment) and additional work requirements (in particular responding to the Fuller Inquiry and developing and resourcing the new DTR duties for HTA, engaging with DHSC). There is a risk of a small overspend currently and ideally, we would recruit additional staff to support extra work (as we have had to divert staff from BAU), but this would move us further into an overspend position.

Our operating **budget for 2024/25** is currently under development, looking at resource requirements for 2024/25 (in particular to absorb additional work such as DTR). DHSC has informed HTA that GIA will reduce by c. 33% in 2024/25, therefore inflation, resources for increased duties and a c. £300k reduction in GIA will need to be funded through a fee increase, which will put pressure on the sector and require careful engagement.

HTA finance team is currently has one internal vacancy and is covering a vacancy in HFEA. High workload increases risk in financial control and our ability to detect fraud and error, etc. It also reduces finance's ability to provide technical support for efficiencies and financial management improvement.

Actions to address risk:

- Engagement with Directors on budget management to ensure robust forecasting.
- Review of 23/24 business plan with SMT to identify pressures and areas that could be de-prioritised if necessary.
- Close engagement with DHSC finance around our in-year position for 2023/24.

- Close engagement with DHSC sponsor team on additional DTR resource requirements and funding, including requests for additional staff (loan) and GIA.
- Engagement on 2024/25 fees and budget with DHSC finance and sponsors as funding requirements and likely fee increase developed. To discuss with HTA Board.
- Focus on finance team capability and capacity (especially recruitment). Review of finance systems and oversight across HTA and HFEA for improvements.

R6: Failure to take advantage of opportunities that allow the HTA to be an efficient regulator responsive to change and aware of the impact that it has on the sectors and activities that it regulates to ensure public trust and confidence is maintained.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	3	12 - High	3	3	9 – High
Tolerance threshold:					9 – Medium

Commentary

At tolerance.

This risk has been updated and redefined for 2023/24 to reflect a central priority supporting efficiency and reform. As with risk 3 the HTA has progressed and delivered a number of projects in the post pandemic period reflecting changes in the way that it works and to ensure it remains responsive to opportunities for working differently. The 2023/24 Business Plan includes a number of projects that will this direction of travel. Activities under risk 3 and this risk 6 coalesce to support the HTA's vision and mission.

It is anticipated that updates on the risk will reflect the progress of identified projects and align with updates and actions identified across other risks specifically risks 3, 4, 5 & 7. This alignment is critical as in previous years the availability of resources (people and financial) have been significant factors in setting the pace and appetite for change. A further consideration and alignment opportunity for the HTA will be with the myriad of central initiatives and programmes that see to take advantage of economies of scale and consolidation of improvement opportunities and skills.

Since the start of 2023/24 there have been a range of different activities including independent reviews such as the McLean review and the Review of Pregnancy Loss that have led us to consider and work with partners on opportunities for change and improvement in regulation.

R7: Failure to optimise the safe use of existing and emerging digital data and technology

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	4	16 – High	4	3	12 – High
Tolerance threshold:					9 – Medium

Commentary
Above tolerance.

Over the last 2 years the HTA has been progressing with the planned development of its digital data and technology (systems and architecture) as part of the Development Programme. The planned development had been incremental based on available resources and aimed to future proof business needs.

Two projects were identified in 2022/23. These were (1) the adoption of an IT Shared Services model and (2) stage 2 development of the Regulatory Insight Model and Index. As identified under risk 6 progress has not been possible due to resource constraints. The HTA's IT function has been an area of consistent pressure and over commitment of internal resource for a number of years. As part of the 2023/24 business plan there has been confirmation of a substantive Head of IT position. This post has now been successfully recruited to, with the incumbent commencing post in November

As with risk 6 the HTA's ability to optimise the use of existing and emerging data, digital and technology opportunities is largely reliant on investment and resource. There is a clear vision and confidence in what could be delivered although the reliance on single roles in this area and wider ambitions means that substantive recruited resource is at capacity.

SMT believe this risk remains above tolerance.

R8: Failure to deliver the agreed Business Plan

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	4	12 – High	4	3	9 – Medium
Tolerance threshold:					6 – Medium

Commentary**Above tolerance.**

The 23/24 Business Plan (consisting of both core operations and change activities) has been created through a codesign process involving Board and staff such that it is intended to be both challenging but achievable.

We operate a formal Portfolio Management approach to the management of our Business Plan delivery, with explicit processes and best practice outputs tracking progress and scrutiny at Business Delivery Team (middle management) fortnightly, Portfolio SMT (senior management) monthly and Board quarterly.

Portfolio Management allows us to be flexible in-year so that as we are reviewing our performance, we can also consider additional requests and pressures as they arise, refining our Business Plan through change control and redeploying resources as needed.

To date, delivery of our core operations has been positive with both our externally reported Key Performance Indicators and internally managed Performance Indicators prioritised and on track for successful achievement at year end.

However, a combination of our Q1 financial outturn (see Risk 5), staffing issues experienced in key technical positions (see Risk 4) and requests to absorb additional work in-year (such as engaging with the Department's proposed Duty to Report) has meant that we have been unable to progress all of the change activities that we had identified for delivery. A Quarter 2 review of the change activities has been undertaken and the Board has been asked to consider scaling back the proposed change activities to reflect the current state of play (see the annex to the Chief Executive's Report for details).

As such, this risk currently remains above tolerance.

Actions to address the risk:

- Scale back ambitions for delivery of change activities during 23/24
- Be more realistic about our capacity to deliver both core operations obligations and the ability to resource ambitions change activities when drafting the 24/25 Business Plan