Audit and Risk Assurance Committee (ARAC)

Date: 27 January 2022

Time: 9.30 – 10.00 (Private Members session with auditors)

10.00 – 12.00 (Main meeting)

12.00 – 12.30 (Private Members session)

Venue: Zoom

Protective Marking: OFFICIAL

Agenda

1. Welcome and apologies **(10 mins)**

2. Declarations of interest

3. Minutes of Meeting 14 October 2021 meeting (AUD 1/22)

4. Matters arising from 14 October 2021 meeting (AUD 2/22)

Internal Audit (15 mins)

5. Item 5 is confidential and not included.

Audit Tracker (15 mins)

6. Audit Tracker Update (AUD 4/22)

External Audit (15 mins)

7. Audit planning report on the 2021-22 financial statement audit (AUD 5/22)

Risk Update (25 mins)

8. Risk Update (AUD 6/22)

   Annex A – Risk Register Summary

   Annex B- Strategic Risk Register

   Annex C – Operational Risk Register

Change Programme (10 mins)

9. Development Programme Update (AUD 7/22)

Cyber Security (10 mins)

10. Cyber Security Update (AUD 8/22)

Policies (10 mins)

11. Policy Schedule

    Anti-fraud, bribery and corruption policy (AUD 9/22)

    Whistleblowing Policy and Procedure (AUD 10/22)

    ARAC Handbook (AUD 11/22)

    ARAC Terms of Reference (for information only) (AUD 12/22)

12. Gifts and Hospitality Register (AUD 13/22)

Regular Reporting (5 mins)

13. Reports on grievances, disputes, fraud and other information (Oral)

14. Topics for future risk discussions (Oral)

Any Other Business (5 mins)

15. Items (AUD 14/22):
    - HTA response to PAC enquiry on Contingent Liabilities (AUD 14a/22)
    - Implementation of IFRS 16: Leases, impact on the Statement of Financial Position (AUD14b/22)
    - Accounting Officer Responsibility Handover (AUD 14c/22)

Audit and Risk Assurance (ARAC) meeting

Date: 27 January 2022

Paper reference: AUD 01/22

Agenda item: 03

Author: TJ O'Connor

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Minutes of the ARAC Meeting held on 14 October 2021

Purpose of paper

1. To seek approval that the minutes of the ARAC Meeting held on 14 October 2021 are a true record of the meeting.

Decision making to date

2. The minutes approved by the Director of Resources before being distributed to the Committee.

Action required

3. To approve the minutes of the ARAC Meeting held 14 October 2021 as a true record of the meeting.

Background

4. The draft minutes from the ARAC meeting held 14 October 2021 were issued to Committee members via email on Wednesday, 29 December 2021. Committee members were asked to provide any feedback, comments, or corrections to these minutes no later than Wednesday 5 January 2022. By this deadline, the HTA Office received the following amendments from Dr Stuart Dollow and one amendment from Dr Charmaine Griffiths. The proposed amendments are shown below:

    -   Minute 15: The Committee noted the amended audit plan for the business year 2021/22 and the significant progress that had been made in clearing audit recommendations. ''and to better understand the nature of the questions and the responses needed.''

    -   Minute 19: A discussion was had around the changes to the plan on page 10 of the progress report, a question was raised around the timing of the proposed changes regarding EDI. It was acknowledged that the GIAA have requested this be reviewed, but members questioned if internal audit was the ~~right priority to be focusing on, in terms of audit.~~ most appropriate approach to provide assurance of HTA progress and whether the resource allocated was excessive.

    -   Minute 61: The Committee approved the Reserves Policy at Annex A, with the proviso that expectations be managed and to operate a reducing trend. ''I am not sure it is fully clear, so please add at the end of the sentence, '...reducing reserve based on business need.''

    -   Minute 64: The Committee noted the above piece of artwork and approved the Gifts and Hospitality policy ''noting that gifts and hospitality from prior years that had previously been noted by the Committee need not be re presented in future.''

![HTA Human Tissue Authority logo]

Minutes of the Audit and Risk Assurance (ARAC) meeting

Date: 14 October 2021

Time: 10.00 - 12.00

Venue: Via Zoom

Protective Marking: Draft

Attendees:

ARAC Members
Professor Gary Crowe (GC), ARAC Chair
Jan Williams (JW)
Dr Stuart Dollow (SD)
Dr Charmaine Griffiths (CG)

Mike Surman (MS), National Audit Office
Rebecca Jones (RJ), Government Internal Audit Agency
Joanne Charlton (JC) Government Internal Audit Agency

Apologies
Laura Fawcus, (LF) National Audit Office

Observers
Jacky Cooper (JC), Health Ethics, Department of Health and Social Care

Dylan Parrin (DP), Senior Policy Manager, Department of Health and Social Care
Amy Parsons (AP), Department of Health and Social Care
Dean Gibbs (DG), (KPMG)

In Attendance

Allan Marriott-Smith (AMS), CEO
Louise Dineley (LD), Director of Data Technology and Development
Richard Sydee (RS), Director of Resources
Nicky Harrison (ANH), Director of Regulation
David Thomson (DT), Head of Business Technology
Morounke Akingbola (MA), Head of Finance
Sandra Crosser (SC), Head of HR
TJ O'Connor (TOC), Executive Assistant, Minutes

Item 1 – Welcome and apologies (Oral)

1. The Chair welcomed Members, the Executive team and colleagues from the Department of Health and Social Care (DHSC), Government Internal Audit Agency, (GIAA), and the National Audit Office, (NAO).

2. Apologies were noted from Laura Fawcus from the National Audit Office.

Item 2 – Declarations of interest (Oral)

3. The Chair asked Members if there were any declarations of interest to be made; none were declared.

Item 3 – Minutes of 17 June 2021 ARAC meeting (AUD 12/21)

4. The Chair asked for any comments on the factual accuracy of the minutes from the previous meeting, there were none.

5. The minutes from the previous meeting were agreed to be an accurate record of the meeting on 17 June 2021.

Item 4 – Matters arising from the 17 June 2021 meeting – (AUD 13/20)

6. The Chair noted the progress with items listed as matters arising from the previous meeting.

7. Louise Dineley, the Director of Data Technology and Development, gave the committee a brief update on action four, regarding communications and engagement, reporting that there is a working draft that identifies and progresses some key actions around stakeholder engagement.

8. The Chair mentioned fraud in the public sector and lack of Board oversight, which may be revisited as a Deep Dive discussion. The Chair suggested that training to highlight this topic could be undertaken in January 2022.

9. Committee members were updated regarding a call the Chair had with Clare Wend-Henson, the staff forum representative, who reported that the office is suitable and those on office contracts have returned to the office.

10. The Chair noted that there were good levels of support available regarding the wellbeing agenda, adding there were no concerns raised around areas of shortcomings.

Item 5 – Internal Audit Reports – (AUD 14/21)

11. Jo Charlton presented this paper and audit reports to the Committee.

12. The Committee noted two reports from the 2021/22 audit plan. These covered a finding of significant assurance from an audit undertaken of the HTA approach to staff wellbeing.

13. The second report was a finding of limited assurance relating to the evidence that supported the HTA's submission of the NHS Digital Data Security and Protection Toolkit (DSPT).

14. The Committee acknowledged that this was the HTA's first submission of the DSPT and welcomed the commitment to undertake further work to strengthen the evidential base for the next submission due in June 2022.

15. The Committee noted the amended audit plan for the business year 2021/22 and the significant progress that had been made in clearing audit recommendations.

16. Joanna Charlton from the GIAA, (Government Internal Audit Agency), reported that she has been working closely with the HTA and has seen a marked improvement in risks being reduced.

17. The Committee was informed that preparation planning for resources needed was underway. Evidence will be collated up to the end of March, before reviewing Q1.

18. A discussion was had around the changes to the plan on page 10 of the progress report, a question was raised around the timing of the proposed changes regarding EDI. It was acknowledged that the GIAA have requested this be reviewed, but members questioned if this was the right priority to be focusing on, in terms of audit.

19. It was agreed that although EDI is a priority, allocating fifteen days to this issue may not be needed. It was agreed to limit the days devoted to EDI, with it being completed in this year's internal audit.

20. It was mentioned that the Board would seek assurance that EDI is adequate, with it suggested that this would be a useful target for internal audit at this point.

21. Business planning is to be deferred to later in the year. Committee members asked for some changes to the business plan, with the business planning and the ''to be'' brought together to occur within this year's plan.

Item 6 – Audit Tracker - Cover Paper (AUD 15/21)

22. Morounke Akingbola, the Head of Finance, presented the Audit Tracker to the Committee.

23. The Committee was provided with the following update:

- MA reported that there were twenty-two outstanding items with fourteen remaining.

- MA drew attention to the Utilisation of Capabilities item, with Allan Marriott-Smith reporting that this item is still scheduled for the new year, when the new CEO Colin Sullivan will review once he is in post.

- MA reported there were three recommendations outstanding in the Critical Incidents area, adding that points one and four will be addressed once the business plan is fully embedded.

- A staff handbook in draft form has been completed and is ready to be shared. MA reported that using and retaining documentary evidence about users was not agreed.

- The Chair requested that once items have past their due dates, the new proposed completion dates should be added to the audit tracker. Momentum should continue to close off the items and reduce the audit tracker before the next meeting.

Item 7 – External Audit (Oral)

24. The National Audit Office engagement Director for the HTA, Mike Surman, presented an oral update to the Committee and introduced Dean Gibbs, Audit Director at KPMG, as the lead for the HTA's external audit for 2021/22.

25. MS explained that the audit will be processed differently this year. The NAO will outsource the audit work and collaborate with other government departments. DG will be conducting the audit over the next three years.

26. The Committee thanked MS and DG for their work to make this transition as smooth as possible. The Committee also welcomed confirmation that the proposed audit team would be in place for the next few years.

27. The overall responsibility of the audit will remain with the NAO, who will retain responsibility for reviewing the audit work. MS and DG will work as one team. There will not be much of a difference in the overall approach to how the audit is conducted.

28. A detailed hand over from MS and RS to DG is planned for next week.

Item 8 – Risk Update (AUD 16/21)

29. Richard Sydee presented this paper to the Committee, providing an update on the Strategic Risk Register. RS highlighted Risk 1 - *failure to regulate appropriately* and reported the return of the plan for VRAs (Virtual Regulatory Assessments) in Q1 and Q4.

30. The strategic risk register was discussed by the Committee. It was noted that a full site visit and assessment plan was now in place for the second half of the business year. The positive impact this would have on the HTA's ability to regulate appropriately was noted by the Committee.

31. The Committee noted the continued above tolerance status of Risk 2 - *failure to manage an incident* and acknowledged the unprecedented demands that several regulatory matters were placing on the senior management team, with progress recognised.

32. The Committee noted Risks 3, 5 and 6.

33. The Committee undertook a deep dive review of Risk 4 - *failure to utilise capabilities effectively*. RS reported that it is expected that the tolerance for Risk 4, which has been a considerable demand on resources, would reduce. The Committee were assured on the ratings levels.

34. RS reported that he expects the tolerance for Risk 5 - *Insufficient or ineffective management of financial resources,* to reduce.

35. Risk 6 - *failure to achieve the benefits of the organisational Development Programme,* has been removed from the Strategic Risk Register for now. There is a need to delay development ambitions due to limited capacity at present.

36. The business plan continues to be reviewed, with a number of unknowns in Q2 including the COVID-19 inquiry. The inquiry will start from April onwards, it is not yet clear what the HTA's involvement in that will entail.

37. LD reported that a better use of data and technology is being explored, with heavy investment in this area deployed over the last sixteen months.

38. The Committee noted the work undertaken to improve the systems and the processes that support the work of the HTA and acknowledged the improvements in technology that had been implemented.

39. The difficulties in recruiting to certain posts were noted by the Committee, it welcomed the progress on recruiting a replacement for the Head of Business Technology, similarly, the plans that have been agreed to manage the HTA between October 2021 and January 2022, ahead of the new Chief Executive taking up post.

40. The Committee accepted the ratings as presented on the spreadsheet and advised a couple of the risks should be reducing.

41. The Chair declared assurances on the ratings levels had been met and acknowledged the difficulty of prioritising resources at the same time as dealing with the critical incident.

Item 9 – Change Programme (AUD 17/21)

42. Louise Dineley presented this paper and gave a development programme updated to the Committee, updating on Q2 deliverables, and looking ahead to Q3 and the Programme deliverables for the next quarter.

43. LD reported on a series of scenarios that support flexibility and the reprioritisation of resources to business activities.

44. The COVID enquiry was brought up with it mentioned that it would be liable to involve a significant amount of work. LD reported that preparations have started, while waiting for further details.

45. The Horizon Scanning and the COVID enquiry were mentioned with the need to look further ahead. LD reported that the internal and Horizon Scanning was reporting into SMT.

46. The development planning system has been impacted in Q3, by the approaching departure of David Thompson, the Head of Business Technology. The work has been reframed to bring it to an appropriate pause. The plan is to restart this work when DT's replacement starts.

47. The Committee noted the update and progress of the deliverables of the HTA's development programme.

48. It was mentioned that Risk 6 - *failure to achieve the benefits of the organisational Development Programme*, needs to be reframed.

Action 1: Risk 6 - *failure to achieve the benefits of the organisational Development Programme*, to be reframed.

Item 10 – Cyber Security (AUD 18/21)

49. David Thomson, the Head of Business Technology, provided an update on Cyber Security to the Committee.

50. The Cybersecurity dashboard was discussed. The Chair asked that the dashboard be supplemented to cover best practice in other areas, including staff awareness training and what exists to ensure the cyber risk of people working remotely is minimised.

51. DT reported that training for all staff has been completed in Q2, with all new starters receiving training from DT.

52. The Committee requested further improvements to the dashboard to further improve the assurance provided by this report.

Action 2: The Cybersecurity dashboard to be extended to cover best practise in other areas, including staff awareness training.

Item 11 – Policies and Procedures

53. Morounke Akingbola, the Head of Finance, presented the HTA Counter Fraud, Bribery and Corruption Strategy 2021-2024 document, the

feedback from the DHSC (Department of Health and Social Care); Anti-Fraud Unit, (AFU); and the HTA Fraud Risk Assessment document to the Committee.

54.   The Committee reviewed revisions to the HTA's Counter Fraud, Bribery and Corruption strategy, noting the recommendations of the DHSC (Department of Health and Social Care) AFU.

55.   MA offered to share a more detailed spreadsheet that uses metrics that can be measured.

56.   The Committee approved the HTA Counter Fraud, Bribery and Corruption Strategy 2021-2024 at Annex A.

57.   The Committee approved the feedback from the DHSC, HTA Counter Fraud Functional Standards Review, at Annex B.

58.   The Committee approved the HTA Fraud Risk Assessment at Annex C, subject to enhancements on the outcomes the LA will provide an update next time.

Item 12 – Reserves Policies

59.   Morounke Akingbola presented the Reserves Policy to the Committee. The Committee were asked if they approved the revision to the Reserves Policy.

60.   The Committee reviewed revisions to the Reserves policy.

61.   The Committee approved the Reserves Policy at Annex A, with the proviso that expectations be managed and to operate a reducing trend.

Item 13 – Gifts and Hospitality Register

62.   MA presented the Gifts and Hospitality Register to the Committee.

63. The Committee noted that an undocumented piece of artwork that had been displayed at the HTA's previous office, has been gifted to the Government Arts Collection, with a deed of gift having been signed on behalf of the HTA by the Director of Resources.

64. The Committee noted the above piece of artwork and approved the Gifts and Hospitality policy.

65. MA presented the Declaration of Interests, Gifts and Hospitality Policy, found at Annex C, to the Committee.

66. The Committee approved the Declaration of Interests, Gifts and Hospitality Policy.

Item 14. Reports on grievances, disputes, fraud, and other information (Oral)

67. No reports of grievances were discussed.

68. There was nothing to report to the Committee under fraud or dispute.

Item 8 – Any other business (AOB)

69. The Chair asked if the Committee had any other items of business that they would like to discuss, none were raised.

70. The Chair thanked AMS on behalf of the Committee and wished him well. Allan also thanked the Committee.

71. The Chair thanked the Committee and brought the meeting to a close.

AUD 02/22 - ARAC Matters Arising from October 2021 and Forward Plan

Risk exploration topics

Topic	Meeting	Progress
Topics covered		
Risks posed by sectors and the HTA's approach to protect public confidence • The HTA Inspection Rationale	February 2017	On the agenda for the February 2017 meeting. **Complete.**
Risks posed by sectors and the HTA's approach to protect public confidence Breadth of activity, regulatory approach and risk assessments for various aspects of the Human Application Sector – Follow-up from Authority seminar in February 2017.	May 2017	This item has been scheduled to occur as a follow up to the authority member seminar scheduled for the morning of the February Authority Meeting. **Complete.**
HTA interaction with DIs/DI Training and Recruitment	November 2017	Due to competing work priorities within the Regulation Directorate, The Chair of ARAC has agreed replace this topic with an item looking at the recommendations arising the from the Risks in the Human Application Sector project. We will seek another date for the DI work deep dive, but the meeting after next is likely to look at recruitment and retention risks.
Risks in the Human Application Sector project.	November 2017	Complete.
Management and succession arrangements to assure the continuity of licensing and regulation activity	February 2018	Complete.
Risks associated with Cyber Security	June 2018	Complete. Standing agenda item
The risks and assurance associated with the HTA's staff induction process.	October 2018	At 19 June 12018 ARAC Meeting, the Committee elected to explore the risks and assurance associated with the HTA's staff induction process. **Complete.**
Risks posed by sectors and the HTA's approach to protect public confidence.	TBC	**HA and PM done.** Poor risk profile with some of the other sectors.
Outstanding Topics		
Risks associated with the HTA's Licensed Establishment Relationship programme	TBC	As agreed at the 1 February 2018 ARAC Meeting. At 19 June 12018 ARAC Meeting, the Committee agreed to postpone its investigation of the HTA's Licensed Establishment Relationship Programme, which was scheduled for 23 October 2018 ARAC meeting. The Committee elected instead, to explore the risks and assurance associated with the HTA's staff induction process. LEEP was covered at the October ARAC meeting and has now disbanded as a programme.
HTA continuous business planning arrangements for the triaging of business planning activity	TBC	Originally scheduled for 19 June 2018 but postponed by the ARAC committee at its meeting on 1 February 2018. New date to be confirmed.
Media handling- Critical incident handling	TBC	Subject to Internal audit.
Risks posed by sectors and the HTA's approach to protect public confidence.	TBC	**HA and PM done.** Poor risk profile with some of the other sectors.
Fraud in Public Sector priority of Board oversight	TBC	This needs to be done.
Executive to decide whether an examination of the data from the Professional Stakeholder Evaluation is an appropriate topic for an ARAC deep dive.	Action from July 2020 Board meeting	TBC - ARAC Chair to confirm

* No deep dives since January 2020

AUD 02/22 - ARAC Matters Arising from October 2021 and Forward Plan

Meeting	Action	Responsibility	Due date	Progress to date	Status
12-Jun	Action 2: To review and sign off the Records Management Policy at the October 2019 meeting.	Director of Resources	1-Oct	It is proposed that the IA recommendations on Records Management are closed. Since the audit in 2019 a significant amount of work has been done to improve how we manage our information. A significant development was the adoption of a Electronic Document Records Management System in quarter 4 2020/21. Further strengthening of our records and wider information is planned in 2021/22 with the design and adoption of an Enterprise Content Management System. The Records Management has been factually updated to reflect these changes and will be presented to SMT for approval in early July.	Completed
15-Oct	Action 4: The Executive to provide an update on stakeholder engagement, including engagement with Designated Individuals (DI) at future ARAC meeting.	Director of Data, Technology and Development	17-Jun-2021	This action is part of the redrafting of a revised C&E Strategy. A verbal update will be provided by Louise Dineley during the meeting.	Completed
28-Jan	Action 5: The FOIA guidance document to be reviewed and approved by June 2021.	Board Secretary	14-Oct-2021	The Executive has reviewed the guidance document, and following the re-organisation of the roles (effective 1 June 2021), this document will be reviewed further by the new post-holder. It is anticipated that this review and agreement of the new guidance will be completed by October 2021.	Live
17-Jun-21	Action 1: To present an updated dashboard report at the October 2021 ARAC meeting with a particular focus on threats.	Head of Business Technology	14-Oct-21	This will be presented at the October meeting	Complete
17-Jun-21	Action 2: An update to be provided on staff awareness and training of cyber security.	Head of Business Technology	14-Oct-21	This will be presented at the October meeting	Complete
14-Oct-21	Action 1: Risk 6 - *failure to achieve the benefits of the organisational Development Programme*, to be reframed	Director of Data, Technology and Development	27-Jan-22	This risk has been re-drafted and is enclosed within the Strategic Risk Register at item xx/22 of this agenda	Live
14-Oct-21	Action 2: The Cybersecurity dashboard to be extended to cover best practise in other areas, including staff awareness training	Head of Business Technology	27-Jan-22	Further amendments and have been made to the Cybersecurity dashboard, this will be discussed at item xx/22 of the agenda	Live

Other work

Meeting	Work in Progress	Responsibility	Due date	Progress to date	Status
November Board meeting	Development of Risk Appetite and Tolerance for each of the Strategic risks	Director of Resources/Head of Finance and Governance	Completed	The Board agreed (November 2020) that positive progress had been made and that taking a more granular approach to risk appetite and tolerance was important. It was agreed that ARAC should take this piece of work forward on behalf of the Board, with the Board maintaining oversight and ownership of risk.	Completed

Future training

Topic	Meeting	Provider	Progress
Training complete			
Joint ARAC Member/Management Team training seminar – undertaking risk assurance mapping and interdependency across the wider health group	February 2017	Internal Auditor/Director of Resources	To focus on wider suggested best practice in accordance with the Risk Management Policy and Strategy and consideration of wider interdependence across the health group. **Complete.**
Value for money auditing and the optimal deployment of resources		NAO	NAO have been invited to host a training session on 18 May 2017. **Complete.**
A NAO perspective on the risks emerging within the health sector	February 2018	NAO Catherine Hepburn	**Complete**.
Training and/or discussion on risk updates - ensuring Members gain assurance on how risks are recorded and managed.	June 2019	Jeremy Nolan, (GIAA)	At the ARAC meeting on 23 October, Members invited Jeremy Nolan to facilitate discussion on risk management and how Members can assure themselves that risks are being managed and recorded correctly. **Complete.**
IFRS training	January 2020	NAO	Complete.
Outstanding training			
Observation and feedback from another ARAC Chair	June 2018	Anne Beasley, formerly Director General of Finance and Corporate Services at the UK Ministry of Justice	Rescheduled to occur after the ARAC meeting in June 2018 but postponed until 23 October due to the availability of the observing Chair.
NAO presentation the issues and challenges experienced by other ARACs.	February 2019	George Smiles,(NAO)	At the ARAC meeting on 01 February 2018, Members invited George Smiles to provide them with a presentation at the October ARAC meeting on the issues and challenges experienced by other ARACs. **Postponed**
Fraud Awareness	June 2020	TBC	TBC

* No training since January 2020

AUD 02/22 - ARAC Matters Arising from October 2021 and Forward Plan

Standing items	Assurance reports from Internal Audit Audit recommendations tracker report Risk update includes strategic risk register review and update on UK transition Polices/procedures updates Cyber security	
		Meeting Specifics to be covered
Meeting		
January 2022	Assurance reports from Internal Audit	Review and approval of the Internal Audit proposed Audit plan for the financial year
	Audit recommendations tracker report	Review of the Audit & Risk Assurance Committee's performance including Members' skills and training
	Strategic risk register review	Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting)
	Polices/procedures updates	
	Anti-Fraud Policy (bi-annually)	
	Whistleblowing Policy	
	Schedule of policies	
June 2022 `	Audit recommendations tracker report	Receive Internal Audit Annual Report
	Strategic risk register review	Approval of the Annual Report and Accounts
		SIRO Report
	Policies/procedures updates	
		Review of the External Auditors ISA 260 report (management letter)
		Consider key messages for the Audit & Risk Assurance Committee's report on its activity and performance (to the Authority)
October 2022	Assurance reports from Internal Audit	Approval of External audit's planning report
	Audit recommendations tracker report	Review of the Audit & Risk Assurance Committee's Governance including Handbook and Terms of Reference
	Strategic risk register review	Operational Risk Register review (not standing agenda item)
	Policies/procedures update	

Policy and Procedures reviewed by ARAC		Frequency of review
Expenses Policy HTA/POL/032	Policy covers reimbursement of Travel, Subsistence and other expenses	Annual
Reserves Policy HTA/POL/049	Policy states the minimum level of cash reserves that the HTA should ideally keep as a contingency	Annual
Antifraud Policy HTA/POL/050	Policy covers definitions of fraud, responsibilities of HTA employees	Annual
Whistle-blowing Policy HTA/POL/017	Policy covers procedure to be followed if they have concerns about improper behaviour	Annual
Declaration of Interest, Gifts and Hospitality Policy	Policy covers the procedure for receiving/declining gifts	Annual

Internal Audit - Confidential

Audit and Risk Assurance (ARAC) meeting

Date: 27 January 2022

Paper reference: 4/22

Agenda item: 6

Author: Morounke Akingbola, Head of Finance

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Audit Tracker

Purpose of paper

1. To provide the Committee with an update on the outstanding recommendations in HTA's Audit Tracker.

Decision making to date

2. The Audit Tracker was reviewed by the SMT (Senior Management Team) on 14 January 2022.

Action required

3. ARAC Members are requested to comment and note progress made

Update

4. The Audit Tracker was last presented to the Committee at its June meeting. At that time there were 38 audits in total of which 26 were completed as per the Executive.

5. Since then, there has been 2 new audits conducted which were: Data Security Protection Toolkit and Annual Governance process. These audits were completed in early quarter 4.

6. Below is a summary of the audits and the number that have been completed in the last 4 months. The new audits audit increase the total outstanding to 49.

7. During the January review, 6 recommendations were agreed as closed with our internal auditors. These were:

    - Payroll & Expenses recommendation 4;
    - Cyber Security Essentials, recommendation 4;
    - Inspection Process During COVID, recommendation 1.1;
    - Anti-Fraud Controls, recommendation 1.2;
    - Business Continuity, recommendation 1.5 and
    - Annual Governance process, recommendation 1.3

Summary of audits

FY	Audit	Total Audit Recs	Closed Oct-Jan	Total Out-standing (Jan)
2018/19	Records Management	8	N/a	8
2019/20	Utilisation of Capabilities	2	1	1
	Critical Incidents	6	3	3
	Business Continuity	7	5	2
	Payroll and Expenses	1	1	0
2020/21	Anti-Fraud Controls	1	1	0
	Cyber Security Essentials	6	5	1
	Risk Management (EU Transition)	4	4	0
	Payables and Receivables	3	2	1
	Development of the inspection process during COVID-19	3	3	0
2021/22	Staff Wellbeing	1	1	0
	Data Protection Security Toolkit	3	1	2
	Annual Governance process	4	1	3
	Totals:	**49**	**28**	**21**

8. The Committee are requested to note and agree the following:

    - Payables and Receivables audit – the action to complete is a low level one that is not likely to happen in the short-term and the Committee are asked whether it would be prudent to remove it from the tracker but it will be an objective for the Head of Finance and therefore not lost.
    - Data Security Protection Toolkit – recommendation 2.1 (lessons learned), the executive feel this is complete but will need clarification from our auditors as to what evidence is needed to close it.

Summary of outstanding recommendations

Year	Audit	Completed		Outstanding		TOTAL
		On time	Late	Not due	Overdue	
2018/19	Records Management	-	5	-	3	8
2019/20	Utilisation of Capabilities	-	1	-	1	2
2019/20	Critical Incidents	1	2	-	3	6
2019/20	Business Continuity	-	5	-	2	7
2019/20	Payroll and Expenses	1	-	-	-	1
2019/20	Anti-Fraud Controls	1	-	-	-	1
2020/21	Cyber Security Essentials	4	1	-	1	6
2020/21	Risk Management (EU Transition)	3	1	-	-	4
2020/21	Payables and Receivables	1	1	1	-	3
2020/21	Development of the inspection process during COVID-19	3	-	-	-	3
2021/22	Staff Wellbeing	-	1	-	-	1
2021/22	Data Security Protection Toolkit	1	-	-	2	3
2021/22	Annual Governance process	1	-	3	-	4
		16	**17**	**4**	**12**	**49**

Exceptional items
Records Management - these recommendations have been parked as agreed at the June ARAC meeting with GIAA are revisiting these in 2022/23 on completion of the Development Programme.

There are 16 recommendations outstanding, 4 of which are not due and 12 which we expect to remove by the end of this financial year.

HTA Audit Tracker including ratings and evidence

Audit	FY	Rec No.	Recommendation	RAG	Agreed Actions	Progress	Owner	Due date	Completed (Y/N)	Completion date	Evidence provided/HTA Comment	Date
Utilisation of Capabilities	2019/20	6	Consideration should be given to the development of a key roles register which would identify key posts and the contingency arrangements in place should an emergency arise including a nominated deputy and comprehensive job instructions.	Medium	A capability framework will be developed which will also identify the key people and key roles across the organisation. Knowledge and experienced required for each role will be documented along with training expectations for that role. Where possible a nominated deputy will be identified. However, given the size of the organisation and the recent stress audit, workload and overstretch will need to be carefully considered.	*Comments from Oct-19, Jan-20 removed due to lack of space* **June 2020** Due to the redesign work being led by Director for Data, Technology and Development, for the return following COVID-19 this work cannot be completed until organisational design work has been completed and a skill assessment has been made for the support of the HTA going forward. **October 2020** As of June update **January 2021** SMT commissioned work on 18 January on short and medium term functional needs. Structure and roles will follow from this. The assessment will be completed in this financial year **January 2022 update** The re-design work needs to commence before this recommendation can be addressed. Question as to when the org design will happen needs to be asked.	Head of HR/SMT	Nov-19	No		SMT commissioned work on 18 January on short and medium term functional needs. Structure and roles will follow from this. The assessment will be completed in this financial year. Work will not commence on this recommendation until this work is complete. In the interim, governance documents describe key organisational processes and handover checklists mitigate risks when staff leave the organisation.	
Critical Incidents	2019/20	1.3	We recommend that management review the actions outstanding on the CIRP alongside the operational risk register with the purpose of either completing or closing the actions to ensure that they have considered and evaluated risks relating to business continuity arrangements.	Medium	Not fully agreed– we are concerned that recommendations 1.3 and 1.4 represent collectively a significant piece of work that, although useful, would not add significantly to the level of assurance. We will feed these recommendations into any work we may undertake to as part of our annual review of the operational risk register	**October 2020** Not due **January 2021** We will feed these recommendations into any work we may undertake as part of our annual review of the operational risk register. **June 2021** See rec 1.4 **January 2022 update** Directorate Operational Risk Registers are now in place and continue to be refined and reflect actions relating to continuation of service.	Quality and Gov Manager	01/12/2020	No	01/12/2020	GIAA have gone back to the original auditor for clarification 11/1/22	
Critical Incidents	2019/20	1.4	The operational risk register requires development to demonstrate how the controls/mitigations in place address the strategic risk of failing to manage an incident. It should outline contingency arrangements and the date of the latest management review and/or testing of the control	Medium	See above	**June 2021** The ORR was revised back in Dec-20. We have taken the action that we agreed to undertake. **January 2022 update** As per recommendation 1.3, new ORR's are in place and continue to be refined. Review dates to be added.	Quality and Gov Manager	01/12/2020	No	01/12/2020		
Critical Incidents	2019/20	1.6	We recommend that appropriate training is identified and implemented for role owners and delegated role owners with critical incident responsibilities.	Medium	Agreed – we will identify relevant Business Continuity Management System (linked to ISO 22310) foundation and Implementer courses for our CIRP administrator and programme manager	**June 2020** This work has been delayed. Our response to COVID19 has required some reprioritisation. Given our successful reliance on our plans during the pandemic we are confident that they remain sufficiently robust. **October 2020** As per the June update ongoing management of the COVID19 response has meant a focus on continued BC activities, role holder training seems inappropriate at present but will be rolled out once a new policy has been finalised. **December 2020** Training was been identified however, the time required (20 hours) is proving prohibitive. **June 2021** We have identified some training and are looking for a suitable time to implement, which we expect in the 2021/22 business year. **January 2022 update** The Head of HR is currently trying to source training.	Director of Resources / Head of HR	01/06/2020	No			
Business Continuity	2019/20	1.6	HTA to document any BCP training carried out by staff, including dates when refresher training is needed.	Medium	Agreed – we will look to identify individuals an ensure this is part of 2020/21 training plans were pertinent to an individual's role	**January 2022 update** Sourcing appropriate training has been difficult. Both cost and time are an issue, however two providers have been found and shared with Head of HR for exploration. There is also Civil Service Learning which has a course	Head of HR	30/06/2020	No			

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HTA Audit Tracker including ratings and evidence

Audit	FY	Rec No.	Recommendation	RAG	Agreed Actions	Progress	Owner	Due date	Completed (Y/N)	Completion date	Evidence provided/HTA Comment	Date
Business Continuity	2019/20	1.7	HTA to ensure any induction as part of the office relocation includes training and awareness on BCP for all staff.	Low	Agreed	**June 2020** Not due. **October 2020** Not due **January 2021** This will be actioned after the office relocation is completed. **June 2021** There is an induction process that all staff will undertake when office working resumes and we are at near full capacity.	Director of Resources	01/11/2020	No		On-boarding template shared with GIAA 12/1/22 which lists whether staff are taken through BCP. Rejected as there is no reference to the BCP or link within the document.	
Cyber Security Essentials	2020/21	1.5	To produce incident response plans to aid the restoration of IT service in the event of disruption or service outage	Medium		**June update 2021** This has not been completed. Once the new business continuity policy is approved and the critical incident response plan has been updated, incident playbooks will be drafted to support a number of scenarios and in line with the requirements for BC/DR and critical incident response **January 2022 update** HTA contingency relates to our IT Service Provier as outside of this is beyond the HTA's control as it relates to Azure/O365 Microsoft. IT team currently working on this.	Head of IT	Dec-20	No			
Payables and Receivables	2020/21	2	Authorisation limits should be built into the finance system. This will ensure that where approvers attempt to approve transactions over and above their limits, there are system controls in place to prevent this.	Low	Agreed. Involves the HTA purchasing a system that has built in approvals. We are looking at this in conjunction with co-location of HFEA	**January 2022 update** This is low priority for the current business year. It is expected that we will visit this again in the new business year. Request due date be amended.	Director of Resources	31/03/2022	No		RJ to check with JC whether it can be removed as its low level and in the future. Could be picked up by a later audit.	
Data Security Protection Toolkit	2021/22	1.1	HTA to familiarise themselves the evidential needs of the Toolkit to make sure that appropriate documentation is available for independent assessment and directly contributes to the assertion statement.	High	This was the HTA's first submission of the DSPT and has been a learning experience in terms of evidential provision and audit oversight. Further work is planned to develop the HTA's understanding of the evidence required and will be evidenced through our response to recommendation 1.2.	**January 2022 update** An assessment has been made against the revised standards and requirements for June 2022. This review has identified action and support required from different areas of the business which seeks to meet the requirements and improve on the 2021 assessment. Paper due to be submitted to SMT in January.	Head of Business Technology	31/12/2021	No			
Data Security Protection Toolkit	2021/22	1.2	HTA to develop a structured approach to future Toolkit population under the guidance and direction of the Head of Business Technology supported by line of business representatives specifically tasked with acquiring tangible evidence of the actual controls employed to manage data security and protection.	Medium	As noted above we will build on this first submission, utilising the outcomes from the successful completion of recommendation 2.1 further enhance our approach to, and processes for, evidence gathering ahead of the next DSPT submission due currently in March 2022.	**January 2022 update** An assessment has been made against the revised standards and requirements for June 2022. To note the next sbmission deadline is June 2022 not March as identified. The independent assessment is scheduled for completion in Q1 2022/23	Head of Business Technology	31/12/2021	No			
Data Security Protection Toolkit	2021/22	2.1	Conduct a formal lessons-learned exercise based on a gap analysis of Toolkit content/lack of available evidence to support development of the framework described at Recommendation 1.2; and Reach out to similar organisations deemed more mature in the process of Toolkit completion to learn from their experience, processes and techniques to accelerate knowledge and expertise around the demands and expectations of the Toolkit population process.	Medium	The SIRO will chair a lessons-learned exercise to explore evidential gaps and support improved processes. This will include contacting colleagues in other Health ALBs for advice on their approach to substantive evidence to support DSPT submissions.	**January 2022 update** A lessons learned was conducted and the SIRO met with two other ALBs to explore their approach.Learning to be shared to inform plan for submission in June 2022.	Senior Risk Information Officer	30/09/2021	Yes		Clarification with GIAA what evudence is needed to close this recommendation.	
Annual Governance process	2021/22	1.1	The Authority should ensure that the Governance Statement for 21/22 contains all the essential features as set out in HMT Managing Public Money.	High	Agreed – these will be incorporated in to the 2021/22 Governance statement	**January 2022 update** A review of MPM will be undertaken to ensure all essential features are included within the 21/22 AGC.	Head of Finance and Governance	30/06/2022	No			
Annual Governance process	2021/22	1.2	The Board should ensure that they either conduct a self-assessment of Board Effectiveness in 21/22 or revisit the GIAA advisory review from 20/21 to assess the extent to which those findings/suggestions remain relevant and act accordingly to inform the 21/22 Governance Statement.	High	Agreed – subject to the Chair's approval this will be conducted at the February 2022 meeting	**January 2022 update** The Board Effectiveness review is to be scheduled for February 2022 as per Director of Data, Tech and Dev.	Board Secretary	31/03/2022	No			

AUD 04/22

HTA Audit Tracker including ratings and evidence

Audit	FY	Rec No	Recommendation	RAG	Agreed Actions	Progress	Owner	Due date	Completed (Y/N)	Completion date	Evidence provided/HTA Comment	Date
Annual Governance process	2021/22	1.4	Version control of the various drafts and audit trails of review should be maintained to provide assurance that all suggested amendments and comments are actioned before the governance statement is finalised.	Low	Agreed – this will be utilised during the 2021/22 process	**January 2022 update** This cannot be evidenced until the accounts are finalised in Q1 of 2022	Head of Finance and Governance	30/06/2022	No			

NAO

National Audit Office

Human Tissue Authority ('HTA')

Audit planning report on the 2021-22 financial statements audit

Report to those charged with governance
January 2022

FinancialAuditPlanning

This report presents details of our proposed approach for the audit of 2021-22 financial statements

We plan our audit of the financial statements to respond to the risks of material misstatement and material irregularity. This report sets out how we have built our assessment of risk, what we base materiality on, those risks we expect to be significant and how we will respond to those risks. We also set out in this report details of the team carrying out the audit, the expected timing of the audit and our fees.

Actions for the Audit and Risk Committee ('ARC')

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

- Whether our assessment of the risks of material misstatement to the financial statements is complete (including any matters those charged with governance consider warrant particular attention during the audit, and any areas where they request additional procedures to be undertaken);

- Whether management's response to these risks are adequate;

- Our proposed audit plan to address these risks;

- Whether the financial statements could be materially misstated due to fraud, and communicate any areas of concern to management and the audit team

We would also like to invite the committee to consider our fraud risk assessment on page 7.

We would also like to take this opportunity to enquire of ARC about the following areas:

- Other matters those charged with governance consider may influence the audit of the financial statements

- HTA's objectives and strategies, and the related business risks that may result in material misstatements

- Possibility, knowledge of and process for identifying and responding to the risks of fraud

- Oversight of the effectiveness of internal control

- Whether any non-compliance with any laws or regulations (including regularity) have been reported to those charged with governance (e.g. from staff, service organisations or other sources)

- Policies, procedures and systems for recording non-compliance with laws, regulations and internal policies.

Mike Surman, NAO Engagement Director

Dean Gibbs, KPMG Engagement Director

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

National Audit Office

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Overview

Audit Risks (pages 8 to 9)

We plan our audit of the financial statements to respond to the risks of material misstatement to transactions and balances and irregular transactions.

We have identified the following risks which have the most significant impact on our audit:

R1. Presumed risk of management override of controls

R2. Presumed risk of fraud in revenue recognition

We have identified the following areas of audit focus:

A1. Implementation of IFRS 16: Leases in 2022-23

A2. New payroll disclosures

Materiality (page 11)

When setting materiality, we consider both qualitative and quantitative aspects that would reasonably influence the decisions of users of the financial statements.

Our overall materiality has been determined based on prior year gross expenditure. We will reassess this as part of our final accounts audit to verify financial performance is in line with expectation. Should we be required to revise materiality, we will communicate this to ARC.

Overall account materiality (2%)	**£107,000**
Error reporting threshold	**£2,000**

Audit team, fee and timetable

Mike Surman will be responsible for the overall audit. Dean Gibbs will lead the engagement for KPMG. The full engagement team is presented on page 15.

Our audit fee for this year is The recurring fee for the core audit work is £30,000. The fee has increased by £2,200 (8 per cent) compared to 2020-21. The increase in the audit fee and reflects the results of a competitive tender exercise that the NAO performed over the summer and is broadly in line with fee increases in the wider audit market.

National Audit Office

Changes to our assessment of risk since 2020-21　　Financial**Audit**Planning

We have set out below how our risks have changed compared to those we identified in our 2020-21 audit. Following the office relocation and agreement of the lease arrangement, we have removed this an area of significant risk. We have recognised a new area of focus relating to payroll disclosure requirements being introduced in 2021-22 by the Financial Reporting Manual.

Risks and areas of focus diminishing or superseded since 2020-21	Risks and areas of audit focus identified in 2020-21 that remain relevant for 2021-2022		New risks and areas of focus for 2021-22
	Risks that are broadly consistent with last year	Risks that have evolved and developed since last year	

Significant Risks　　Significant Risks　　Significant Risks　　Significant Risks

Office relocation to Stratford

Presumed risk of management override of controls

Presumed risk of fraud in revenue recognition

Areas of Audit Focus　　Areas of Audit Focus　　Areas of Audit Focus　　Areas of Audit Focus

Covid-19 impact　　Exiting the EU

Implementation of IFRS 16: Leases

New payroll disclosures

National Audit Office

Building our assessment of risk

FinancialAudit**Planning**

We are well placed to develop an understanding of the risks to Human Tissue Authority drawing on your own assessment, the historic assessment of risk and the broader context.

Human Tissue Authority's assessment of risk

HTA strategic risk register sets out a number of risks. We have engaged with management to understand the background to these risks, movement in impact and likelihood and have considered how these inform our assessment of audit risks.

Failure to regulate appropriately	**Failure to utilise capabilities effectively**
Failure to manage an incident	**Insufficient or ineffective management of financial resources**
Failure to manage regulatory expectations	**Failure to achieve benefits of the organisational Development Programme**

Past assessment of audit risk

The 2020-21 audit highlighted a number of areas of audit risk and focus, we have built on this historical assessment to consider whether these remain risks for the year.

R1. Presumed risk of management override of controls	**R2. Presumed risk of fraud in revenue recognition**	**R3. Office relocation to Stratford**
A1. Exiting the European Union	**A2. Implementation of IFRS 16: Leases**	**A3. Covid-19 impact**

Our wider work

We have drawn upon our wider assurance work to inform our risk assessment.

Guide for ARCs on Financial Reporting Management during Covid-19	**Cyber and information security: Good practice guide**	**Climate change risk: A good practice guide for Audit and Risk Committees**	**Principle of Effective Regulation**

Broader context

Our risk assessment draws on the understanding of the broader environment in which HTA operates.

Implementation of IFRS 16	**New payroll disclosures**

National Audit Office

Our initial assessment of the risk of fraud

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We shall communicate, unless prohibited by law or regulation, with those charged with governance any other matters related to fraud that are, in our auditor's judgment, relevant to their responsibilities. It is our responsibility as auditors to report to those charged with governance:

- Any risks of material misstatement identified due to fraud
- Any matters we think are relevant to those charged with governance regarding management's process for identifying and responding to the risks of fraud in the entity

Below, we have included details of our initial assessment of the risk of fraud relevant to HTA and how this may impact on the financial statements.

Risk of material misstatement due to fraud

We consider the incentives and opportunities that may arise for material fraud to occur either within financial reporting or against the Authority. The incentives for committing fraud by management differ in the public sector from those in the private sector as there is not an incentive to maximise profit, however we recognise that management may seek to override controls in order to report financial performance in line with their funding allocation from the sponsoring Department.

We consider that this risk is most likely to occur as a result of adjustments being made at the end of the year in order to amend the reported financial performance. In line with auditing standards we consider the risk that this could occur through adjusting revenue, however in line with Audit Practice Note 10 we also consider the risk that this could occur through manipulation of expenditure.

Our response to this risk is set out on page eight and includes analysing the manual transactions posted around the end of the year that amend the reported financial performance of the Authority in order to assess whether inappropriate transactions have been posted to amend the reported financial performance.

Matters regarding management processes for identifying and responding to the risks of fraud

Our historic procedures have not identified specific concerns with the control environment in place to address the risk of fraud.

National Audit Office

Our response to the significant risks*

Financial**Audit**Planning

R1. Presumed risk of management override of controls

Why we have identified this as a risk

Management is in a unique position to perpetrate fraud because of its ability to manipulate accounting records and prepare fraudulent financial statements by using its position to override controls that otherwise appear to be operating effectively. Under International Standards on Auditing (UK), there is a presumed risk of material misstatement due to fraud arising from management override of controls.

The standard requires that auditors perform audit procedures to address this risk, focusing on three key areas: journal entries, bias in management estimates and significant or unusual transactions.

Work we plan to undertake in response

We will review the design and implementation of controls over journal entries to assess whether they are sufficiently robust to prevent inappropriate transactions being posted. We utilise a data based approach in order to determine higher risk transactions against a series of criteria, such as those amending financial performance at the end of the year.

Our interim and final audit work will consider and assess:
- the appropriateness of journal entries and other adjustments processed in preparing the financial statements;
- testing a sample of journals selected on a high risk-based criteria;
- accounting estimates made at the end of the year in order to consider whether there are indications of management bias within the estimate;
- any significant transactions outside of HTA's normal course of business, or that otherwise appear to be unusual; and
- the controls for identifying and assessing related party transactions and ensuring they are appropriately disclosed.

*The auditor shall identify and assess the risks of material misstatement at:
(a) the financial statement level;
(a) the assertion level for classes of transactions, account balances, and disclosures
to provide a basis for designing and performing further audit procedures.

Risks of material misstatement at the financial statement level refer to risks that relate pervasively to the financial statements as a whole and potentially affect many assertions.

National Audit Office

Our response to the significant risks*

Financial**Audit**Planning

R2. Presumed risk of fraud in revenue recognition

Why we have identified this as a risk

Under International Standards on Auditing (UK), there is a rebuttable presumed risk of fraud in revenue recognition in all entities. HTA's primary source of income is fees for licenses collected from regulated bodies, and this income is many times materiality. As such, this presumed risk has not been rebutted.

This significant risk relates only to the fraud element of revenue recognition around the year end – other elements of revenue recognition are not considered a significant risk.

Work we plan to undertake in response

We will assess the design and implementation of controls in place over the issuing and recording of license fee income. We will also assess controls designed to ensure income is recognised in the correct period, including how management reconciles activity reported.

As part of our substantive procedures, we will:

- Assess the design and implementation of controls for recording activity to ensure that year end income accruals are based on accurate activity information;
- Reconcile the year end accruals made for a sample of customers to activity data submitted to ensure they have been accurately recorded; and
- Test pre- and post-year-end receipts, to confirm whether revenue has been recognised in the correct financial year (cut off) and whether the underlying activity had occurred in the year (completeness).

We will also as part of our procedures perform a comparative analytical review of income collected from key individual entities year on year and investigate significant differences and test a sample of invoices raised during the year.

*The auditor shall identify and assess the risks of material misstatement at:
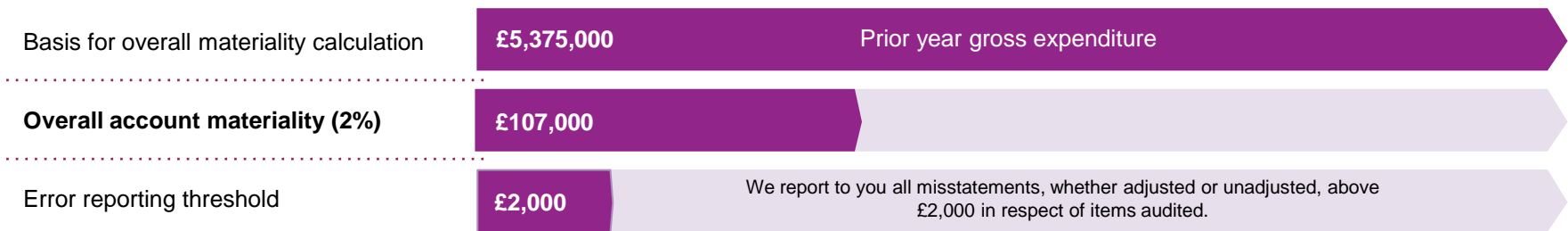(a)   the financial statement level;
(a)   the assertion level for classes of transactions, account balances, and disclosures
to provide a basis for designing and performing further audit procedures.

Risks of material misstatement at the financial statement level refer to risks that relate pervasively to the financial statements as a whole and potentially affect many assertions.

NAO National Audit Office

Areas of audit focus

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The following are matters which we consider have a direct impact on the financial statements but do not represent significant risks of material misstatement as defined by ISA (UK) 315.

Title	Audit Area Affected	Audit Response
A1. Implementation of IFRS 16: Leases in 2022-23	Disclosures	IFRS 16 is being applied by HM Treasury in the FReM from 1st April 2022. This significantly impacts how lessees account for their leases and will bring most leases onto the balance sheet. Although this does not impact the accounting treatment for 2021-22, reporting bodies are required to include disclosure of how the standard would impact the accounts were it to be applied this year, by assessing all their current lease arrangements and other contracts which may meet the IFRS16 definition of a lease. One of HTA's key leases is for the Stratford site, for which our 2020-21 audit identified uncertainty over how a rent-free period received by DHSC would be passed on to the HTA. We will assess how the HTA has identified the leases that it has entered into to ensure that there is a complete and accurate lease register. We will assess the calculations undertaken by the HTA of the expected impact of the standard to ensure they can be agreed to underlying documentation such as lease agreements and that the calculations have been prepared correctly.
A2. New payroll disclosures	Remuneration Report	The 2021-22 GAM introduced a series of new payroll ratios that require disclosure within the Remuneration and Staff Report. These are an extension to the median pay ratio to incorporate 25th and 75th percentiles and disclosure of changes to the components of remuneration. We will assess whether the HTA has prepared disclosures in line with the requirements of the GAM. We will assess the completeness and accuracy of the underlying reports used to prepare the ratios and confirm that the ratios have been calculated correctly.

National Audit Office

Materiality

Basis for overall materiality calculation	**£5,375,000**	Prior year gross expenditure
Overall account materiality (2%)	**£107,000**	
Error reporting threshold	**£2,000**	We report to you all misstatements, whether adjusted or unadjusted, above £2,000 in respect of items audited.

These levels remain comparable to those used in the prior year.

Our overall account materiality is based on gross expenditure, since expenditure is the main driver of HTA's accounts and is the core area of focus for the users of financial statements.

A matter is material if its omission or misstatement would reasonably influence the decisions of users of the financial statements. The assessment of what is material is a matter of the auditor's professional judgement and includes consideration of both the amount and the nature of the misstatement.

The concept of materiality recognises that absolute accuracy in financial statements is rarely possible. An audit is therefore designed to provide reasonable, rather than absolute, assurance that the financial statements are free from material misstatement or irregularity. We apply this concept in planning and performing our audit, and in evaluating the effect of identified misstatements on our audit and of uncorrected misstatements, if any, on the financial statements and in forming the audit opinion. This includes the statistical evaluation of errors found in samples which are individually below the materiality threshold but, when extrapolated, suggest material error in an overall population. As the audit progresses our assessment of both quantitative and qualitative materiality may change.

We also consider materiality qualitatively. In areas where users are particularly sensitive to inaccuracy or omission, we may treat misstatements as material even below the principal threshold(s).

These areas include:
- the remuneration report;
- disclosures about losses and special payments;
- our audit fee; and
- irregular income and expenditure.

National Audit Office

Timing of the audit and audit fee

Financial**Audit**Planning

The proposed timetable comprises an interim visit commencing 7th March 2022 for two weeks and a final visit commencing 18th April 2022 with certification of accounts planned for July 2022.
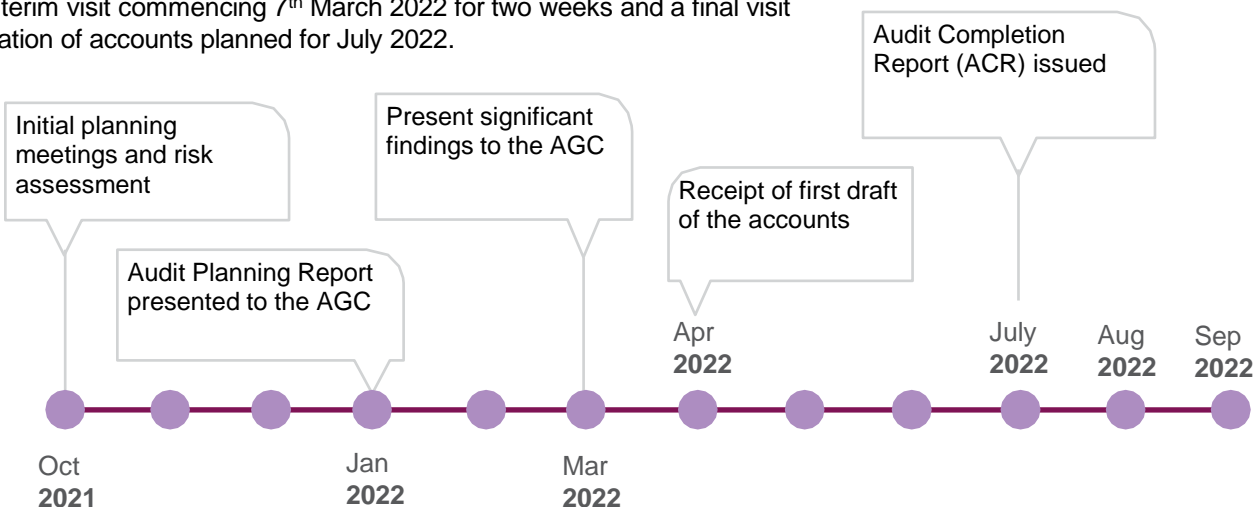
Fees

The fee for the audit is £30,000. The fee has increased by £2,200 (8 per cent) compared to 2020-21. The increase in the audit fee reflects the results of a competitive tender exercise that the NAO performed over the summer and is broadly in line with fee increases in the wider audit market.

The principle agreed with Parliament is that our fee is set to recover the full costs of the audit, rather than make a profit from or subsidise an audit. The NAO determines its fees with reference to standard hourly rates for our staff, which are reviewed annually, and updated when costs change.

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

- delivering a complete Annual Report and Accounts of sufficient quality, subject to appropriate internal review, on the date agreed;

- delivering good quality supporting evidence and explanations within the agreed timetable;

- and making staff available during the audit.

If significant issues arise and we are required to perform additional work this may result in a change in our fee. We will discuss this with you before carrying out additional work.

Audit Completion Report (ACR) issued

Initial planning meetings and risk assessment

Present significant findings to the AGC

Receipt of first draft of the accounts

Audit Planning Report presented to the AGC

Oct **2021**
Jan **2022**
Mar **2022**
Apr **2022**
July **2022**
Aug **2022**
Sep **2022**

Planning

In consultation with Management, Audit and Governance Committee, Internal Audit and other Key stakeholders, review HTA's operations, assess risk for our audit and evaluate the control framework.

Determine audit strategy.

Interim fieldwork

Assessment of control environment.

Test expenditure and income up to M9.

Final fieldwork

Test expenditure and income and significant balances and disclosures

Completion

ACR: present our findings and recommendations.

Seek management representations.

C&AG issues opinion.

Management Letter: provide final recommendations on control matters identified.

Debrief

Meeting to discuss lessons learned and improvements for the following year.

NAO National Audit Office

Our audit approach – Other Matters

Financial**Audit**Planning

Other Matters

Audit scope and strategy

This audit plan covers the work we plan to perform to express an opinion on whether the financial statements are free from material misstatement and are prepared, in all material respects, in accordance with the applicable financial reporting framework.

The plan is also designed to ensure the audit is performed in an effective and efficient manner. Our audit approach is a risk based approach, ensuring that audit work is focussed on significant risks of material misstatement and irregularity.

In areas where users are particularly sensitive to inaccuracy or omission, a lower level of materiality is applied, e.g. for the audit of senior management remuneration disclosures and related party transactions.

When undertaking our risk assessment we take into account several factors including:
Inquiries of management
Analytical procedures
Observation and inspection of control systems and operations
Examining business plans and strategies

Our risk assessment will be continually updated throughout the audit.

Independence

The NAO and KPMG are independent of HTA in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to listed entities/public interest entities. We have fulfilled our ethical responsibilities in accordance with these requirements and have developed important safeguards and procedures in order to ensure our independence and objectivity.

Information on NAO quality standards and independence can be found on the NAO website: https://www.nao.org.uk/about-us/our-work/governance-of-the-nao/transparency/.

We will reconfirm our independence and objectivity to the Audit Committee following the completion of the audit.

National Audit Office

Our audit approach – Other Matters

Financial**Audit**Planning

Other Matters

Management of personal data

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

We have established processes to hold this data securely within encrypted files and to destroy it where relevant at the conclusion of our audit. We confirm that we have discharged those responsibilities communicated to you in the NAO's Statement on Management of Personal Data at the NAO.

The statement on the Management of Personal Data is available on the NAO website:

http://www.nao.org.uk/freedom-of-information/publication-scheme/how-we-make-decisions/our-policies-and-procedures/policies-and-procedures-for-conducting-our-business/

Use of framework partners

The NAO has appointed KPMG LLP to undertake the detailed work to support the C&AG's opinion. On a day-to-day basis the audit will be managed and the work carried out by KPMG LLP staff, under the direction of the NAO. The responsibility for recommending the form of audit opinion to the C&AG shall be retained by the NAO.

Using the work of internal audit

We liaise closely with internal audit through the audit process and seek to take assurance from their work where their objectives cover areas of joint interest.

While we do not intend to make direct use of their work, as this is not considered to be the most efficient audit approach, we will use their reports to inform our wider understanding of the business of the HTA, and our ongoing risk assessment.

Communication with the NAO

Organisations we audit tell us they find it helpful to know about our new publications, cross-government insight and good practice.

Our website holds a wealth of information from latest publications which can be searched, to pages sharing our insights on important cross-cutting issues. We also publish blogs and send email notifications to subscribers about our work on particular sectors or topics. If you would like to receive these alerts, please sign up at: http://bit.ly/NAOoptin. You will always have the option to amend your preferences or unsubscribe from these emails at any time.

National Audit Office

Appendix 1: Audit team

Financial**Audit**Planning

Anna Kinghan
Portfolio Director

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Mike Surman
NAO Engagement Director

T: 020 7798 5415
E: mike.surman@nao.org.uk

Laura Fawcus
NAO Engagement Manager

T: 020 7798 8846
E: Laura.Fawcus@nao.org.uk

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Dean Gibbs
KPMG Engagement Director

T: 07776 163710
E: Dean.Gibbs@kpmg.co.uk

Jyoti Makkar
KPMG Engagement Manager

T: 07341 884102
E: Jyoti.Makkar@kpmg.co.uk

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National Audit Office

Appendix 2: Scope and responsibilities

Financial**Audit**Planning

In line with ISAs (UK) we are required to agree the respective responsibilities of the C&AG/NAO and the Accounting Officer/Client, making clear that the audit of the financial statements does not relieve management or those charged with governance of their responsibilities.
These responsibilities are set out in the Letter of Understanding we issued in April 2019 and are summarised here.

Area	Accounting Officer/management responsibilities	Our responsibilities as auditor
Scope of the audit	• Prepare financial statements in accordance with *the Human Tissue Act 2004* and HM Treasury guidance and that give a true and fair view. • Process all relevant general ledger transactions and make these, and the trial balance, available for audit. • Support any amendments made to the trial balance after the close of books (discussing with us). • Agree adjustments required as a result of our audit. • Provide access to documentation supporting the figures and disclosures within the financial statements. • Subject the draft account to appropriate management review prior to presentation for audit.	• Conduct our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)). • Report if the financial statements do not, in any material respect, give a true and fair view. • Review the information published with the financial statements (e.g. annual report) to confirm it is consistent with the accounts and information obtained during the course of our audit.
Fraud	• Primary responsibility for the prevention and detection of fraud. • Establish a sound system of internal control designed to manage the risks facing the organisation; including the risk of fraud.	• Provide reasonable assurance that the financial statements (as a whole) are free from material misstatement, whether caused by fraud or error. • Make inquiries of those charged with governance in respect of your oversight responsibility.

National Audit Office

Appendix 2: Scope and responsibilities (cont'd)

Financial**Audit**Planning

Area	Accounting Officer/management responsibilities	Our responsibilities as auditor
Regularity	• Ensure the regularity of financial transactions. • Obtain assurance that transactions are in accordance with appropriate authorities, including the organisation's statutory framework and other requirements of Parliament and HM Treasury.	• Conduct our audit of regularity in accordance with Practice Note 10, 'Audit of financial statements of public sector bodies in the United Kingdom (2020)', issued by the Financial Reporting Council. • Confirm the assurances obtained by HTA that transactions are in accordance with authorities. • Have regard to the concept of propriety, i.e. Parliament's intentions as to how public business should be conducted.
Propriety	• Ensure the propriety of financial transactions • Ensure that patterns of resource consumption should meet high expectations of public conduct, and robust governance and respect Parliament's intentions, conventions and control procedures, including any laid down by the Public Accounts Committee.	• Propriety is not readily susceptible to objective verification and, as such, is not expressly covered in the opinion on financial statements. When issues of propriety come to light in the course of the audit of financial statements, the auditor considers whether and, if so, how they may be reported.
Governance statement	• Review the approach to the organisation's governance reporting. • Assemble the governance statement from assurances about the organisation's performance and risk profile, its responses to risks and its success in tackling them. • Board members, with the support of the Audit Committee, evaluate the quality of internal control and governance, and advise on any significant omissions from the statement.	• Confirm whether the governance statement is consistent with our knowledge of the organisation, including its internal control. • Consider whether the statement has been prepared in accordance with HM Treasury guidance, including Managing Public Money.
Accounting estimates and related parties	• Identify when an accounting estimate, e.g. provisions, should be made. • Appropriately value and account for estimates using the best available information and without bias. • Identify related parties. • Appropriately account for and disclose related party transactions.	• Consider the risk of material misstatement in respect of accounting estimates made by management. • Perform audit procedures to identify, assess and respond to the material risks of not accounting for or disclosing related party relationships appropriately.

National Audit Office

Appendix 3: Follow up to recommendations we made in the previous years

Financial**Audit**Planning

In previous years we made the below recommendations to HTA. Below is an update on the status of these recommendations.

Controls around significant judgements	High risk

Finding
We were unable to obtain a full and proper assessment against relevant accounting standards (IAS17) of the draft Stratford agreement, from management.
As such, we have concluded there were no controls are in place to appropriately consider, document and review judgements around the new lease.

Our recommendation
HTA should put in place a control process to ensure that any significant transactions and estimates are thoroughly considered against the accounting standards.
This consideration should be documented and reviewed by the Board and for best practice, the Audit and Governance Committee.

Management response
Management evaluated the MOTO and were satisfied that it was an operating lease as assessed against IAS 17. Going forward we will ensure the notes to the accounts reflect this and will ensure it is noted by our Audit and Governance Committee and if necessary the Board.

Audit update
We have discussed with management the judgments required in 2021-22 and would expect to see a similar governance process operate for the 2021-22 accounts.

High risk: major issues for the attention of senior management which may have the potential to result in a significant deficiency in internal control	**Medium risk:** important issues to be addressed by management in their areas of responsibility.	**Low risk:** problems of a more minor nature which provide scope for improvement

National Audit Office

Appendix 3: Follow up to recommendations we made in the previous years (cont'd)

Financial**Audit**Planning

In previous years we made the below recommendations to HTA. Below is an update on the status of these recommendations.

Clarification of terms within the Memorandum of Terms of Occupation (MOTO)	Medium risk

Finding
There were a number of points raised within the MOTO that were unclear, including:
1. Whether HTA will be invoiced at 7% or 9% of the total; and
2. Whether HTA will be invoiced from day one of the lease i.e. November 2020 on a straight line basis or whether an actual rent free period of 18 months will be granted with rent being payable at the gross value from month 19 onwards.

We have assessed the impact of these ambiguities on the in year expenditure and lease commitments disclosure. The impact is immaterial, but HTA should follow this up with DHSC and seek clarification for future years.

Our recommendation
HTA should seek clarification on the issues set out from DHSC to ensure future accounting entries are complete and accurate.

Audit update
From inquiries with management we understand that it has not been possible to obtain confirmation from the Department at the time of developing our audit plan. We understand management are continuing to follow up with the Department to confirm the details of the lease agreement ahead of preparing the year end accounts.

High risk: major issues for the attention of senior management which may have the potential to result in a significant deficiency in internal control	**Medium risk:** important issues to be addressed by management in their areas of responsibility.	**Low risk:** problems of a more minor nature which provide scope for improvement

National Audit Office

Appendix 3: Follow up to recommendations we made in the previous years (cont'd)

Financial**Audit**Planning

In previous years we made the below recommendations to HTA. Below is an update on the status of these recommendations.

Receivables impairment provision – DHSC debts		Medium risk

Finding
HTA use a simplified approach to impairing debts, based on a percentage of the receivables, informed by historic debt write offs.
However, this is performed over the whole listing, including Department of Health and Social Care debts, which makes up a significant proportion of the year end receivables balance, and DHSC group debts are usually guaranteed by the Department, as set out within the Group Accounting Manual (GAM).
We assessed the impact on the provision in 2020-21 as immaterial and reported this as an unadjusted error, however we suggested that management revisit the calculation for 2021-22.

Our recommendation
We recommend HTA revisit the receivables impairment provision policy and calculation in future years, to ensure the provision is not impairing DHSC debts which are guaranteed by the Department as per the GAM.

Audit update
We have discussed with management and agreed that a provision will not be made against DHSC debts as a result of ageing or assessed credit worthiness. We will confirm whether this has occurred as part of our year end audit.

Grant in aid draw downs		Medium risk

Finding
The cash balance is significantly high for HTA and has been rising for a number of years. We understand HTA have had discussions with the Department around utilising this balance (and have a policy in place to retain a certain level of cash) but the Department have not been responsive in approving this.

Our recommendation
We recommend that HTA continue to pursue discussions with the Department to ensure the HTA are not drawing down Grant in Aid in advance of need.

Audit update
A paper was presented to the October Audit and Governance Committee setting out management's reserves policy. This noted that the HTA is constrained in its ability to reduce reserves due to the need to operate within its funding allocation.

High risk: major issues for the attention of senior management which may have the potential to result in a significant deficiency in internal control	**Medium risk:** important issues to be addressed by management in their areas of responsibility.	**Low risk:** problems of a more minor nature which provide scope for improvement

National Audit Office

Appendix 3: Follow up to recommendations we made in the previous years (cont'd)

Financial**Audit**Planning

In previous years we made the below recommendations to HTA. Below is an update on the status of these recommendations.

Aged receivables debt collection	Low risk

Finding
Upon reviewing the receivables listing, we identified that aged debtors from over a year ago had only been chased once shortly after the receivable was overdue and not subsequently chased in any other debtor checks.

Our recommendation
We would recommend for HTA to chase outstanding aged debts more than once if necessary, to maximise the likelihood of the debt being settled. We also noted that the first chaser, for whatever reason, may not have been received in some cases and subsequent chasers would help rectify this.

Management response
Agreed. Our credit control process normally involves sending three chaser letters followed by telephone calls prior to escalation. We are aware of those debts that are from 2019/20 and will continue to pursue them.

Audit update
The HTA reported as part of its update on strategic risks to the October 2021 ARAC that debt levels for older receivables had reduced. We will follow up the operation of the planned debt collection procedures during our interim audit to assess the consistency with which they have operated.

High risk: major issues for the attention of senior management which may have the potential to result in a significant deficiency in internal control	**Medium risk:** important issues to be addressed by management in their areas of responsibility.	**Low risk:** problems of a more minor nature which provide scope for improvement

National Audit Office

Appendix 4: Future accounting standards

Accounting standard	Detail	Future direction for HTA
IFRS 16: Leases **Implemented from April 1st 2022** For all bodies applying the FReM, where they haven't already adopted IFRS 16 in 2020-21 or a previous year, implementation will be in 2022-23. HMT deferred the implementation of IFRS 16 to 2022-23 to reduce pressure on finance teams in the Covid 19 pandemic, though some Departments, in consultation with HMT have taken the opportunity to early adopt.	IFRS 16 eliminates the operating/finance lease distinction for leases and imposes a single model geared towards the recognition of all but low-value or short term (<12m) leases. The proposals arise partly from the IASB's view that: • disclosures around operating lease commitments have lacked prominence and tended towards understatement; and • even in leases where the underlying asset is not acquired for its whole useful life, the lessee nevertheless acquires an economic right to its use, along with obligations to make good on minimum lease payments. These will now be recognised on the Balance Sheet as a 'right of use' asset and lease liability reflecting the obligation to make lease payments. The lease liability will be measured at initial recognition as the value of future lease payments, with the asset additionally including any initial direct costs incurred by the lessee, plus an estimate of any dismantling/restoration costs. Subsequent measurement of both asset and liability will need to respond to any changes in lease terms. Successful transition will depend on organisations pro-actively capturing additional information about leases – new and existing – which they expect to remain in place at the date of adoption of IFRS 16, especially regarding future minimum lease payments. Organisations should also ensure systems for capturing cost information are fit for purpose, can respond to changes in lease terms and the presence of any variable (e.g. RPI-based) lease terms where forecasts will need to be updated annually based on prevailing indices. There are no significant changes to the accounting requirements where you are acting as a lessor but disclosure requirements around risk exposure are required.	HTA disclosed in the 2020-21 financial statements that the main impact from the standard was expected to be on the new lease for the Stratford site and the term that was expected to be used. It also disclosed that this was expected to have a material impact. We will liaise with the management early in 2021-22 audit to ensure the expected impact is in line with the relevant standards, as detailed quantitative disclosures will be required in 2021-22 (in line with IAS 8). As well as determining the initial liability and asset to be recognised and the impact on the Statement of Comprehensive Income following adoption in April 2022 there will be a requirement to assess the fair value of the asset.

Appendix 5: Future changes to auditing standards
Financial**Audit**Planning

ISA (UK) 315 (Revised) : Identifying and Assessing the Risks of Material Misstatement

Effective from 2022-23

ISA 315 is the critical standard which drives the auditor's approach to the following areas:

- Risk Assessment
- Understanding the entity's internal control
- Significant risk
- Approach to addressing significant risk (in combination with ISA 330)

The International Auditing & Assurance Standards Board (IAASB) concluded that whilst the existing version of the standard was fundamentally sound, feedback determined that it was not always clear, leading to a possibility that risk identification was not consistent.

The aims of the revised standard is to:

- Drive consistent and effective identification and assessment of risks of material misstatement
- Improve the standard's applicability to entities across a wide spectrum of circumstances and complexities ('scalability')
- Modernise ISA 315 to meet evolving business needs, including:
  - how auditors use automated tools and techniques, including data analytics to perform risk assessment audit procedures
  - ow auditors understand the entity's use of information technology relevant to financial reporting
- Focus auditors on exercising professional scepticism throughout the risk identification and assessment process.

The key impacts are:

- Significant increase in work on entity's use of IT in business and system of internal control.
- Clearer workflow within the standard to highlight the importance of the auditor's understanding of the entity and environment, the applicable financial reporting framework, and system of internal control.
- New concepts: e.g. inherent risk factors, spectrum of inherent risk
- Changed definitions: notably, the definition of 'significant risk'
  - **Significant risk** – An identified risk of material misstatement:
    - For which the assessment of inherent risk is close to the upper end of the spectrum of inherent risk due to the degree to which inherent risk factors affect the combination of the likelihood of a misstatement occurring and the magnitude of the potential misstatement should that misstatement occur; or
    - That is to be treated as a significant risk in accordance with the requirements of other ISAs (UK).

National Audit Office

Appendix 5: Future changes to auditing standards

Financial**Audit**Planning

ISA (UK) 240: The Auditor's Responsibilities Relating to Fraud in an Audit of Financial Statements

Effective from 2022-23

Misstatements in the financial statements can arise from either fraud or error. The distinguishing factor between fraud and error is whether the underlying action that results in the misstatement of the financial statements is intentional and involves deception or is unintentional. ISA (UK) 240 deals with the auditor's responsibilities relating to fraud in an audit of financial statements.

The revision to the standard aims to clarify the obligations of auditors to identify and assess the risk of material misstatement due to fraud, as well as including supplemental requirements and guidance to enhance the auditors' procedures.

Key changes are:

- The objectives of the auditor have been revised to emphasise the requirement to obtain reasonable assurance about whether the financial statements are free from material misstatement due to fraud.

- There is a greater focus on professional scepticism including that audit approaches don't show bias to looking for corroborative evidence or excluding contradictory evidence.

- There are new requirements for the auditor to determine whether the engagement team requires specialised skills or knowledge to perform their work on fraud, including their assessment of fraud risk, associated procedures and evaluation of the evidence obtained.

- There is additional guidance regarding the discussion required by ISA (UK) 315 among the audit engagement team. This is to discuss the susceptibility of the entity's financial statements to material misstatement due to fraud or error. The revised ISA (UK) 240 emphasises the need for an exchange of ideas among all engagement team members about fraud risk factors.

- The auditor shall make inquiries of management, or others within the entity who deal with fraud allegations, to determine whether they have knowledge of any actual, suspected or alleged fraud, including cases of fraud raised by employees or other parties.

- Auditors are to hold a discussion with those charged with governance regarding the risks of fraud in the entity and to consider the implications for the audit.

- The auditor must communicate with those charged with governance matters relating to fraud (unless prohibited by law or regulation) and the auditor's assessment of the risks of material misstatement due to fraud.

- Auditors must evaluate whether their assessment of the risk of material misstatement due to fraud remains appropriate at audit conclusion, that sufficient appropriate audit evidence has been obtained, and that the financial statements are not materially misstated as a result of fraud.

- The auditor's report shall explain to what extent the audit was considered capable of detecting irregularities, including fraud.

National Audit Office

Appendix 6: Fraud matters

Financial**Audit**Planning

ISA (UK) 240 'The auditor's responsibility to consider fraud in an audit of financial statements' requires us, as your auditors, to make inquiries and obtain an understanding of the oversight exercised by those charged with governance.

Fraudulent Financial Reporting: Intentional misstatements including omissions of amounts or disclosures in financial statements to deceive financial statement users.

What can constitute fraud?

Internal misappropriation of assets: Theft of an entity's assets perpetrated by management or other employees.

External misappropriation of assets: Theft of an entity's assets perpetrated by individuals or groups outside of the entity, for example grant or benefit recipients.

Rationalisation/attitude: Culture of environment enables management to rationalise committing fraud – attitude or values of those involved, or pressure that enables them to rationalise committing a dishonest act.

Incentive/Pressure: Management or other employees have an incentive or are under pressure.

Fraud risk factors

Opportunity: Circumstances exist – ineffective or absent control, or management ability to override controls – that provide opportunity

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ISA inquiries

Our inquiries relate to your oversight responsibility for

- Management's assessment of the risk that the financial statements may be materially misstated owing to fraud, including the nature, extent and frequency of such assessments;

- Management's process for identifying and responding to the risks of fraud, including any specific risks of fraud that management has identified or that has been brought to its attention;

- Management's communication to the Audit Committee (and others charged with governance) on its processes for identifying and responding to the risks of fraud; and

- Management's communication, if any, to its employees on its views about business practices and ethical behavior.

We are also required to ask whether you have any knowledge of any actual, suspected or alleged fraud and discuss with you the risks of fraud in the entity.

Audit approach

We have planned our audit of the financial statements so that we have a reasonable expectation of identifying material misstatements and irregularity (including those resulting from fraud). Our audit, however, should not be relied upon to identify all misstatements or irregularities. The primary responsibility for preventing and detecting fraud rests with management.

We will incorporate an element of unpredictability as part of our approach to address fraud risk. This could include, for example, completing procedures at locations which have not previously been subject to audit or adjusting the timing of some procedures.

We will report to the Audit Committee where we have identified fraud, obtained any information that indicates a fraud may exist or where we consider there to be any other matters related to fraud that should be discussed with those charged with governance.

NAO National Audit Office

Appendix 7: Guidance for governance

FinancialAudit**Planning**

Support to Audit Committees

We have developed a range of guidance and tools to help public sector Audit Committees achieve good corporate governance. This includes specific guidance on financial reporting and management during Covid-19

https://www.nao.org.uk/search/pi_area/support-for-audit-committees/

https://www.nao.org.uk/report/guidance-for-audit-and-risk-committees-on-financial-reporting-and-management-during-covid-19/

Climate Risk: A good practice guide for Audit and Risk Assurance Committees

Audit committees play a key role in scrutinising and advising the Board and Accounting Officer on risks arising from climate change. This guide will help ARACs recognise how climate change risks could manifest themselves and support them in challenging senior management on their approach to managing climate change risks

Climate change risk: A good practice guide for Audit and Risk Assurance Committees - National Audit Office (NAO) Report

Corporate Governance Code for central government departments

The document was released in April 2017 and lays out the model for departmental boards, chaired by Secretaries of State and involving ministers, civil servants and non-executive board members. The principles outlined in the code will also prove useful for other parts of central government and they are encouraged to apply arrangements suitably adapted for their organisation.

https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments-2017

Guidance for governance

Sustainability reporting

This guidance is to assist with the completion of sustainability reports in the public sector. It sets out the minimum requirements, some best practice guidance and the underlying principles to be adopted in preparing the information.

https://www.gov.uk/government/publications/public-sector-annual-reports-sustainability-reporting-guidance-2020-to-2021

Good practice in annual reports

The Building Public Trust Awards recognise outstanding corporate reporting that builds trust and transparency. The interactive PDF below illustrates a range of good practice examples across annual reports in both the public and private sector.

https://www.nao.org.uk/report/good-practice-in-annual-reports-february-2021/

Disclosure Guides

Our disclosure guides for clients help audited bodies prepare an account in the appropriate form and that has complied with all relevant disclosure requirements.

http://www.nao.org.uk/report/nao-disclosure-guides-for- entities-who-prepare-financial-statements-in-accordance-with-the-government-financial-reporting-manual-frem/

NAO National Audit Office

Appendix 8: Good Practice in Annual Reporting

Financial**Audit**Planning

The Audit Committee plays a key role in scrutinising the Annual Report and Accounts, ensuring the quality of disclosures and its understandability for users.

To support the Audit Committee in this role, we have published our **Good Practice in Annual Reporting** guide.

The Guide, issued in February 2021, provides specific examples of best practice we identified during our review of a sample of 2019-20 annual reports. The good practice principles are grouped under the following headings: supporting accountability, transparency, accessibility and understandability (on the right) and these should be evident across the common sections of an annual report (on the left).

We hope you find this Guide useful as you prepare your Annual Reports for 2020-21.
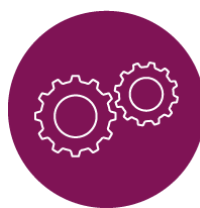
| **Strategy** | **Risks** | **Operations** | **Governance** | **Measures of success** | **Financial performance** | **Understandable** |
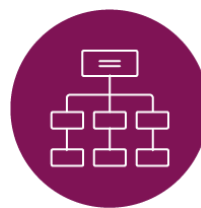
Could you be a winner in 2020-21?
If you would like to nominate your organisation for the Building Public Trust Awards for your 2020-21 Annual Report and Accounts, please speak to your NAO Team or contact us at **Building.Public.Trust@nao.org.uk**.

National Audit Office

OFFICIAL

Appendix 8: Good Practice in Annual Reporting

Financial**Audit**Planning

Essential features of a good annual report

Supporting

- telling the [...] and bala[...]
- complian[...] requirem[...]
- clear acti[...]

Transparency

- frank and honest analysis;
- consideration of the challenges an organisation is facing;
- appropriate use of data; and
- quantification of risks and performance measures.

Accessibility

- highlights key trends in the financial statements;
- concise summaries of key points; and
- consideration of how the organisation engages with key stakeholders and meets their needs.

Understandable

Use of:
- plain English to explain difficult concepts;
- infographics and diagrams to communicate important messages; and
- clearly integrated structure to help users navigate it effectively.

National Audit Office

Latest review date – 13/01/22

Strategic risk register 2021/22
Risk summary: residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
R1: Failure to regulate appropriately	Delivery (a-d & f) and Development (a-d) objectives	**10 – Medium**	At tolerance	⇔⇔⇔⇔
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	**9 - Medium**	Above tolerance	⇑⇔⇔⇓
R3: Failure to manage expectations of regulation	Delivery e) and Development c)	**9 - Medium**	At tolerance	⇔⇔⇔⇔
R4: Failure to utilise our capabilities effectively	Delivery, Development and Deployment (a, c, and d)	**12 - High**	Above tolerance	⇔⇔⇔⇓
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	**6 - Medium**	Above tolerance	⇔⇔⇔⇔
R6: Failure to achieve the benefits of the organisational Development Programme	Development (a-d) objectives	**9 - Medium**	At tolerance	⇔⇔⇔⇔

* Strategic objectives 2019-2022:
** 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	**2**	**5**	**10 - Medium**
Tolerance threshold:					**10 - Medium**

Commentary
At tolerance. We have a good regulatory framework, with a strong assured position on our key regulatory processes from an Internal Audit review within the past two years. Activity in the PM sector is now stable with no current activity on emergency mortuary licensing. The pilot temporary licensing of a very small number of funeral directors' premises to support national public health post-mortem Covid surveillance sampling has not expanded, with only 4 sites active. SMT are considering our approach to this pilot project. Quarter 3 has seen a full schedule of inspections, using either VRAs and / or site visits, this is broadly in line with pre-pandemic activity and this level of activity is planned to continue through quarter 4 We continue to use all other regulatory tools and processes, such as managing and responding to incident reports (Serious Adverse Events and Reactions and HTA Reportable Incidents), whistleblowing / informant information and ongoing engagement with our regulated sectors, with investigations and active regulatory action having continued. We continue to actively manage a small number of more unusual regulatory matters with establishments SMT believes this risk remains stable, at tolerance, in January 2022.

R2: There is a risk that we will be unable to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident: relating to an activity, we regulate; caused by deficiency in the HTA's regulation or operation; where we need to regulate, such as with emergency mortuaries; that causes business continuity issues.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20	**3**	**3**	**9 - Medium**
Tolerance threshold:					**6 - Medium**

Commentary
This risk concerns our ability to respond to incidents irrespective of their nature or cause, which could be from matters outside the HTA's remit or control as well as matters for which we are directly responsible. The Executive has therefore set a lower tolerance level on this risk as our ability to respond appropriately is within the HTA's control. The HTA believes that our incident management response plans have been well tested and found to be robust and effective through their deployment in managing the impact of the pandemic and related restrictions and in their adaptation for use in managing the potential impacts of EU Exit following the end of the Transition Period. We have continued to use these arrangements in preparing and managing the potential consequences of an incident that occurred at an HTA-licensed establishment which, although not a regulatory matter, has required significant HTA resource. This incident has placed continued demands on senior management, particularly since the departure of the CEO at the end of October 2021. The incident also placed significant impact on our Communications / Media team, in addition to those leading the relevant sector. SMT notes that our arrangements have stood up well to the most critical phase of this incident although there have been inevitable impacts on the delivery of some strategic activities within the communications team. Having increased the risk scoring in July we are now of the opinion that the likelihood of this risk materialising has subsided – we now score this risk as 9 - Medium.

R3: There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.

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
At tolerance. We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DHSC (Department of Health and Social Care) and stakeholders regarding the announced Independent inquiry and we provide clear lines to the media when necessary. Although this has been a challenging area of work we believe it has been managed well over the last quarter. In 2020/21, the Development programme included a specific workstream to strengthen horizon scanning on emerging changes to policy and activities where the HTA may be required to act or offer an authoritative voice. This approach has been embedded in 2021/22 alongside the piloting of alternative and additional approaches to engagement. We continue to support the wider Government agenda to encourage development and innovation across UK life sciences and contribute to work looking at better regulation across all sectors of UK business. In late quarter 2/ early quarter 3 the HTA convened round table discussions with key external stakeholders. These sessions represented the first of a series of roundtables aimed at supporting innovation and growth in the life sciences sector. The first two roundtables were focused on issues raised over retention of tissue blocks and slides from coronial post-mortems for research and on supporting innovation in the Human Application sector. The HTA have submitted areas of potential legislative change to the Department in response to requests and this, should it be taken forward, would clarify and strengthen the HTA's remit going forward. The HTA supported the UK Health Security Agency's pilot project to test the feasibility of post-mortem surveillance sampling for COVID-19 through the licensing of a small number of Funeral Directors in one region. The HTA is in discussion with the UKHSA about the future direction of this work as most of these few fixed term licences are due to expire before 31 March 2022. All these matters are being actively managed. SMT note that the critical incident, which could have led to significant misperception of the HTA's role has not so far done so and appears not to have had a detrimental impact on the HTA's reputation. At their January meeting SMT agreed this risk remains unchanged, at tolerance.

R4: There is a risk that we will fail to utilise people, data, and business technology capabilities effectively.

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

Commentary
Above tolerance. From Quarter one of 2021/22, the HTA started implementing a partial organisational redesign to address capability gaps identified during the previous year and has started an ambitious recruitment campaign for 10 posts including that of a Deputy Director adding further support and resilience to the Senior Management Team. By August 2021, appointments had been made to seven and a half posts, with plans to progress the recruitment to the remaining 2.5 Wte in Q3 2021/22. Progress in the recruitment to the remaining posts has been consciously paused to facilitate input from the incoming CEO to both roles and future organisational design. Key vacancies remain relating to the planning and portfolio manager and Chief Information & Technology Officer. Interim appointments have been made to both posts and will be subject to a review and update in quarter 4. The combined pressures of the critical incident and vacancies led to the need to reprioritise activity across quarter 3, as captured on other risks this has had some implication for strategic delivery in relation to communications and the development programme. A renewed focus on the business plan for Quarter 4 recognises and prioritises key activities across Quarter 4 that are either in direct support of current business activity or are dependencies for ongoing project activity which will continue in the next business year.   Recruitment and retention remain a key priority for the HTA. The HTA's new Chief Executive, Dr Colin Sullivan, began his new role on 1 January 2022 and this is clearly a key mitigator of some organisational risk. Although some key vacancies remain unfilled on a permanent basis progress continues to be made and key roles in Communications, Business Planning and IT have interim resource in place and activity is underway to continue with recruitment in quarter 4. This risk was increased during Quarter 3, and although still above tolerance SMT believe this risk has reduced since the last review and will continue to do so over this quarter.

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 – High	**3**	**2**	**6- Medium**
Tolerance threshold:					**3 - Low**

Commentary
Above tolerance.   Our financial review at the end of quarter 3 provides assurance that expenditure for the full year will be in line with budgets. We forecast a balanced year end position, with risk more likely to see small underspends emerging if planned activity cannot progress as planned.   We await a further commission from the Department regarding the 2021 Spending Review, we do not anticipate specific savings measures for 2022/23, but are mindful that some reductions in our Grant in Aid could be required across the SR period given the tight settlement provided for the core departmental and ALB activity.   Recommendations on 2022/23 fees were discussed and Board agreement reached on fee levels at the November Board meeting. Although CPI has increased significantly since this agreement any upward pressure on the HTA's expenditure for 2022/23 will be dependent on the availability and scale of any public sector pay award remit in 2022. Continued inflation and current levels could result in more significant pressures from 2023 onwards.   SMT have agreed that this risk is unchanged.

R6: There is a risk that we fail to achieve the full benefits of the organisational Development Programme

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	3	9 – Medium	**3**	**3**	**9- Medium**
Tolerance threshold:					**9 - Medium**

Commentary
At tolerance.   The Development Programme has been adversely impacted this year by the availability and commitment of resources (people and financial). The project deliverables in late quarter 2 and quarter 3 have been reframed to support incremental progress. The continued uncertainty of available investment into early December 2021 has negatively impacted on the programme's progress. On 18 January, SMT agreed the resourcing and investment to a reprioritised set of commissions and deliverables for quarter 4. These commissions included targeted work to strengthen data and intelligence, support the development of the target operating model and development stakeholder engagement.   The agreement of this resource will support identified developments. The risk is at tolerance as plan for delivery are implemented.

Reviews and revisions

(11/03/21) SMT review March 2021

SMT reviewed all risks - generally our risk levels are stable and there have been no significant changes from the last review conducted in February. A detailed review of our risk summary is being conducted.

(30/03/21) SMT review March 2021

SMT reviewed the risk and set tolerance levels for each risk. It was agreed that further review will be undertaken in early April prior to sharing this summary with both the Board and ARAC (Audit and Risk Assurance Committee) in May and June, respectively. To note, is the relationship between risks one and two and their respective tolerance levels as they are interdependent.

(29/04/21) SMT review April 2021

Updates to the narrative, reflect the new arrangements for this financial year. This new format will allow SMT to review the strategic risks and their respective tolerance levels and implement the necessary activities to either reduce residual risks to tolerance or maintain them at an accepted level.

Risk six, SMT felt no longer reflects where we are now that key work pages within the Development Programme have been completed.

(27/05/21) SMT review May/June 2021

The above risk summary was reviewed by SMT, and it was agreed that the risk scorings have remained stable. Risk four was discussed in detail in light of the change in senior staff that will take place in quarter three and the revised structure that will be implemented over the coming months. To ensure the recruitment process continues, SMT have agreed to extend HR support to the end of the process.

(09/07/21) SMT review July 2021

SMT had a brief discussion of the overall risks with a view to a deeper dive at the end of July.

(06/08/21) SMT review August 2021

SMT have taken a detailed look at the underpinning assessment of each risk. In particular the following risks were flagged; R4 where the recruitment of key staff may have an impact on the both the likelihood and impact. It was agreed that this would be deferred till the new starters were in post and fully embedded. It was agreed that at least this risk will need to be reframed, possibly in line with the strategy update. R2 – Sandpiper may be driving up the residual risk score, and it was felt that this should also be reflected in the inherent risk as a new cause has materialised. R1,

the re-introduction of site visits in conjunction with VRA's may reduce the scoring and will be looked at again in the autumn.

(09/09/21) SMT review September 2021

SMT deferred a final review of risks until the 6 October 2021. All risks remain unchanged from the August 2021 review, although narratives have changed significantly to provide more current updates on risk levels.

(18/11/21) SMT review November 2021

SMT discussed the risks and in particular the impact that the current incident that has become public is having on workloads. The current vacancies that exist are also adding pressure across the business. A more detailed discussion is to take place early December.

(13/01/22) SMT review January 2022

A detailed discussion took place with our new Chief Executive in attendance. The SMT downgraded risks 2 and 4.

Strategic Aims

Delivery: Deliver a right touch programme of licensing, inspection, and incident reporting, targeting our resources where there is most risk to public confidence and patient safety.
(a) Deliver effective regulation of living donation.
(b) Provide high quality advice and guidance in a timely way to support professionals, Government, and the public in matters within our remit.
(c) Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who   do not comply with our standards.
(d) Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.

Development: • Use data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target resources effectively.
(a) Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
(b) Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements.
(c) Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation.

Deployment: Manage and develop our people in line with the HTA's People Strategy
(a) Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
• Provide a suitable working environment and effective business technology, with due regard for data protection and information security
• Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation

Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HTA's strategy or purpose.

Whether it is possible for the HTA to do anything to control the risk (so external risks such as weather events are not included).

Rank

The risk summary is arranged in risk order.

Risk scoring system

We use the five-point rating system when assigning a rating to the likelihood and impact of individual risks:

| Likelihood: | 1=Rare | 2=Unlikely | 3=Possible | 4=Likely | 5=Almost certain |
| Impact: | 1=Very low | 2=Low | 3=Medium | 4=High | 5=Very High |

Risk Scoring Matrix					
5. Very High	5 Medium	10 Medium	15 High	20 Very High	25 Very High
4. High	4 Low	8 Medium	12 High	16 High	20 Very High
3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
1.Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
Likelihood					
Risk score = Impact x Likelihood	1.Rare (≤3%)	2.Unlikely (3%-10%)	3.Possible (10%-50%)	4.Likely (50%-90%)	5.Almost certain (≥90%)

(IMPACT is shown along the vertical axis)

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HTA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlikely to change unless the organisation's role or environment changes dramatically.

Risk tolerances are the boundaries for risk taking. The risk appetite statement informs the development of risk tolerances for the HTA and provides guidance on how the risk appetite statement is to be applied in everyday business activities and decisions.

Assessing inherent risk

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

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

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance, it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L			1	2	3			
1	**Failure to regulate in a manner that maintains public safety and confidence and is appropriate** **(Risk to Delivery objectives a-d & f Development objectives a-d)** Risk Owner: **Allan Marriott-Smith**	*Causes* • *Failure to identify regulatory non-compliance* • *Regulation is not transparent, accountable, proportionate, consistent and targeted* • *Regulation is not sufficiently agile to respond to changes in sectors* • *Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IAs)).* • *Inadequate adherence to agreed policies and procedures in particular in relation to decision making* • *Poor quality or out of date policies and procedures* • *Failure to identify new and emerging issues within HTA remit* • *Failure to properly account for Better Regulation* • *Insufficient funding in regulated sectors* • *Failure to deal with regulatory consequences of the Transition Period and the period after 31 December 2020.* • *Failure to properly manage the business impact of the coronavirus pandemic.* *Effects* • *Loss of public confidence* • *Compromises to patient safety* • *Loss of respect from regulated sectors potentially leading to challenge to decisions and non-compliance* • *Reputational damage*	5	3	Ongoing	**Regulatory model** Regulatory model comprising a mixture of proactive regulatory assessment (e.g. through site visit inspections and sector engagement) and reactive tools (such as responding to incidents reported to the HTA, investigations of concerns raised etc). Process for consideration of police referral maintained and used. Annual collection of activity data in HA sector; biennial collection of compliance updates data from other sectors.	5	2	Following the suspension of routine site visit inspections at the onset of Covid-19 pandemic restrictions, work was undertaken in 2020/21 to develop a risk assessment and a virtual regulatory assessment tool. VRAs are now incorporated into business alongside a decision making framework to inform decisions about whether to undertake a site visit, VRA or hybrid inspection. Development Programme-led activity from 2020/21 to develop a new Target Operating Model to re-state and clarify the key elements in our approach to regulation. A full inspection timetable has been implemented from quarter 3 of the 21/22 business year.	10	X			Preventative	Board developed and approved the current HTA Strategy and was aware of the risks and opportunities associated with the suspension of routine site visit inspections during Covid restrictions and how VRAs were being incorporated into BAU. Board were aware of the issue of failing to meet the legal obligation to carry out a site visit of HA establishments at least once every two years because of the suspension of routine site visits during Covid. SMT agreed late May 2021 to resumption of routine site visits in HA sector once restrictions are lifted, alongside continuing use of VRAs. Routine site visit elements are now being included in HA inspections, although some are VRA only, determined on a risk-based approach. Continuing use of all other regulatory tools during the pandemic restrictions, including managing HTARIs and SAEARs, investigations, advice to regulated sectors (such as seminars in Anatomy sector, Professional Newsletters). Development and use of emergency mortuary licensing regime during the	In-depth evaluation of pilot programme of 10 x virtual regulatory assessments in the HA sector in quarter three 2020/21 carried out and reported to the HTA Board Meeting February 2021 and a further evaluation of the expansion into remaining sectors in summer 2021. VRAs incorporated into BAU in all sectors, as evidenced in Business Plan and inspection schedule. Internal Audit late Quarter 3 / early Quarter 4 2020/21 on 'Inspection Process during Covid-19' - report agreed late May 2021; Moderate assurance; considered by ARAC; all actions now complete (per ARAC Quarter 3 2021). Renewal of some emergency mortuary licences although most have now been revoked as no longer required. SMT consideration of request by UKHSA to extend the small number of Funeral Director removal licences (for post-mortem public health surveillance for Covid-19) agreed on basis of bringing them into a normal regulatory regime ie LAAV, open-ended licences funded by appropriate fees. (Head of Regulation written to UKHSA Project Lead 21 Dec. 2021.) Police referral made late 2019/20 has been investigated by the police, supporting Witness Statements provided by the HTA, decision pending with CPS.
						Regulatory decision making framework			Heads of Regulation using dashboards to track open cases and ensure there is effective follow-up, in accordance with the HTA's decision-making framework.		X			Preventative	Reports summarising numbers of Regulatory Decision Meetings included in monthly performance pack and recorded in CRM. Case Review Meetings all summarised in CRM.	Satisfactory Internal Audit Report (strong assurance) November 2020. Lessons learned from Regulatory Decision Meetings (RDMs) held January 2020 and used to inform update to Regulatory Decision Making SOP. Regulatory Decision Making SOP updated February 2020. Evidence of regulatory decision making framework being used in practice e.g. Case Review Meetings recorded in CRM, numbers of RDMs reported in monthly performance data pack.
						Annual scheduled review of Strategy					X	X		Preventative	Outputs from annual strategy review translate into revised annual Strategy	Annual Board Strategy session held 27 April 2021 informed annual strategy refresh. Latest update of HTA Strategy published November 2021.
						The HTA has produced a detailed business plan for the remainder of the year. These plans are approved by SMT and balance core regulatory functions, development priorities and resource deployment considerations.			In the continuing absence of a role with specific responsibility for the business plan, SMT and their respective Heads have ensured there is regular review and updating of the operational business plan and monthly performance pack. Consultancy-led review developed a portfolio management approach that SMT could adopt, including some initial tools. Interim Portfolio Planning Manager (contractor) appointed on short-term contract to develop and implement this new approach, between December 2021 and February 2022.		X	X		Preventative	Operational business plan for 2021/22 (using Excel spreadsheet template developed in 2020/21) in use and reviewed regularly by SMT. Contractors engaged Quarter 1 2021/22 to support development of business planning through adoption of a portfolio management approach. 2020/21 narrative Business Plan for 2021/22 published during Quarter 3 (Covid-related delay).	Progress on the Portfolio Management approach regularly discussed at SMT meetings. SMT receives monthly reports of Management Information for review and action. Interim Portfolio Planning Manager appointed December 2021.

				X	Detective	Internal audit conducted on Key Regulatory Processes late 2018/19, receiving substantial assurance and noting good areas of best practice. Internal audit on the Inspection Process during Covid-19 conducted late 2020/21 see R4. Moderate assurance and management actions complete, as noted by ARAC Quarter 3 2021.	Internal Audit 2019: Final report received April 2019 and showed substantial assurance. The two low priority recommendations were followed-up with management actions completed during 2019/20, namely review of SOPs for key regulatory processes (completed) and training on core legislative framework, HT Act which was delivered in March 2020. Internal Audit 2021: low priority actions all complete by Autumn 2021.
Well established processes support our core regulatory business.	Development and introduction of new regulatory process (VRA) managed as a project with Director of Regulation as SRO, Head of Regulation (for Research and Anatomy) as Deputy SRO, and a RM as Project Manager. Project now in process of closure with formal closure report to be discussed by SMT in January 2022. Post-closure actions are in hand. (December 2021.) Detailed evaluation carried out on two occasions, prior to adoption in HA sector and expansion into other sectors. Completion of further management actions identified by Internal Audit of effectiveness of the inspection process - by Quarter 3 2021. (Reviewed by ARAC.) (Principally ensuring other regulatory processes and documentation (SOPs) were updated to take account of VRAs.)						

Quality management systems

HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model	The HTA's Quality Manager left in 2019/20 and has not been replaced. This function has not been formally re-allocated. A Regulation Manager with experience in QMS continues to coordinate activities to ensure policies are reviewed and updated, with input and support from the Quality Forum as relevant.	X	Preventative/ Monitoring	Management oversight and reporting trough the monthly performance pack. This work had been expected to transfer to a newly created role during Quarter 2 2021/22 but this has not happened, hence the RM is still coordinating this work.	Limitations in QMS still remain. Scheduled reviews have now been re-instated by the RM who is covering this work following the departure of the quality manager in 2020/21. QMS and monthly performance reporting pack includes evidence of degree to which the documents are current.	

People

Adherence to the HTA People Strategy which has been substantially amended and approved by the Board		X	Preventative	Management information and assessment presented to the Board quarterly.	Chief Executive's report to the Board now includes HR report - last presented to November 2021 meeting. Mid-year reviews completed during Quarter 3 2021.	
Training and development of professional competence		X	Preventative	Annual PDPs, which include Development Objectives, Corporate Training Programme (led by Head of HR), Career Investment Scheme proposals to SMT, induction programme for new entrants, with a bespoke programme for RMs.	Evidence of corporate training programme, including quarterly mandatory training. Quarterly Regulation-led Training sessions held virtually in July 2021, September 2021 and scheduled for January 2022. 'Lunch and Learn' programme.	
Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas	As vacancies arise, SMT take the opportunity to review business requirements and target building capability and filling skills gaps. An organisational redesign for aspects of the HTA's work was developed during late 2020/21 to enable key gaps and capability issues to be addressed and a large-scale recruitment programme for 10 posts, including the redesign, initiated in Quarter 1 of 2021/22.	X X	Preventative/ Monitoring	SMT assessment of skills requirements and gaps as vacancies occur. Organisational design. Recruitment policy.	Staffing levels and risks reported quarterly to the Board most recently July 2021. Large recruitment programme for 10 vacancies started May 2021, incorporating the new roles created by the organisational redesign of key support functions and search for key additional capability identified as required in the RM cadre. Recruitment policy reviewed by SMT May 2021 to be completed by autumn 2021.	

EU Exit (End of Transition period and HTA Exit SIs 'grace period')

Fortnightly Transition Period oversight meetings from February 2020 with+H4:Q16+H4:Q15 Close liaison with DHSC to ensure communications are in line with government policy and that appropriate arrangements are made to support DHSC and stakeholders during the transition period. HA Guide, ODT Framework and other external guidance being updated in line with new legislation to ensure we can regulate accordingly.	Weekly project meetings from Quarter 3 2020/21. Dedicated project manager (external contractor) and Regulation Directorate and comms team resource. Weekly Project Governance meetings from mid-January 2021 (after daily / thrice weekly stand-ups ceased). Continued close liaison with DHSC policy and communications teams and EU Exit and Trade teams, including participation in DHSC-led meetings with ALBs. Project maintaining active oversight of risks, issues, and resource requirements.	X X	Preventive / Detective / Monitoring	Weekly reporting by ANH to SMT under standing item on SMT agenda. Internal Audit Quarter 3 of 2020/21 - moderate assurance. SMT lead for project - ANH (Director of Regulation). Formal project re-established from Quarter 3 2020/21. SMT papers for key decisions.	EU Exit - dedicated project manager (contractor) appointed Quarter 3 2020/21 until 31 July 2021. (Project due to be closed and handed over to business as usual by 31 July 2021.) EU Exit / UK Transition Project documentation and records in Teams Channel. Internal Audit on Risk focusing on EU Exit - reported January 2021, moderate assurance, completion of management actions tracked in audit tracker by ARAC. Standing item on SMT weekly minutes - EU Exit update - reported in minutes.	

Regulatory model

	Development work being undertaken to become a more data-driven risk based regulator as part of the HTA Development Programme.	X	Preventative			

Other

	Strengthening horizon scanning arrangements	X	Preventative			

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L								
2	**Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:** • **relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)** • **caused by deficiency in the HTA's regulation or operation** • **where we need to regulate, such as with emergency mortuaries** • **that causes business continuity issues** **(Risk to all Delivery Development and Deployment objectives)** Risk owner: **Nicky Harrison**	**_Cause_** • _Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)_ • _Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)_ • _Failure to work effectively with partners/other organisations_ • _Breach of data security_ • _IT failure or attack incident affecting access to HTA office_ • _External factors such as terrorist incident, large scale infrastructure failure or pandemic_ **_Effect_** • _Loss of public confidence_ • _Reputational damage_ • _Legal action against the HTA_ • _Intervention by sponsor_	5	4	_Future but increased likelihood over next few months_	Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff	3	3		6	X	X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Subject to internal audit reported to ARAC in February 2020 Version 19 of CIRP published July 2019. CIRP deployed in March 2020 to manage coronavirus pandemic. CIRP used as framework for managing Sandpiper critical incident. Business Continuity and Critical Incident Response Plans updated and approved by SMT on 10 June 2021.
						All specific roles identified in the Critical Incident Response Plan are filled.					1 X	2	3	Preventative	Evidence of regular review and updating of the CIRP and no specific CIRP roles left vacant or, if role is vacant, cover arrangements put in place.	CIRP reviewed and updated to version 19 in July 2019. Further minor changes proposed February 2020 updated roles following staff changes. Business Continuity and Critical Incident Response Plans updated and approved by SMT on 10 June 2021.
						Media handling policy and guidance in place and Critical Incident Response Plan includes requirement to involve Comms team. Comms Team have embedded media handling and development of lines to take into business as usual.			Comms Team maintain close working relationships with colleagues across the business and proactively raise awareness of the need for Comms role in shaping lines and dealing with media. Experience of engaging and managing a contract with Crisis comms consultants to		X			Preventative	Policy reviewed as scheduled. Reports on any key media issues and activity in the Chief Executive's Report. Evidence of active Comms Team participation in issues with potential for media or public interest.	Media issues are included in the quarterly Board reporting as they arise and as relevant. Media enquiries successfully managed during critical incident phase of Sandpiper.
						Availability of legal advice					X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy			Engagement with other potential investigatory authorities, such as NHS Counter Fraud Authority		X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Police referral process used regularly by SMT and captured in SMT minutes. Police referral process shown to have been effective in 2020/21 with a referral to police for a potential breach of the HT Act being taken forward in an active investigation. Police referral policy being updated - considered by the Board November 2021 and on the agenda for finalisation February 2022.
						Onward delegation scheme and decision making framework agreed by the Board					X	X		Preventative	Standing Orders and Board minutes	Standing Orders published May 2017, updated at Board meeting in November 2021.
						Regulatory decision making framework			Regulatory Decision Making process and SOP regularly reviewed and disseminated to staff.		X			Preventative	Reports to Board of key decisions in Chief Executive's Report to the Board.	Number of Regulatory Decision Meetings detailed in monthly management performance pack, for review by SMT. Regulatory Decision Making SOP reviewed and updated March 2020 with the next review due by March 2022.
						IT security controls and information risk management					X	X		All	SIRO annual review and report Internal audit reports	Cyber security review - standing agenda item at ARAC - last discussed June 2020. Cyber Security has been a standing agenda item in the form of a dashboard report at each ARAC meeting.
						Critical incident response plan regularly reviewed and tested			Actions associated with the internal audit reported in February 2020.		X	X		Preventative	Critical Incident Response Plan and notes of test, reported to SMT Use of CIRP reported to SMT.	CIRP used to manage response to coronavirus pandemic from March 2020. CIRP deployed for a short period in May / June 2021 to deal with confidential matter. CIRP used as basis for Sandpiper response planning in Autumn 2021.

			Evaluate test exercise of incident and feedback to all staff.		Question over whether a test of the Plan is required in light of the recent stress test presented by the coronavirus pandemic and more recently in the HTA's response to Sandpiper, managed as a critical incident.		X			Preventative	SMT content that activation and use of CIRP during first wave and first lockdown superseded the need for a test. SMT note CIRP framework used in managing the HTA's planning for and response to the critical incident arising from the police investigation codenamed 'Sandpiper'.	Noted in ARAC Audit Tracker.
			Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA.		Awareness raised of PM sector reporting requirement (HTARIs) at external training events, eg 9 April 2021 - Level 3 Diploma (Anatomical Pathology Technology) trainee APT HTA lecture, 18 September 2020 - Level 3 Diploma (Anatomical Pathology Technology) trainee APT HTA lecture Quarterly meeting with NHSBT to review ODT SAEARs cases over 90 days and any complex cases. Publication of quarterly incident numbers in the professional e-newsletter may remind establishments to report. HTA website COVID-19 guidance emphasises that all licensed research and anatomy establishments should have an internal system for reporting adverse events and asked them to consider how best to handle adverse events during the pandemic.		X			Preventative / Detective / Monitoring	Inspections (and audits for ODT) include assessment of licensed establishments' knowledge and use of the relevant HTA incident reporting process. For example, as part of the current VRAs in the HA sector, we are specifically looking at each establishment's incident logs to check a) that they recoding incidents locally, and b) that incidents that should have been reported as SAEARs, were. Annual SARE (Serious Adverse Reactions and Events) HA SAEARs data reported to European Directorate for the Quality of Medicines (EDQM). Monitoring establishments' reporting of incidents through the HTARI, HA SAEARs and ODT SAEARs groups and advice, guidance and CAPAs regarding those incidents.	Findings at inspection (onsite or VRAs). Minutes of quarterly meeting with NHSBT to review SAEARs cases in ODT sector - latest meeting was December 2021. Most recent SARE report submitted summer 2021. Publication of closed SAEAR and HTARI incident summaries included in the HTA publication scheme - published quarterly - and reporting in the Board's data annex. Publication of incident numbers in the regular (bimonthly) Professional Newsletter.
			Management of any risk of incidents likely to arise from the end of the 6 months post-Transition Period grace period for EEA/GB import / export licensing continues to be managed through the defined UK Transition project. The Director of Regulation is SRO, with a dedicated project manager and project resource and close continuing engagement with DHSC.		Continuing engagement with DHSC on ongoing aspects of the UK Transition Period Project, including the Northern Ireland Protocol (and engagement with NI Executive Department of Health).					Preventative / Detective / Monitoring	Director-level oversight as SRO (Director of Regulation), weekly Project meetings, 'stand-up' over the 6 weeks either side of 31/12/20, regular reporting to SMT through standing agenda item and specific papers for key decisions.	Regular reports to SMT - standing item on SMT agenda from February 2020. Internal Audit 2019/20 (Moderate assurance and management actions completed by Autumn 2021). Project formally closed October 2021 and remaining actions handed over to business. Pending clarification of whether any further changes might arise from any changes to the Northern Ireland Protocol.

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK I	RESIDUAL RISK L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
3	**Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach** (Risk to Delivery objective e, and Development c) Risk Owner: **Louise Dineley**	**_Cause_** **External factors** • No scheduled review of Human Tissue Act and associated regulations, or Quality and Safety Regulations (other than for EU Exit) • Rapidly advancing life sciences • Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates • Introduction of deemed consent for Organ donation in England • Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario **Matters which certain stakeholder groups believe require review** • Scope of relevant material e.g. waste products • Licensing requirements e.g. transplantation research • Regulation relating to child bone marrow donors • Issues raised by emergence of social media e.g. non-related donors • Strengthening of civil sanctions for non-compliance **Matters which stakeholders/public may expect to be inside regulatory scope** • Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure • Police holdings • Products of conception and fetal remains • Data generated from human tissue • Funeral directors • Forensic research facilities • Cryonics • Body stores / Taphonomy • Imported material • Clinical waste • **Other** • Inadequate stakeholder management **_Effect_** • Diminished professional confidence in the adequacy of the legislation • Reduced public confidence in regulation of matters relating to human tissue • Reputational damage	4	3	Ongoing	Horizon scanning process in place that creates and maintains an up to date log of issues known to the HTA with respect to the legislation (updates, amendments or emerging issues) to inform DH and manage messages	3	3		9		X		Monitoring	Ongoing log	_Log in place and shared with Board in outline at the Strategic planning session in 2021._
						Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope			_Comms & Engagement strategy under development to strengthen the HTA's approach and impact of stakeholder engagement. Updated C&E Strategy planned for Q4._		X			Preventative/ Detective	Stakeholder Group meeting minutes Authority minutes (including Public Authority Meeting) TAG and HWG meetings Evidence of engagement with other relevant stakeholder forums, not necessarily organised by HTA.	_Last Stakeholder and Fees Group meeting in October 2019; Histopathology Working Group February 2020; Transplant Advisory Group October 2019._ _Public Authority Meeting in July 2021 - held virtually._ _Professional newsletters issued regularly - last one September 2021._ _Sector-specific engagement e.g. with anatomy sector webinars and engagement with the post-mortem sector through multi-agency forums (Death Investigation Group, Excess Deaths Working Group)._
						Active management of issues raised by the media – including the development of the HTA position on issues			_Lines currently under review and update_		X			Preventative/ Detective	Quarterly reports to Board on communication (including media) activities	_Last report to November Board meeting (2021)._
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence						X		Monitoring	Quarterly Accountability meetings with DH superseded during the pandemic by DHSC attendance at Board meetings for assurance plus DHSC sponsor team's engagement with HTA.	_Most recent confirmation in letter from Marina Pappa of DHSC Sponsorship Team to AMS dated 21 July 2021 re Quarter 1 2021/22. AMS met with Sponsorship team regularly during 2021._
						Action where we believe it will support public confidence					X			Preventative	Updated guidance in response to the coronavirus emergency published on the website, further sector specific guidance	_Update to the Board and DHSC at Board meeting July 2021._
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge			_Demonstrate ongoing engagement of Devolved Assembly in Wales and N Ireland. Effective engagement and collaboration demonstrated through the revision of Code D._		X			Preventative	Duty and its uses understood by SMT and Chair	_Advice and guidance continues to be provided, for example on the Private Members Bill - Organ Tourism and Cadavers on Display, first introduced into Parliament in 2020 and reintroduced in 2021._ _Engagement with DHSC over Sandpiper issues - advice submitted to Secretary of State 15 December 2021. Also engagement with Welsh Government officials on this matter._ _Ongoing engagement with NI Executive over NI Deemed Consent and need for HTA to update its Code of Practice (F) in recognition of this._
						No further changes to HTA's Standards since significant changes launched April 2017. Significant activity to update Codes of Practice for Organ Donation and Transplantation (and consent) to support the introduction of deemed consent (May 2020)			_Further work planned in 2021/22 to review and update codes of practice . Focus will be on factual update._		X			Preventative	_Updated draft guidance produced for revised Code D. Updated draft of Codes of Practice D to enhance consent expectations for imported bodies and body parts for public display._	_Draft revised Code of Practice D (Public Display) to align consent expectations for imported bodies and body parts with those for material originating in England, Wales and Northern Ireland received Parliamentary approval in July 2021._
						Extensive Professional Evaluation Survey undertaken in Q4 2019/20, reported to Board in July 2020 and used to inform further developments.			_Further work planned in Q3 & 4 to pilot new approaches to stakeholder engagement_		X			Preventative	_Evidence from Professional Evaluation used as an evidence and information source to inform and drive improvements_	_Evidence from Professional Evaluation presented to the Board in July 2019._
						Communications work package set up as part of UK Transition project to ensure we are managing our licensed establishments' expectations of what is required at the end of the transition period. As part of this WP we will also attempt to reach out to unknown end users to make them aware of their new regulatory licensing requirements and timelines.			UK Transition Communications Plan updated several times during the life of the project. RM taking responsibility for leading stakeholder engagement and coordinating activities of RM Stakeholder Managers.					Preventative	Weekly UK Transition Project meetings - standard agenda item is discussion of Communications Work Package.	UK Transition project documents (in dedicated Teams channel), weekly meeting agendas and action points plus weekly updates to SMT. UK Transition project closed October 2021.

					Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners) to inform planning for key pressures such as ongoing response to Covid-19; winter pressures, Transition Period and the period after 31 December 2020. In the last 6 months the HTA has demonstrated its role in strategic and partnership working as part of the wider Life Sciences & regulatory system and has demonstrated a responsiveness to legislative amendments and updates.		*Ongoing engagement with partner organisations to build opportunities for collaboration and support to the life sciences sector.*		x			*Preventative*	*Development programme workstream Strengthening of Horizon scanning has identified 4 areas to progress in 2021/22.*	*Regular reporting to SMT and through formal routes*

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
4	**Failure to utilise people, data and business technology capabilities effectively** **(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)** Risk Owner: **Louise Dineley**	**Cause** • _Lack of knowledge about individuals' expertise_ • _Poor job and organisational design resulting in skills being under used_ • _Poor line management practices_ • _Poor project management practices_ • _Poor leadership from SMT and Head_ • _Loss of productivity as a result of the effects of changes to ways of working_ • _Data holdings poorly managed and under-exploited_ • _Inadequate business technology or training in the technology available_ • _Lack of ring-fenced resource for 'no-deal' EU Exit_ **Effect** • _Poor deployment of staff leading to inefficient working_ • _Disaffected staff_ • _Increased turnover leading to loss of staff_ • _Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed_ • _Poor use of technology resulting in inefficient ways of working_ • _Inadequate balance between serving Delivery and Development objectives_	3	4		**People capability**	4	3	_All major projects have project management rigour further enhanced through benefits realisation and plans to assess ROI at year end._	9	1	2	3			
						People Strategy for the period 2019 to 2021 is in effect			Recruitment to identified vacancies and skills gaps completed. Succession planning and future skills needs to be developed further as part of a workforce model. Work planned for Q3 & 4.		X	X		Preventative/ Monitoring	Board approval of the Strategy	Board approved the Strategy at its meeting in February 2019 and is provided with regular updates on all facets of its progress in quarterly board reporting. Most recently in July 2021
						Full suite of people policies and procedures (including performance management)					X			Preventative/ Monitoring	Full suite of policies in place and available on Wave	https://intranet.hta.gov.uk/pages/policies_forms
						External assessment of utilisation of capabilities							X	Monitoring/ Detective	Internal audit 'Utilisation of capability' provided moderate assurance in July 2019	ARAC received the audit report and monitors progress against recommendations - most recently June 2021.
						Adherence to the HTA Workforce Capability Development Framework					X			Preventative	SMT approved the Framework in September 2020 - as a response to internal audit recommendations	ARAC to receive update on the Framework at its meeting in October 2020
						Investment in the development of the HTA leadership team					X			Preventative	External consultants engaged to assess team and individual development needs and design appropriate interventions	The current programme of work was completed in June 2021.
						Handover process is formalised via a checklist to ensure corporate knowledge is retained					X			Preventative/ Monitoring	Handover checklist is in place and in operation.	Evidence provided to internal audit June 2021.
									More formal assessment of future capability needs and how these should be met including through better knowledge of internal skills. Work to adopt a portfolio management approach to support more effective resource deployment and identification of skills required.		X	X		Preventative/ Monitoring	Director and Head of HR assessing capability needs as part of future operating model HTA Workforce Capability Development Framework sets out how capability needs will be met Head of HR has implemented a register of skills within the HTA	SMT will be agreeing its approach to filling specific immediate capability needs in October Development Programme is picking up medium to long term capability needs.
									Establish a formal role within SMT terms of reference to look holistically at people and capability issues across the organisation focussing on short and long term impacts and deliverables.			X		Preventative/ Monitoring	SMT terms of reference and SMT minutes	SMT ToRs revised and approved. HMT ToRs in development HTAMG ToRs to be revised subsequently
						Data capability										
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)			Ongoing development of the electronic management of all information and records. Phase 1 complete. Phase 2 underway.		X		X	Preventative/ Monitoring	Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security.	CRM upgrade completed successfully in March 2019
						Appropriate procedures to manage personal data including GDPR compliance.					X		X	Preventative/ Monitoring	Internal audit on GDPR compliance provided moderate assurance.	Internal audit report in March 2019. Part of ongoing Cyber and data security and SIRO reporting. Now absorbed in BAU Information Governance and Cyber Security work
						Business technology capability										
						Staff training in key business systems and mandatory training on policies and required controls.					X			Preventative	Systems training forms part of the induction process for new starters	Ongoing records of all new starters trained in key business systems. New remote induction programme was launched in Summer 2020.
						IT systems protected and assurances received from 3rd party suppliers that protection is up to date			Reporting to ARAC on Cyber Security and system security in place.		X	X	X	Preventative/ Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Annual SIRO report agreed SMT June 2021
						Business technology										

						Identify refresher training and targeted software specific training needs.		X			Preventative	Evidence of targeted training in last quarter to support the roll out and adoption of EDRMS. Further strengthening of core training requirements included in updated induction programme.	
					System performance analytics available and reported monthly		Use of data analytics to inform and drive changes in practice.						Analytics provide assurance on system performance and support targeted intervention with members of staff as necessary.	

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L			1	2	3			
5	Insufficient, or ineffective management of, financial resources (Risk to Deployment objective b Risk Owner: Richard Sydee	**Cause** • *Fee payers unable to pay licence fees -* • *The number of licenced establishments changes, leading to reduced fee income* • *Management fail to set licence fees at a level that recover sufficient income to meet resource requirements* • *Failure to estimate resource required to meet our regulatory activity* • *Poor budget and/or cash-flow management* • *Unexpected increases in regulatory responsibilities* • *Unforeseeable price increases / reductions in GIA* • *Fraudulent activity detected too late* **Effect** • *Payments to suppliers and/or staff delayed* • *Compensatory reductions in staff and other expenditure budgets* • *Increased licence fees* • *Requests for further public funding* • *Draw on reserves* • *Failure to adhere to Cabinet Office Functional Standards* **Leading to:** • *Inability to deliver operations and carry out statutory remit* • *Reputational damage and non payment of fees*	5	4	Ongoing	Budget management framework to control and review spend and take early action	2	3		3		X	X		All	Budgetary control policy reviewed annually and agreed by SMT	Revised version reviewed by SMT in November 2020. AUD 16b/21
						Financial projections, cash flow forecasting and monitoring						X			Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report to Board in November 2021
						Licence fee modelling									Preventative	Annual update to fees model	No change to fees agreed by the Board November 2021 meeting
						Rigorous debt recovery procedure						X			Preventative	Monthly finance reports to SMT and quarterly to Authority	Level of outstanding debt is being reduced. Older debt are being collected. Although we maintain a tight grip on our position, the overall environment is more uncertain than normal.
						Reserves policy and levels reserves						X			Monitoring	Reserves policy reviewed annually and agreed by ARAC	Last agreed by ARAC October 2020
						Delegation letters set out responsibilities						X	X		Preventative	Delegation letters issued annually	Issued in April 2021
						Fees model provides cost/income information for planning						X			Preventative	Annual review of fees model, reported to SMT and Authority	Went to the Board November 2021
						Annual external audit								X	Detective	NAO report annually	Unqualified Accounts produced June 2021
									Monitoring of income and expenditure (RS) **Ongoing**				X	Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report October 2021
									Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) **Ongoing**		X	X		Detective	Quarterly Finance Directors and Accountability meetings	FD from NHS Resolution, HRA, NICE and CQC maintain contact over common issues weekly. Quarterly meetings with DHSC which cover finance and non-finance issues/risks.
									Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards		X	X		Preventative	Counter fraud Strategy and Action Plan developed and presented to ARAC Oct-19. Annual training of staff completed n Q4	Cabinet Office - CDR submissions made quarterly last submission April 2021 (Q4 2020/21). Counter-fraud activities now part of BAU.

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L			1	2	3			
6	**Failure to achieve the full benefits of the** HTA Development Programme *(Development objectives a-d)* **Risk owner** *Louise Dineley*	**Causes** • *Uncertainty of funding* • *Programme and project benefits poorly defined and understood* • *Inadequate programme and project governance arrangements* • *Poorly specified programme and projects* • *Insufficient programme, project and change management skills* • *Inadequate leadership of change* • *Inability to access the necessary skills required at a affordable cost* • *Lack of staff buy-in to change* • *Management and Head stretch of delivering transformation alongside business as usual and other development activity* • *Insufficient agility in (re)deploying people to change projects* • *Poorly specified procurement and inadequate contract management* • *Realisation of single points of failure for DDAT and People Strategy* **Effects** • *Wasted public money* • *Failure to achieve the central strategic intent of the Authority* • *Distracts senior management from operations at a time when demands have increased* • *Reputational damage* • *Unaffordable cost over run* • *Staff demotivation* • *Data remains under-utilised* • *Technology inadequate to meet future needs (cost, functionality)* • *Limited ability to achieve improvements in efficiency and effectiveness* • *Pace of change is inadequate and impacts negatively on other work*	3	3		SMT experience of organisational change, programme and project management.	3	3	*Change Manager appointed in August 2020. Ongoing organisational preparedness remains a key workstream in the 21/22 plan.*	9	X			Preventative	Recruitment of an HTA Programme Director	The Director of Data, Technology and Development appointed in October 2019 will act as Programme Director.
						HTA approach to the management of change projects *(underpinned by project management methodologies)*					X			Preventative	Dedicated permanent project manager appointed	PM in place an operating effectively
						A number of trained project managers among HTA staff			*Project Management skills further strengthened by introduction of a toolkit and induction session by PM*		X			Preventative		
						Experience of procurement and contract management					X			Preventative		
						Existing mechanisms for engaging staff			*Plans developing for strengthening internal communications function*		X			Preventative		
						Well established corporate governance arrangements and financial controls						X		Monitoring	*Internal audit of key controls*	Assurance provided by Internal Audit of adequacy of key financial controls
						Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding			*Further alignment of projects on the business plan to strengthen phasing of actions, resource deployment and consolidation of actions to encourage smarter working.*		X			Preventative	*Progamme plan in place*	Update reported to July Board meeting
						Project management rigour including benefits to be realised.			Embed Benefits Realisation Management methodology within programme		X			Preventative		
						Monthly reporting to SRO in place			Introduce a Programme Management function		X			Preventative		Ongoing focus in 21/22 to embed PMO skills and build wider capability across the business
									Board approval to proceed at key Gateway decision points			X		Monitoring		
									Training plan to encompass project and change management and HTA approach		X			Preventative		*Change management training activity is now in progress following the appointment of the HTA Change Manager. Mandatory all staff sessions were undertaken in quarter 3. Further osu planned in Q4*
						Strengthened planning supports a single message and focus on an agreed set of priorities			Development of procurement plan to deliver the DDAT Strategy		X			Preventative		*Plan in place, work ongoing in 2020/21.*
									SROs identified for Programme and individual projects		X			Preventative		*High level plan in place for 2021/22*
						Project management includes a monitoring of costs			Schedule a regular programme of staff engagement events		X			Preventative		*Reset and relaunch event planned in Q4 providing focus to developments over the next 15 months. Review of stakeholder engagement also extends to inviting a wider contribution to future development plans.*
						Scope of projects aims to deliver benefits including on a phased and incremental design			Establish an external stakeholder communications and engagement plan		X			Preventative		*Work progressed in Q4 20/21*
									Recruitment of new Board Member(s) with digital and organisational change experience			X		Monitoring		
						Agreed priorities in Business Plan and underpinning foundations for future strategy maintain required pace							X	Monitoring/ Detective		
						Identified success measures and benefits to be realised for the Development Programme and individual projects							X	Preventative		

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Risk ID No.	Date risk identified	Description of Risk	Causes	Impact (what would happen if risk not mitigated?)	Likelihood	Impact	IR score	Management Controls/mitigation strategy - what controls address the risk? If future plan add date of delivery	Type of control (Preventative, Detective)	DD/MM/YY	Likelihood	Impact	R/R score	Is the RR currently tolerable ? If no, provide action plan	Proximity (when is risk likely to happen)	Risk owner	Target closing date	Status (Open/Closed)	Date closed	Comments
RD1	10/12/2021	**Short Title: RM resource capability** There is a risk that Regulation Managers possess narrow capabilities (knowledge, skills and experience) specific to one sector rather than having a broader range of capabilities spanning multiple sectors.	Regulation Managers are line managed in sector teams but many are signed-off to work in other sectors outside of their line management team, giving flexibility in deploying specialist regulatory resource to risk.	The HTA may have insufficient depth or breadth of specialist resource to maintain effective regulatory oversight across all sectors and have resource available to support additional work, such as Sandpiper, Covid-related or the Development Programme.	2	4	8	Mitigations already in-hand: ...	Preventative	14/01/2022	2	2	4			Jessica Porter		Open		Note: Whilst COVID has reduced ODT activity, transplantation is continuing and we need to consider whether there are new risks arising from transplant centres functioning at reduced levels and in different ways during Covid.
RD2	10/12/2021	**Short title: Regulatory consistency** There is a risk of inconsistency emerging in the delivery of regulatory activities, including the delivery of inspections, assessing standards and managing shortfalls, and the classification and management of incidents (HA and ODT SAEARs and HTARs).	Remote working over an extended period and the loss of regular in-person contact (at the office, at site visits and at the formerly quarterly face-to-face Regulation Training Mornings) may result in staff with less frequent contact with colleagues and the spontaneous opportunities that previously arose from that contact to learn from each other over time...	Any significant inconsistency in regulatory approach (or perception) could lead to increased challenge to regulatory decisions and potential reputational damage to the HTA and loss of credibility.	2	3	6	Mitigations: ...	Preventative	14/01/2022	1	4	4			Kelly Sherlock		Open		
RD3	10/12/2021	**Short title: Regulatory data insights** There is a risk that regulatory operations (planning, risk assessment and operational decision-making) lacks appropriate data insight. Overall, there is a risk of a reduction of resources with both specialist knowledge of the regulatory framework and the technical skills to extract, interrogate and analyse regulatory data from the HTA's core systems (predominantly CRM) or data submitted to the HTA through regulatory processes (e.g. evidence to support inspections).	Data skill requirements are not defined in Regulation Directorate roles and levels of competence and confidence vary. Loss of former colleagues with deep business knowledge and expertise in extracting, interrogating and analysing data, including from our core system (CRM)...	Limited ability within the Regulation Directorate to effectively use or commission the use of regulatory data to inform risk assessment, planning and regulatory decisions.	2	3	6	Mitigations: ...	Preventative	14/01/2022	2	2	4			Christopher Birkitt		Open		
RD4	10/12/2021	**Short Title: Unlicensed establishments** There is a risk that establishments may be conducting licensable activity without holding a licence.	Some organisations that are in scope for licensing may lack awareness of their legal obligations to be licensed and of the regulatory framework and the HTA. Some organisations may be aware of these requirements but choose not to fulfil their obligations...	Unregulated activity could lead to failure to meet legal and regulatory standards, which could potentially lead to public harm and reputational damage (loss of confidence) in the HTA.	1	3	3	Existing mitigations include the HTA's communications activity e.g. website, professional newsletter, social media plus ongoing operational collaborative work with HRA in the research sector...	Preventative	14/01/2022	1	3	3			Robert Watson		Open		
RD5	10/12/2021	**Short Title: Covid impacts** Covid could reduce resource availability and our ability to maintain our planned regulatory activity.	The rise in case numbers and increased transmissibility of Covid since Quarter 3 2021/22 due to the emergence of the Omicron variant. This could: 1) Impact HTA staff (e.g. updated risk assessments indicating it being unsafe for some staff to undertake travel to and carrying-out of inspections, staff being ill with Covid, staff caring for family members with Covid, additional government restrictions)...	Inability to deliver to current business plan, in particular the on-site inspection schedule. This could lead to the HTA again failing to meet its statutory obligation to undertake site visit inspections at least every two years in the HA sector.	4	8	8	Mitigations: ...	Preventative	14/01/2022	2	2	4			Jessica Porter		Open		
RD6	01/12/2021	**Short title: New inspection model – VRAs & site visits** There is a risk that the expected benefits of hybrid inspections are not realised, or achievable, and that there is an unintended reduction in the level/quality of regulatory oversight where they are employed.	The cause of this risk is the requirement to carry out on-site inspections in the HA sector that places constraints on the formal of inspections in this sector, limiting the benefits achievable via hybrids. Additionally, the is a possibility of there being a wider lack of clarity about the intended benefits of VRAs and the circumstances in which they should be used, particularly in the context of hybrid inspections, which could mean that their full benefits are not identified, tracked or realised. IT and technology limitations could limit the potential benefits of VRAs, as has been experienced to date.	The potential impacts of this risk are: an increase in workloads; failure to reduce workloads, both internally and externally; regulatory risk; and reputational risk.	4	3	12	Mitigations: ...	Preventative	14/01/2022	3	3	9			Rob Watson		Open		
RD7	29/12/2021	**Short title: HTA resource available to contribute into cross-government response and Independent Inquiry into mortuary offending** There is a risk that the HTA has insufficient suitably skilled, knowledgeable and experienced resource (people) and funds to fulfil its commitments to the cross-Government response to mortuary offending, both work initiated by the HTA and work initiated by others but involving or placing obligations on the HTA.	The cause of this risk is the current uncertainty about the scope, approach and timescales of the cross-government response, presenting challenges to Q4 2021/22 and 2022/3 business plans since the delivery of this work will be a high priority. The potential for significant additional demands on the HTA's Regulation Directorate resources cannot be fully assessed or mitigated until the terms of reference, full scope, governance arrangements and timescales of the independent inquiry and cross-government response are confirmed...	This may impact the organisation's ability to deliver on its commitments and obligations under the cross-government response to mortuary offending and / or its core regulatory activity and other business plan objectives.	4	4	16	Mitigations: ...	Preventative	14/01/2022	4	4	16	No. The mitigating actions are still in course of development and so have not yet had chance to reduce the inherent risk score.		Kelly Sherlock	31/03/2023	Open		

Risk of… due to… resulting in…

Event, Cause, Effect

Risk Scoring Matrix

IMPACT		1.Rare (≤3%)	2.Unlikely (3%-10%)	3.Possible (10%-50%)	4.Likely (50%-90%)	5.Almost certain (≥90%)
	5. Very High	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1.Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium

Likelihood

Risk score = Impact x Likelihood	1.Rare (≤3%)	2.Unlikely (3%-10%)	3.Possible (10%-50%)	4.Likely (50%-90%)	5.Almost certain (≥90%)

VERY HIGH: 20 to 25 - Too late

HIGH: 12 to 20 - Act Now

SECTOR RISK TOLERANCE

MEDIUM: 6 to 10 - Act soon

LOW: 3 to 4: Monitor

VERY LOW: 1 to 2: Monitor

INTELLIGENCE TEAM RISK LOG

Risk Area	SRR No.	Risk ID No.	Category	Description of Risk and cause	Impact (what would happen if risk not mitigated?)	Inherent risk			Management Controls/mitigation strategy - what controls already exist that address the risk?	Due Date DD/MM/YY	Residual Risk (RR)			Is the RR currently tolerable? (if no, provide action plan)	Proximity	Risk owner	Target closing date	Status (Open/Closed)	Date closed	Comments
						Likelihood	Impact	IR score			Likelihood	Impact	RR score							
1. Risk area - planning								0					0							
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AUD 06/22 Annex C NEW - HTA - Operational Risk Register - HR Dec 2021

RESOURCES (FINANCE) RISK REGISTER

Risk Area	SRR No.	Risk ID No.	Date risk identified	Category	Description of Risk	Causes	Impact (what would happen if risk not mitigated?)	Likelihood	Impact	IR score	Management Controls/mitigation strategy - what controls address the risk? If future plan add date of delivery	Type of control [Preventative, Detective]	DD/MM/YY	Likelihood	Impact	RR score	Is the RR currently tolerable? (if no, provide action plan)	Proximity (when is risk likely to happen)	Risk owner	Target closing date	Status (Open/Closed)	Date closed	Comments
4		1	01/10/2021	People	Data and Technology roles are difficult to recruit	Market is very competitive, skill sets are scarce. Other regulators can offer higher salaries and longer career pathing opportunities	We would have vacant roles or a high turnover when using interims. The Development programme progress is interupted or stalled	5	3	15	We currently fill the role with interims to provide the resource while looking to fill the role with a permanent member of staff. We need to be prepared to pay the market rate or near to in order to attract the skills we need to deliver the HTA Goals. We have a good relationship with a number of agencies to enable a pipeline of talent. In the longer term, when our organisational structure is confirmed, we can look to create a succesion plan for critial known hard to fill roles	Preventative		2	1	2		0-3 Months	SC		Open		
4		2	01/09/2021	People	Higher salaries required for specific roles to meet market forces	related to Risk #	People Retention impact with a perceived inequity in salary bands	4	4	16	Designing our organisational structure to reflect the needs of the HTA, will enable a Skills Gap analaysis to be conducted, which in turn will identify the areas of greatest concern.	Detective		2	2	4			SC		Open		
4		3	01/07/2021	People	Cultural reset	It was recognised a cultural reset was needed following a number of unsubstantiated allegations in the summer of 2021.	It was agreed this should be conducted by the new CEO, from January 2022. If this is not conducted, the wider concerns of recent changes to the HTA's culture could continue to cause disruption and poor behaviour.	3	3	9	When our CEO Colin Sullivan joins a cultural reset can be organised as part of his new ways of working and expectations of staff behaviours and deliverables .	Preventative	01/06/2022	1	1	1			SC		Open		
4		4	01/09/2021	People	Impact of COVID pandemic and wider winter infections	The Pandemic continues to impact all staff in various ways. The impact of not working in one locaiton, has for some negative mental health concerns. The Culture of the HTA has also been impacted by the 'silo'd' approach by some to working remotely.	Related to Risk #3 with the need to embed a new ways of working /hybrid working culture. The original COVID strain has evolved with new strains being identified that could result in further restrictions on movement. The impact of 'lockdown' last winter has resulted in increased infections this winter with more expected. all this could lead to reduced capacity to conduct busienss as usual.	3	3	9	The Cultural rest along with the substantial wellbeing programme underway should help to eliminate most of the risk in this area. HR with the support of LM's will continue to monitor staff morale and resilience	Preventative		2	2	4		0-3 Months	SC	01/12/2022	Open		
4		5	01/10/2021	People	Sandpiper - investigation and public enquiry	Sandpiper whilst the activity of the individual was a criminal act, the impact of the resulting investigation and public enquiry on staff wellbeing could result in significant absence or staff retention.	Reduced wellbeing across the HTA with unexpected absence or vacancies resulting in an impact to deliver goals within timeline.	3	3	9	The new CEO joining in January will provide additional leadership in the investiation and public enquiry. The current Wellbing programme with enhanced staff support directly related to Sandpiper in mitigation, along with monitoring from LM and HR, should highlight issues early.	Preventative		2	2	4			SC		Open		
4		6	01/10/2021	People	Sandpiper - investigation and public enquiry	Risk of media attention to specific staff members, particularly those active on social media.	Individual and their family members wellbeing, with additional negative media attention on the HTA	3	4	12	Have launched a new social media policy and a Media Attention policy. Clear advise to staff how to proceed if they find themselves the focus of media attention.	Preventative		3	4	12			SC		Open		
4		7	01/09/2021	Org wide	Inability to access all relevant inforamtion	Storing or disposing of records not according to policies. Staff not being aware of record management policies and procedures.	Inappropriate storage of records. Inability to retrieve or dispose of records as required or is approprite. Breach of GDPR requirements. Failure to identify breaches of GDPR, which could lead to a fine or reputational damages.	3	4	12	New processes being developed and embedding guideance being prepared to guide staff as to how to store inforamtion and what platforms to use.	Preventative		2	2	4			SC		Open		
4		8	01/09/2021	Org wide	Inability to repond approporately for inforamtion	Introduction of Teams and OneDrive allowing storage of information in siloed areas. Information being communicated or stored in siloed locations or being kept in heads and not recorded.	Inability to retrieve or identify information appropriately and effectively. Information not incorporated or identified during evidence collation exercises e.g. when performing searches for related documents. Inability to access key information due to storage location used i.e. in Teams for which users do not have access. May not meet statutory obligations around FOI requests etc.	3	4	12	New processes being developed and embedding guideance being prepared to guide staff as to how to store inforamtion and what platforms to use.	Preventative		2	2	4			SC		Open		

AUD 06/22 Annex C NEW - HTA - Operational Risk Register - Data, Technology and Development Risk Register

Data, Technology and Development Risk Register

Risk Area	SBR No.	Risk ID No.	Date risk identified	Category	Description of Risk	Causes	Impact (what would happen if risk not mitigated?)	Likelihood (Inherent)	Impact (Inherent)	IR score	Management Controls/mitigation strategy - what controls address the risk? If future plan add date of delivery	Type of control (Preventative, Detective)	Due Date DD/MM/YY	Likelihood (RR)	Impact (RR)	RR score	Is the RR currently tolerable? If no, provide action plan	Proximity (when is risk likely to happen)	Risk owner	Target closing date	Status (Open/Closed)	Date closed	Comments
1.Staffing levels	4	1.4	03/12/2021	People	Loss of staff members/delayed recruitment to vacant posts	Lack of career progression and skill developments opportunities. Uncertainty around future organisational structure.	Inability to deliver BAU deliverables as well as additional pieces of development work. Increased work demands on existing staff, increasing risks to staff well-being and morale, leading to greater attrition rates.	4	4	16	Provide varied tasks to staff to develop new and build on existing skills. Encourage staff to attend training courses and provide support to personal development. Support flexible working arrangements of staff where possible. Engage with staff frequently and enquire about well being, directing staff to various support mechanisms if required.	Preventative		3	3	9					Open		
2.External demands	3	2.3	03/12/2021	Regulatory	Unexpected external commissions or requests for advice	Lack of single point of contact to send commissions to for response. Personal email contacts used for individuals who have since left the organisation. Lack of allowance for unexpected requests within business planning for resource and time. Lack of understanding by external stakeholders of HTA remit.	Failure to respond to external commissions or advice requests appropriately. Knock on effects to BAU and other pieces of work due to resource needing to be focused on requests. Limited time frames may lead to limited and not incorporate business wide responses.	5	3	15	Communicate to external parties need of time to provide and coordinate responses to requests. Provide clear responses, with clearly defined limits of HTA remit. Ensure only provide advice and responses to areas within HTA remit to avoid future confusions or requests outside HTA remit. Incorporate time into across business planning for unexpected requests.	Preventative		3	2	6					Open		Commissions and requests for advice received on regular basis from sponsor DHSC, often with limited or tight deadlines for return of information.
3.Horizon scanning	3, 2, 1	3.3, 2, 1	03/12/2021	Regulatory	Failure to establish an effective Horizon Scanning (HS) function	Established HS systems and processes not adhered to, tools become unfit for purpose. Lack of engagement by staff in capture and recording of items on HS log.	Failure to identify emerging issues, inform priorities and define areas for improvement and development. Missed opportunities to be adequately prepared, resulting in needing to be reactive rather than proactive in response.	4	4	16	HS process in place and HS Group members have objectives assigned to role, which include collating HS items from their respective business areas and updating entries on HS log. Log reviewed monthly at a designated HS Group meeting and by all Heads for emerging issues and themes. Monthly report prepared for the SMT on emerging issues and items for awareness. Further developments are in progress to ensure business wide participation in horizon scanning and capture of issues; and, to introduce a quantitative scoring mechanism to aid identification of emerging issues and areas requiring the SMT review.	Preventative	28/02/2022	2	3	6	Yes		JE		Open		
4.CI Practice	3	4.3	03/12/2021	Regulatory	Codes of Practice factually inaccurate	Introduction of deemed consent in England and legislative changes in Scotland for organ donation. Policy change in consent expectations for imported bodies for public display has	Factual inaccuracies could mislead stakeholders or leave HTA open to challenge on policy positions. Continuing to use outdated Codes that do not meet accessibility criteria and have broken hyperlinks could impact public confidence in the HTA	3	4	12	Plans to address factual inaccuracies currently identified within the Codes. Inaccuracies have been mapped along with annotations for changes required added to editable versions of the Codes.	Preventative		1	2	2	Yes		JE		Open		Paper drafted for the SMT with recommendation to address the inaccuracies within the Codes by end of this business year using an interim revision approach that does not require Parliamentary approval.
5. Policies	1	5.1	03/12/2021		Inaccurate, poor quality or out of date policies	Poor quality or out of date policies and procedures. Failure to identify emerging issues and requirement for policy changes. Insufficient cross organisation and external engagement. Failure to adhere to polices and procedures.	Loss in stakeholder and public confidence. Failure to demonstrate adherence to government incentives and account for Better Regulation. Misleading of stakeholders in legislative requirements. Legal challenge on policy positions and regulatory decisions. Failure to deal with regulatory consequences of legislative changes.	3	4	12	Quality management systems and decision making framework. HTA people Strategy, training and development of professional competence. Implementation of Horizon Scanning process from which emerging issues are identified and communicated via a monthly report to the SMT. Active engagement of Policy Team with internal staff and Policy leads at sponsor DHSC and Devolved Administrations. Further external engagements to facilitate the identification of future policy items.	Preventative/Detective		2	3	6	Yes				Open		
6. Resourcing (projects)	5	6.5	07/12/2021		Non or delayed delivery of project deliverables due to resources allocated are diverted at short notice.	Requirement of Independent inquiry, response to OIS or Covid Enquiry diverts key resource from project activity (across DTD and Regulation). Number of interim posts with short notice / termination periods could leave gaps in key roles in projects.	Project work under resourced and Q4 deliverables across strategic projects not met.	3	3	9	Projects with the DTD portfolio have clear plans in place to monitor and manage the delivery of projects. External contractors are supporting the delivery of key deliverables.	Preventative	31/03/2022	2	3	6	Yes	0-3 Months		01/03/2022			
7. Website Redevelopment	4	7.4	07/12/2021		Failure of the website redevelopment project to pass NHSx live assessment on 24 March 2022.	The project does not meet NHSx service standards. Priority areas for the project to deliver are: User Testing, PEN Testing, Accessibility Audit and running service in BAU.	A decision will be needed regarding continuing the website redevelopment project into Q1 of 2022/23 with a reassessment towards the end of Q1. This will have both budget and resource implication on Business Year 2022/23	2	5	10	The website project has a project plan which sees delivery against service standards. Further to this on an ongoing basis through the public beta phase is the project is assessing progress against the 13 NHSx service standards. For further assurance through the stage there are regular touch in with NHSx to receive guidance and clarification regarding whether our progress will meet assessors criteria.	Preventative	24/03/2022	1	5	5	Yes	0-3 Months	SD	24/03/2022	Open		
8. IT service disruption	2	8.2	08/12/2021		IT Disruption and Infrastructure/Communications failure	External forces can destroy traditional infrastructure and leave offices and homes without power including internet. Poorly configured equipment can cause similar issues. Old equipment requires increased maintenance and over time causes poor performance directly affecting users ability to work efficiently	Loss of power leading to lack of service for days/maybe weeks. Poorly configured systems implemented could be affect services and prevent basic tasks including sending/receiving email. Old equipment would make it difficult to carry out regular and frequent tasks such as Teams meetings and/or virtual regulatory assessments.	3	4	12	There are no controls that can prevent external sources causing damage to traditional communication lines. A number of staff members are issued with HTA owned mobile devices to facilitate business continuity. More than 50% of staff are on home worker contracts with varying geographical locations around the country, reducing the likelihood all areas would be impacted. All support services are outsourced and managed by 3rd parties and regular communication and change processes that are in place reduce the likelihood of badly configured services. Equipment is regularly updated and latest patches applied. Equipment periodically reviewed and outcomes determine need for replacement.	Preventative		2	3	6							
9. Cyber threats	2	9.2	08/12/2021		HTA users unable to carry out normal duties due to cyber Security threats including but not limited to Viruses, Malware, Phishing and Spam that impact.	Hacker attempts to breach data security systems enabling access to company systems, confidential information, data and user areas.	HTA systems would fail function efficiently leading to inability to deliver the business as usual and other regulatory activities. Unauthorised access to confidential data and user areas. Loss in stakeholder confidence.	4	5	20	All email inbound and outbound go through a filtering solution to minimise the amount of suspect email and that tools are regularly updated to cope with new risks. All machines are protected by antivirus and firewall that limits and with restrictions to prevent access to suspect web sites. Rules are updated constantly based on new virus variants and suspect web sites. PEN tests are carried out annually to find weaknesses in our systems and appropriate actions taken in response to findings. Staff undergo regular mandatory training to promote awareness of cyber security. Incidents and cyber threats are communicated across the organisation when encountered to increase staff awareness of actions required.	Preventative/Detective		2	5	10							
10. Data Breach	2, 4	10.2, 4	08/12/2021	Data	Data Breaches both internally and externally	Individuals access confidential information for personal gain. This could be digital information or paper based	Confidential information ends up in the public domain leading to loss in public and stakeholder confidence and reputational damage.	3	5	15	Controls and data handling policies in place to prevent unauthorised access to documents stored digitally. Data handling policies and procedures in place for data held in paper format e.g. inspection note books. Laptops/IT devices, encrypted and user password protected.	Preventative/Detective		1	5	5							
11. Failed service delivery	2, 4	11.2, 4	08/12/2021		Outsourced providers cease to deliver services to HTA.	Poor management of 3rd Party providers and agreements. Non adherence to performance metrics within SLA. 3rd Party suppliers cease to exist or no longer provide agreed services.	Failure of cross organisation systems impacting on operation of technology system. This will affect services and equipment. Assurances received from 3rd party suppliers that protection is up to date not received. Loss of development assist and being left without IT support	2	4	8	All contracts regularly monitored through KPIs to ensure alignment to business requirements. All 3rd party suppliers thoroughly vetted prior to undertaking any supplier based contract and reviews of service are taken into consideration when renewing any service contract.	Preventative/Detective		1	4	4							
12. Mobile Device Management	2	12.2	10/12/2021		Lost or stolen mobile device	User misplaces device or it is stolen by a third party	Temporary loss of access to systems in the event of loss. Potential access to confidential information in the event of theft	1	3	3	We have a Mobile Device Management solution that locks down Mobile devices so that in the event of loss/theft we can disable the device immediately.	preventative		1	1	1							
13. Web Browser/Internet Usage	2	13.2	30/12/2021		NHS Digital has flagged Google Chrome as a security vulnerability and have advised that it be removed from users desktop/app	Insufficient security embedded in the browser allow unauthorised access and allow malicious virus malware to by pass our existing Firewall policies	loss of service to the user and potentially the organisation	1	4	4	The plan is to remove Google Chrome from users machines and Mobile Devices and making Microsoft Edge the default browser. This is NHS Digital Approved so meets all the security requirements it will also allows us to utilise InTune that is a service from Microsoft that will allow us to control web site access.	Preventative		1	2	2							
13. Development Programme	5	13.5	07/12/2021		Failure to achieve the full benefits of HTA Development Programme.	The delay / non delivery of contracted deliverables in Q2 / Q3 caused delay and pause to projects within the programme. These delays and pauses has meant deliverables haven't progressed and as such benefits not being released as planned. Further more staff changes has caused hiatus / slowing of progress against key deliverables.	Full resources allocated to development programme not utilised and wider staff buy-in to change activities will be affected. There is a limited ability to achieve improvements in efficiency and effectiveness.	3	3	9	To manage the progress of development programme in Q3 / Q4 vital elements of the programme will be completed e.g. To-Be mapping and launch of HTA Data Model v1.0. The delivery of these elements will provide platform for the growth of development programme projects in 22/23. Development programme progress has been identified as critical area to progress in Business Planning for Q4.	Preventative	07/01/2021	2	3	6	Yes	3-6 Months	LD	31/03/2022	Open		
14. The Data & Intelligence workstream	4, 6	14.4, 6	08/12/2021		Failure to utilise people, data and business technology capabilities effectively and failure to achieve the full benefits of HTA Development Programme.	Being without both effective To-Be modelling and lack HTA Data Model development would mean the HTA will not be able adequately to define and shape the future operating model. This is key to realising the full potential of the Development Programme.	Full resources allocated to the data & intelligence workstream not utilised. Data remains under-utilised. Technology inadequate to meet future needs.	3	3	9	Completion of the key elements of the D&I workstream i.e. the To-Be mapping and development of HTA Data Model v1.0, will provide the platform for the growth of the development programme in 22/23. Clear plans are in place to deliver the D&I objectives over Q3/4 with ongoing review of the milestones.	Preventative		2	3	6			TB		Open		
15.Target Operating Model	6	15.6	03/12/2021		Failure to deliver a suitable Target Operating Model that defines the HTAs future ways of working.	Failure to achieve To-Be modelling to help define and shape future operating model. Uncertainty of funding and therefore scope of changes that will be feasible. Lack of staff buy in to change. Delayed progress within other projects due to loss of staff resources and key skill sets.	Failure to define the framework for the future ways of working and identify the operational changes needed to deliver the strategic intent of the HTA. Impact progress and delivery of overall development programme. Outcomes which are of poor quality and do not meet expectations exposing organisation to risk.	3	3	9	Commission drafted for to-be modelling tender, with aim to be completed by end of Q4. Several iterations of the TOM have been drafted and shared with Development Programme leads for input. Ongoing review of project milestones and deliverables built into project delivery. Agreed processes for evaluation and adjusting outcomes and deliverables built into project management. Planned engagement and consultation across the organisation on proposed Target Operating Model to ensure staff are brought along the journey of change.	Preventative	31/03/2022	2	3	6	Yes	0-3 Months	JE		Open		
16. Partnership working	3, 4, 6	16.3, 4, 6	08/12/2021		Failure to achieve the full benefits of the HTA Development Programme by not working more closely with partner organisations will mean a failure to utilise data effectively.	Failure in developing more meaningful relationships with our partners. Lack of agreement around areas of collaboration including data sharing.	Delays in developing more meaningful relationships with our partners. Data remains under-utilised - both for the HTA and partners. Potential that we do not have the data required to fully assess risk.	3	2	6	Existing memorandums of understanding with key partner organisations. Improved and regular engagements with sponsor DHSC on a number of areas. Partnership working model will form part of the target operating model and future ways of working.	Preventative/Detective		3	2	6					Open		
17. Reputational risk of perceived regulatory failure	1, 2	17.1, 2	07/01/2021		Cases on the near-to-medium term in (or potentially in) the public domain where there is the risk of damage to public confidence in areas the HTA regulate and a perception that the HTA's regulation has failed. These cases include Operation Sandpiper (OS) and Operation Callaway (OC).	The causes are potentially multiple and all or a combination of the following may contribute to a public and political perception of regulatory failure: 1) actual regulatory failure, including missed evidence of shortfalls or failure to take appropriate action. 2) political positioning of the HTA as responsible for activity beyond what is reasonable to expect of its remit and resource 3) ineffective communication of the HTA's regulatory remit and its role in general and in relation to specific cases	Negative media coverage and negative parliamentary comment/in debates and other public affairs arenas. DHSC sponsor team critical of HTA performance as public confidence decreases in safety and ethical soundness of the use, storage and application of human tissue in UK.	4	4	16	Crisis communications consultancy and protocol in place for OS. Replicate process and prepared lines for OC and other cases. Contribute to horizon scanning with dedicated communications risk register.	Preventative/Detective		3	2	6					Open		
18. Records management	4	18.4	13/12/2021		Failure to manage records or policies as set out leading to inability to retrieve or dispose of records.	Storing or disposing of records not according to policies. Failing to have sufficient policies in place on records management. Staff not being aware of record management policies. Systems not sufficient to support record management policies.	Inappropriate storage of records. Inability to retrieve or dispose of records as required or is appropriate. Breach of GDPR requirements. Failure to identify breaches of GDPR, which could lead to a fine or reputational damages.	3	4	12	Record retention policies in place detailing appropriate timescales and circumstances for records to be retained. Mandatory training for all staff on GDPR. Use of record retention labels in EDRMS to facilitate appropriate retention of records in line with policies. Governance documents have identified owners and a document control log for all governance documents is maintained.	Preventative		2	3	6			All		Open		
19. Use of systems as intended	4	19.4	13/12/2021		Lack of visibility of key information due to document storage in siloed file systems.	Introduction of Teams and OneDrive allowing storage of information in siloed areas where originally documents for collaboration were in centralised systems. Information being communicated or stored in siloed locations.	Inability to retrieve or identify information appropriately and effectively. Information not incorporated or identified during evidence collation exercises e.g. when performing searches for related documents. Inability to access key information due to storage location used i.e. in Teams for which users do not have access. May not meet statutory obligations around FOI requests etc.	4	5	20	IT admin have search capabilities covering all siloed areas irrespective user membership.	Detective		4	4	16			All		Open		

Risk of… due to… resulting in…
Event, Cause, Effect

			Risk Scoring Matrix			
IMPACT	**5. Very High**	5 Medium	10 Medium	15 High	20 Very High	25 Very High	Too late!
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High	
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High	Act now
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium	Act soon
	1.Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium	
				Likelihood		
Risk score = Impact x Likelihood		**1.Rare** (≤3%)	**2.Unlikely** (3%-10%)	**3.Possible** (10%-50%)	**4.Likely** (50%-90%)	**5.Almost certain** (≥90%)

AUD 06/22 Annex C NEW - HTA - Operational Risk Register - Data, Technology and Development Risk Register

INTELLIGENCE TEAM RISK LOG

Risk Area	SRR No.	Risk ID No.	Category	Description of Risk and cause	Impact (what would happen if risk not mitigated?)	Inherent risk			Management Controls/mitigation strategy - what controls already exist that address the risk?	Due Date DD/MM/YY	Residual Risk (RR)			Is the RR currently tolerable? (if no, provide action plan)	Proximity	Risk owner	Target closing date	Status (Open/Closed)	Date closed	Comments
						Likelihood	Impact	IR score			Likelihood	Impact	RR score							
1. Risk area - planning								0					0							
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RESOURCES (FINANCE) RISK REGISTER

Risk Area	SRR No.	Operational Risk ID No.	Date risk identified	Category	Description of Risk	Causes	Impact (what would happen if risk not mitigated?)	Likelihood	Impact	IR score	Management Controls/mitigation strategy - what controls address the risk? If future plan add date of delivery	Type of control (Preventative, Detective)	DD/MM/YY	Likelihood	Impact	RR score	Is the RR currently tolerable? (if no, provide action plan)	Proximity (when is risk likely to happen)	Risk owner	Target closing date	Status (Open/Closed)	Date closed	Comments/further mitigations and dates
1. Risk area - operations	5	1.5	10/08/2019	Finance	There is a risk that fraudulent activity goes undetected	Fraud detection systems are currently manual and rely on human intervention, which could fail	Loss of financial resources to the HTA and ultimately the tax-payer and possible reputational damage as losses are mandated to be reported to the Cabinet Office	3	4	12	Utilise the services of the National Fraud Initiative which offers a data-matching service for public sector organisations in addition to manual processes. Regular staff refresher training Reporting of fraud oversight to ARAC Internal Audot recommendations and review of pocedures	Detective	18/01/2022	2	4	8	Yes	3-6 Months	Head of Finance	31/03/2022	Open		
2. Risk area - operations	5	2.5	01/04/2021	Finance	There is a risk of unplanned consumption of finance resource	A lack of understanding of the budgetary process	If significant sums, can impact on the cash-flow of the organisation	3	5	15	Implement Budget Management training for all budget-holders and potential budget-holders Ensure Montly review of Purchase Orders and revised forecasting Regular challenge meetings with Budget holders	Preventative	31/01/2022	2	3	6	Yes	3-6 Months	Finance Manager	31/03/2022	Open		
3. Risk area - operations	5	3.5	01/04/2021	Finance	There is a risk of significant underspend against budget	Lack of challenge at budget meetings Failure to update forecasts Unexpected change in plans or withdrawl of service Siginficany unplanned vacanies	Adverse NAO and IA findings Lack of credibility with sponsior Department and stakeholders Increase in cash reserves	3	4	12	Monthly management accounts produced Quarterly finance meetings Virement policy Monthly SMT reporting and ARAC oversight	Monitoring	30/09/2022	2	4	8	Yes	3-6 Months	Director of Resources	31/03/2022	Open		
4. Risk area - operations	5	4.5	02/07/2021	Finance	Failure of payroll provider	Financial difficulty Ceases to operate	Inability to pay staff salaries for a period of time Staff morale	1	5	5	Review of available financials Confirmation form supplier that alternative is available Supplier experienced breach which required staff to work remotely - access to HTA payroll database was given securely.	Preventative	30/09/2021	1	4	4	Yes	6-12 Months	Head of Finance	23/12/2021	Open		
5. Risk area - resource	5	5.5	21/04/2021	Finance	Inability to make BACs payments for a period longer than 14 days	Insufficient number of approvers due to staff leaving Loss of key finance staff	Supplier payments will not be made - possibly resulting in Contract providers refusing to provide goods/services Key suppliers include HMRC/NHSP which could lead to fines	3	5	15	Currently there are three people who can approve payments	Preventative	01/12/2021	2	4	8	No	0-3 Months	Head of Finance	01/11/2021	Open		Two additional people to be approached to act as approvers **by Nov-21**
6. Risk area - operations	4	6.4	10/09/2021	Finance	Unauthorised expenditure	Purchasing services/goods prior to approval	Monitoring of spend becomes difficult If significant we fail to understand our financial position	4	5	20	Procurement policy in place.	Monitoring	31/03/2022	3	5	15	No	0-3 Months	Head of Finance	30/11/2021	Open		Refresher training on budget management **by Q3 2021**
7. Risk area - operations	4	7.4	23/12/2021	People	Contractors engaged incorrectly breaching HMRC IR35 rules	Lack of understanding of IR35 No communication with finance prior to engagement	Fine from HMRC incorporating PAYE for the contractor and HTA	4	4	16	Finance checkin with HR colleagues Review conducted prior to quarter/year ends	Preventative	31/03/2022	4	2	8	Yes	3-6 Months	Director of Resources	31/12/2021	Open		NB: Currently have a contractor engaged incorrectly. RS/LD to confirm

Audit and Risk Assurance (ARAC) meeting

Date: 27 January 2022

Paper reference: AUD 07/22

Agenda item: 09

Author: Louise Dineley
                        Director of Data, Technology and Development

OFFICIAL

Development Programme Update

Purpose of paper

1. The purpose of this paper is to provide the committee with:
    i.   A look back over the quarter of progress against the Programme plan
    ii. A forward look at Programme deliverables in the next quarter

Action required

2. The committee is asked to:
    i.   Note the update on the quarter three deliverables.
    ii. Note the deliverables and dependencies for quarter four.

Background

3. In 2021/22 we have identified three priority projects. These are:
    *   The establishment and adoption of an Enterprise Content Management System.
    *   The development of the HTA's data and intelligence systems and future capability to adopt a more risk-based approach to oversight and regulatory action.
    *   The implementation of a Target Operating Model.

4. In addition to these priority projects, there are a number of projects and targeted pieces of work that will support the developments and progress. These include:

    - Ongoing organisational preparedness e.g., change readiness training
    - Developing the HTA's workforce with the identification of future skills required, core competencies and business critical roles.
    - Implementation of a revised Communications & Engagement Strategy.

Quarter three 2021/22 – update on deliverables

5. The deliverables for the three priority projects and the programme overall in the quarter are outlined below along with a forecast assessment.

6. *An updated version of the Regulatory Insight Model & Index (RIMI).*
    Status: GREEN
    The development of the Regulatory Insight Model & Index has been hampered in quarters two and three by a dependence on outputs from other areas of work. This dependency has necessitated a reframing of the delivery and product for "go live". By the end of quarter three, version one of the HTA's Data Model has been produced and is ready for roll out. Planning is underway for its implementation and most importantly setting the context of this model as an initial model with plans for incremental and continuous development. The intention is to embed the data model in quarter four with initial roll out prioritising Regulation Managers and Heads of Regulation. Interest and opportunities for further development of the data model and the adoption of its underlying principles to strengthen the use of information and intelligence has been shown by other functions. This extended use will continue to be explored and progressed over the quarter.

7. *The design phase of the transition architecture for the Enterprise Content Management System (ECMS) with development progressing and delivered in full by the end of quarter four.*
    Status: AMBER
    The design phase of the transition architecture is dependent on the mapping of a future state and "to be" process and data flow maps. The delay (referenced in paragraph eight) in the delivery of this product means that this work has progressed as far as it can and is currently paused. In the absence of the "to be" model work has continued in the planning of the next phase of this work with requirements gathered and specifications drafted.   This approach facilitates the ability to move at pace to the design phase once the modelled processes are completed.

8. *A package of "as is" and "to be" process maps, data flow maps and narratives that form the basis of our operating manual and operating system*
    Status: AMBER / RED
    The mapping of the "as is" process mapping was completed as far as possible at the end of October 2021. Previous reports to ARAC had highlighted challenges with the commissioning and delivery of the work noting the exclusion of identifying and mapping data exchange or formal data flows in the outputs. The intention had been to move to an initial round of "to be" mapping in quarter three. This required the commissioning on an external supplier to support the HTA in the delivery. Confirmation of the required investment has formed part of the priority and resource planning for quarter four. At the time of writing this report a commission has been drafted and potential suppliers identified to support this work in quarter four.

    The completion of the "as is" and "to be" processing mapping and its outputs is significant given the dependencies with other projects across the Development Programme. As a result, the pausing and delays to this work experienced in quarters two and three have had an impact on the progress of other development projects such as the next iteration of the Target Operating Model, development of the regulatory insight model as intended and in the identification of future skills requirements and subsequent organisational design. The work scoped and commissioned in quarter four will take account of these requirements and deliverables.

9. *Future workforce skills map to inform workforce development and future operating model*
    Status: AMBER / RED (dependency based)
    The progress of the future workforce skills map has been delayed due to the dependency on the process mapping. As with other projects planning for what needs to be done has continued including the approach to a skills audit and alignment with a future operating model. This work and its delivery will be reframed once a schedule of outputs from the business process mapping has been confirmed.

10. Engagement with stakeholders (internal and external)
    Status: AMBER
    It has been necessary in quarter three to prioritise and deploy the limited communications and engagement team's resource to other projects. Most notable has been the Website redevelopment project and the HTA's management and response to Operation Sandpiper. Despite pressure on resources work has continued to update the stakeholder map and trial new and additional communication routes.

A more detailed update on the HTA's Communications & Engagement Strategy and the impact of the evolving approach is due to be presented to the Board in February.

Deliverables in Quarter Four 2021/22

11. At the time of writing this report the business priorities for Quarter four and resource deployment are in the process of being agreed. Indicatively the Development Programme's priorities and deliverables for the quarter are to:
    - Roll out the HTA Data model version one.
    - To commission and complete the "to be" process mapping and data flows to a standard and with the outputs that support dependencies with other projects.
    - To commence engagement with stakeholders on proposed changes as part of the development programme.

12. These deliverables are dependent on:
    - No further pauses to the development programme and deprioritisation of the projects
    - The investment of resources (people and finance) as agreed within the Business Plan.

ARAC Cyber Security dashboard

27 January 2022

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Introduction
The following slide deck seeks to provide an overview of the cyber security risk to the HTA; the control measures and systems in place and the effectiveness of these measures in managing the risk.

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The Cyber Security Dashboard has been developed using the 6 key outcomes of the HTA's Cyber Security Strategy. This strategy seeks to implement measures to achieve the mandatory protective security outcomes of the Minimum Cyber Security Standard.   This strategy was agreed by ARAC in June 2020. The outcomes are:

Identify : We have in place appropriate cyber security governance processes. We have identified and catalogued the sensitive information we hold. We have identified and catalogued the key operational services we provide. The need for users to access sensitive information or key operational services is understood and continually managed.

Protect : Access to sensitive information and key operational services is only provided to identified, authenticated and authorised users or systems. Systems that handle sensitive information or key operational services are protected from exploitation of known vulnerabilities. Highly privileged accounts are not vulnerable to common cyber-attacks.

Detect : We take steps to detect common cyber-attacks.

Respond : We have a defined, planned and tested response to cyber security incidents that impact sensitive information or key operational services.

Recover : We have well defined and tested processes in place to ensure the continuity of key operational services in the event of failure or compromise.

An initial set of metrics have been identified against each of the strategic outcomes. These metrics aim to provide an overview of the activity, the control measures in place and provide assurance on the management of the risk. In some areas drilling down further to understand any potential risk.
The data for quarter 3 2021/22 has been extracted from the NHS Advance Threat Protection portal and RAG rated under the different outcomes. This portal provides the HTA will the opportunity to monitor performance and further analyse any events or emerging trends. It is anticipated that with some further developments we will be able to access a longer time series and trend data.

Cyber security Performance Q3 2021/22 – at a glance

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Microsoft secure score	Viruses intercepted Q3 2021/22	Device exploit availability (no known)	Device vulnerability
86.42%	100%	48 / 73	A total of 22 devices had 70 known vulnerabilities

Alerts received from NHS X	Number of alerts responded to in 48hrs	Staff mandatory training (Completed Q2 2021/22)	Internet use: Identified access to restricted categories
14 (6 relevant to HTA)	100%	100%	3166

ARAC Cyber Security Dashboard – Overview

In summarising the HTA's position it is important that we look at the level of protection the organisation's systems are providing and also the risk that exists through threat activity. In addition to the protection afforded by systems we also need to maintain a high level of understanding and awareness amongst our staff as user behaviour can be a final control and / or introduce additional risk. IN quarter 2 2021/22 HTA mandatory training recorded 100% compliance against the completion of the cyber security modules. Any member of staff joining the HTA from 1 October 2021 will have had these modules added to the training to be completed.

The dashboard below provides an overview of our systems and the level of risk. This is an automated data generated through our systems, interpreted and accessed through the NHS Threat Protection portal. This presentation provides assurance that HTA 's protection systems are performing as intended.

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Microsoft Secure Score	Antivirus Update Status	HTA Exposure Score	Phishing & Viruses Detected	Spam Detected	
86.42% similar NHS entities scored 46.38% Meaning we have well defined and managed processes in place	99% out of 65 devices MS Defender identifies devices as laptops and servers	34%	43 Viruses over 3 months Less than 0.11% of mail received 37 Phishing attempts sent to 21 recipients 80% were attributed to 3 users	Month	Count
				October	1,132
				November	1,142
				December	1,017
				Total	3,291

Secure score is a defined standard that shows how well we are protected. It also shows how we compare to similar NHS entities. This shows we are significantly better	Our Antivirus solution is monitored and updated real time ensuring we have the latest known virus threat and unknown breaches kept to a minimum	Higher the score the more at risk our devices are 34% is just in the medium bracket and caused by two software issues which are currently being addressed	With the onset of remote working email viruses and phishing attempts have never been more prevalent. The HTA had 43 viruses included in email and 100% was intercepted by our security systems	SPAM accounts for 10% of all inbound email. This figure is what was intercepted by our security systems. User feedback is critical in the event that spam breaches these controls. Incidents are reported to IT for follow up.

AUD 08/22

ARAC Cyber Security Dashboard – IDENTIFICATION & PROTECTION Summary

The HTA has well defined Advanced Threat Protection systems in place as part of its subscription to NHS security arrangements. These systems are underpinned by a comprehensive set of policies and procedures that allow the monitoring and governance of all sensitive data and requests from GDPR to FOI and access to confidential/personal information internally. In addition there is a formal alert system - Respond to NHS Cyber Alerts (RTANCA). This dashboard is an indicator of the policies and controls we have in place to address and manage request and incidents that directly relate to information potentially being extracted for malicious purposes.

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Our systems identified 7 security attempts across 3 devices and 3 unique files.
Across the HTA our systems identified 48 of our devices with no exploits that means device exploitation is good.
We also identified 70 High/Critical Vulnerabilities although actual risk was minimal due to additional security measures such as being behind a firewall, Multi factor Authentication, email scanning, web filtering, regular internal PEN testing.

AUD 08/22	Device Exploit Availability & Device Vulnerability Severity

An exploit is an attack that leverages a known vulnerability. Even though there are vulnerabilities identified they may not be actually exploitable as they have further security controls to prevent the attack

16 Exploits Verified   26 devices identified as Critical

9 Exploits Available   44 devices identified as High

48 No Known Exploit   1 device identified as Low

The ATP identified:
- 70 identified risks were classified as high or critical and can be associated to any one device, or both high and critical can be associated to a device at the same time. The vulnerability risk is potentially minimal due to the additional security measures in place.
- 48 physical devices were confirmed has having no known exploit. This includes user equipment, Servers, Firewalls and other infrastructure devices.

ARAC Cyber Security Dashboard – DETECTION

The Advanced Threat Protection service actively scans and monitors for known exploits and vulnerabilities within all registered HTA devices .A vulnerability on a device is a device that has a weakness in a software system. An exploit is an attack that *leverages* that vulnerability. So while vulnerable means there is *theoretically a way* to exploit something (i.e., a vulnerability exists), exploitable means that there is a *definite* path to doing so, attackers want to find weaknesses that are actually exploitable. The ATP detects attempted attacks and prevents them it also advises HTA IT of preventative measures it needs to take to further minimise the risk of exposure based on known identifiable exploits

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AUD 08/22

Potentially malicious events

Advanced Threat Protection service from NHS Digital identified the following security attacks and successfully remediated the issues
7 Detections (4 were a google update attempt, the remaining 3 are detailed below)
3 Unique Files (2 were malware 1 was a malicious payload – *a virus that stays dormant until activated)*
3 Affected Devices (1 test device, Martin Cranefield, Robert Watson)

Exposure Distribution

Of the malicious threats only

1 device was at high risk
29 devices medium
38 devices low

Health State

ATP identified 67 Active devices in the HTA estate. Applied security policies and default usage policies such as not allowing the use of unauthorised external USB devices have been automatically applied

11 Inactive devices are previously registered devices that have not been in use for more than 30 days The ATP service still keeps a record of them until HTA IT remove these devices from the ATP service assuming they are no longer going to be used. Of these devices 5 are at BCC, 2 are waiting to be collected from staff and the remaining 4 servers that have been decommissioned and replaced in the MS Azure cloud

Attack Surface Reduction

Attack Surface Reduction polices are critical in the protection of mitigating misuse of equipment and preventing cyber threats. The ATP service recommends the rules to apply per device. Currently this only applies to12% of Devices as HTA IT have been piloting the use of ASR policies since December 2021. Due to the success of the pilot HTA IT will be applying ASR policies to all devices during February 2022

ARAC Cyber Security dashboard – RESPONSE & RECOVERY

In quarter 3 2021/22 the HTA received 14 alerts. Of these only 6 required action. The HTA responded to all alert requests within the 48hr time period.

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NHS Cyber Security Alerts

NHSx & NHS Digital require the HTA to respond to critical alerts within 48 Hours. Not all are applicable to the HTA but we have met all the required responses for those that affected us

Top Vulnerable Software

MS Office
Google Chrome
These two applications account for most of the device exploit scores and IT already have remediation plans in place

NHS Cyber Security Alerts 2021

Total of 290 alerts
13 High
49 Medium
34 Low

HTA Affected

14 alert request were made to the HTA 8 were not applicable
6 were addressed and dealt with

RTANCA

All Alert requests were Responded to within 48 Hours
100%

Freedom of Information

Business area	Number of FOI requests
IT	9
Finance	4
Human Resources	6
Regulations (incl. licensing, operations and cross-sector)	11
Total	30

Web Analysis

In the last 30 days there were 3166 web requests to access sites in restricted categories. The web access may be restricted for a number of reasons including content, high bandwidth and legal liability. The access requested may also carry a legitimate business needed. Staff awareness will be raised to the safe use of the intranet and access for business need.

ARAC Cyber Security dashboard – Staff Awareness Training

Strengthening staff understanding and awareness to cyber security risks and threats has been a feature of the mandatory training over the last 3 years. In quarter 2 2021/22 there were a number of modules that aimed to raise staff awareness and understanding of the risks and controls that are in place. 100% of all staff employed by the HTA in quarter 2 completed the training.

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Staff Cyber Security Training Completed

Mandatory Cyber Security Training Proposed 2022/2023

Planned Realtime Simulated Security Training

Q2 2019/2020
Introduction to GDPR
Phishing Awareness
Display Screen Equipment

Q1 2021/2022
Fraud Awareness
Freedom of Information

Q2 2021/2022
Using email and the internet
Information security diagnostic assessment
Accountability & GDPR

2022/2023

Information Security
Personal Data Security
Physical Risks – Information Security
Toolbox (talk)
Consequences of Cybercrime

These tests are part of the NHS ATP security toolkit to test all HTA staff in:

Malware Attack
Phishing Attempts
Credential Harvest (attempt to obtain personal information)
Link to Malware Attack
Consent Grant Attack (this is when you give access to data that do not have the right to see it)

The reports will identify those who pass or fail so more detailed training can be given

Future reporting

Further development of the cyber security dashboard is planned. Below provides an example of the data and potential for trend analysis that will be available to us through planned license upgrades in 2022/23.

Conclusion

- Over the last 12 months our cyber security threat protection has been improved and strengthened.

- The information highlights and details is that HTA is in a good position to monitor and protect its systems, devices and user from potential attacks and with better automation and control go even further to mitigate any risks.

- There already are plans in place to further improve our security stance during 2022. For example:

  - Improving our email threat protection that adds artificial intelligence into the way we respond to email and how it addresses potential threats based on user activity.

  - Enhancing internal cyber security tests that will regularly check our systems outside of the NHS ATP service and provide us with greater insights on further developments and improvements

  - There are further opportunities to improve our cyber security posture by upgrading our licences with Microsoft which have already been taken into consideration for 2022/2023.

Audit and Risk Assurance (ARAC) meeting

Date: 27 January 2022

Paper reference: 09/22

Agenda item: 11

Author: Morounke Akingbola
Head of Governance and Finance

OFFICIAL

Anti-fraud, bribery and corruption policy

Purpose of paper

1. The purpose of this paper is to present to the Audit, Risk and Assurance Committee the Anti-fraud Policy.

Decision making to date

2. None.

Action required

3. The Committee are requested to note that there have been no updates/amendments to the policy.

4. The Committee are requested to approve the review period of 3 years (para 74) and approve the unamended policy.

HTA Policy

Protective Marking: OFFICIAL

Anti-Fraud, Bribery and Corruption Policy

Purpose

1. This document sets out the HTA's policy on fraud, bribery and corruption and the response plan should fraud be detected or suspected.

2. The anti-fraud policy aims to develop a culture across the HTA which raises awareness of the risks and consequences of fraud. This policy aims to help mitigate the risks of fraud and ineffective action.

3. It aims to promote good practice within the HTA through the following:

    a. zero tolerance to fraud;
    b. a culture in which bribery is never accepted;
    c. any allegations of fraud, anonymous or otherwise, will be investigated;
    d. consistent handling of cases without regard to position held or length of service;
    e. consideration of whether there have been failures of supervision. Where this has occurred, disciplinary action may be initiated against those responsible;
    f. any losses resulting from fraud will be recovered, if necessary, through civil actions;
    g. publication of the anti-fraud policy on the HTA intranet site (WAVE);
    h. all frauds will be reported to the Audit and Risk Assurance Committee and the DHSC Anti-Fraud Unit.

Introduction

4. The Human Tissue Authority (HTA) requires all staff at all times to act honestly and with integrity and to safeguard the public resources for which the HTA is responsible. The HTA is committed to ensuring that opportunities for fraud and corruption are reduced to the lowest reasonable level of risk. This paper sets out the policy on the control of fraud and suspected fraud within the HTA.

Scope

5. This policy applies to all the HTA's activities, wherever they are undertaken, to all individuals who work for and on behalf of the HTA, including contract staff, volunteers, and freelancers and to individuals in a commercial relationship with the HTA e.g., the employees of suppliers. Awareness of the policy is made through the induction process.

6. This policy also sets out the responsibilities with regard to fraud prevention, what to do if you suspect fraud and the action that will be taken by management.

7. The aim of the policy is to minimise the risk of any fraud being perpetrated against the HTA, thereby depriving the HTA of assets and resources and potentially damaging the HTA's reputation.

8. Any person who becomes aware of any fraud, bribery, money laundering or other illegal act and does not follow this policy could be subject to disciplinary action.

Definitions

What is Fraud?

9. The term is used to describe such acts as deception, bribery, forgery, extortion, corruption, theft, conspiracy, embezzlement, misappropriation, false representation, concealment of material facts and collusion.

10. For practical purposes fraud may be defined as the use of deception with the intention of obtaining an advantage, avoiding an obligation, or causing loss to another party. Obviously, fraud can be perpetrated by persons outside as well as inside an organisation. The criminal act is the attempt to deceive, and attempted fraud is therefore treated as seriously as accomplished fraud.

11. The Fraud Act 2006 (came into force on 15 January 2017) replaced parts of the Theft Acts of 1968 and 1978 which until then covered the offences of fraud. The 2006 Act introduced provisions for the general offence of fraud which broadened the interpretation of fraud. This is covered under 3 sections:-

    a. Section 2 – Fraud by false representation
    b. Section 3 – Fraud by failing to disclose information
    c. Section 4 – Fraud by abuse of position

12. False representation includes dishonestly making a false representation and intending - by making the representation – to make a gain for oneself or another, or cause loss to another or to expose another to a risk of loss. A representation is false if it is untrue or misleading, and the person making it knows that it is, or might be, untrue or misleading.

13. A person is considered to have committed a fraud through abuse of position if he or she:

      a. occupies a position in which he/she is expected to safeguard, or not to act against, the financial interests of another person;

      b. dishonestly abuses that position; and

      c. Intends, by means of the abuse of that position to make a gain for himself or another, or to cause loss to another or to expose another to a risk of loss.

14. The Fraud Act 2006 also created new offences of:

      a. processing, making, and supporting articles for use in fraud;

      b. fraudulent trading;

      c. obtaining services dishonestly.

15. The definition of fraud can cover a wide variety of misdemeanours and criminal culpability is not necessary for an act to be fraudulent, as the offence can be civil in nature.

16. Frauds can be attempted or carried out in a number of ways, including:

      a. the theft of cash, cheques, equipment;

      b. the falsification of travel and subsistence or other expense claims;

      c. false claims for overtime (or flexible working);

      d. irregularities in the tendering for, and execution and pricing of, supplies to the HTA by contractors of: property, goods, services, works and consultancy;

      e. corruption, including the receipt of payment or other material advantage as an inducement to the award of contracts by the HTA.

17. Computer fraud is where information technology equipment has been used to manipulate programmes or data dishonestly (e.g., by altering, substituting, or destroying records or creating spurious records), or where the use of an IT system was a material factor in the perpetration of fraud. Theft or fraudulent use of computer time and resources is included in this definition.

What is Bribery?

18. A bribe is an inducement or reward offered, promised, or provided in order to gain any commercial, contractual, regulatory, or personal advantage. The advantage sought or the inducement offered does not have to be financial or remunerative in nature and may take the form of improper performance of an activity or function.

19. The Bribery Act 2010 (came into force in July 2011) includes the offences of:

      a. Section 1 – bribing another person;

      b. Section 2 – offences relating to being bribed;

      c. Section 6 – Bribing a foreign or public official; and

      d. Section 7 – Failure of commercial organisations to prevent bribery.

20. Further guidance is at http://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf

Money Laundering

21. Money laundering is a process by which the proceeds of crime are converted into assets which appear to have a legitimate origin, so that they can be retained permanently or recycled into further criminal enterprises.

22. Offences covered by the Proceeds of Crime Act 2002 and the Money Laundering Regulations 2017 may be considered and investigated in accordance with this Policy.

23. The HTA could become indirectly involved in this act where the proceeds of any crime, e.g., fraud, are converted by making a payment to the HTA and then seeking immediate repayment.

What is Corruption?

24. Corruption is defined as "The offering, giving, soliciting or acceptance of an inducement or reward which may influence the action of any person". In addition, "the failure to disclose an interest in order to gain financial or other pecuniary gain".

Legal Basis

25. The HTA's responsibilities in relation to fraud are set out in Annex 4.9 of Managing Public Money
https://www.gov.uk/government/publications/managing-public-money.

Statement of Principles

26. The HTA will not accept any level of fraud or corruption; consequently, any case will be promptly and thoroughly investigated and dealt with appropriately. Any member of staff found to be involved in theft, fraudulent action, or conspiracy to defraud can expect to be dealt with in accordance with the agreed disciplinary procedures. Staff should draw attention to circumstances when they believe that there is improper behaviour by other HTA staff or external contacts of the HTA in accordance with the Whistleblowing Procedure. All matters will be dealt with in confidence and in strict accordance with the terms of the Public Interest Disclosure Act 1998, which protects the legitimate personal interests of staff.

Responsibilities

Chief Executive (CEO) (Accounting Officer)

27. The CEO as Accounting Officer is responsible for establishing and maintaining a sound system of internal control that supports the achievement of the HTA's policies, aims and objectives. The system of internal control is designed to respond to and manage the whole range of risks that the HTA faces. The system of internal control is based on an on-going process designed to identify the principal risks, to evaluate the nature and extent of those risks and

to manage them effectively. Managing fraud risk is seen in the context of the management of this wider range of risks.

Director of Resources

28. Overall responsibility for managing the risk of fraud has been delegated to the Director of Resources. Their responsibilities include:

   a. Undertaking at least an annual review of the fraud risks associated with each of the key organisational objectives.
   b. Establishing an effective anti-fraud policy and fraud response plan, commensurate to the level of fraud risk identified.
   c. Assisting in the design of an effective control environment to prevent fraud.
   d. Establishing appropriate mechanisms for:
      i. Reporting fraud risk issues;
      ii. reporting significant incidents of fraud or attempted fraud to the CEO;
      iii. Reporting to DHSC and Cabinet Office in accordance with Managing Public Money Annex 4.9;
      iv. Co-ordinating assurances about the effectiveness of the Anti-Fraud Policy to support the Annual Governance Statement;
      v. Liaising with the Finance Team and the Audit and Risk Assurance Committee;
      vi. Making sure that all staff are aware of the organisation's Anti-Fraud, Corruption and Bribery Policy and know what their responsibilities are in relation to combating fraud;
      vii. Ensuring that appropriate anti-fraud training is made available to staff as required;
      viii. Ensuring that appropriate action is taken to minimise the risk of previous frauds occurring in future.

   e. Ensuring that vigorous and prompt investigations are carried out if fraud occurs or is suspected; Taking appropriate legal and or/disciplinary action (in conjunction with HR) against perpetrators of fraud.
   f. In conjunction with HR, taking appropriate disciplinary action against supervisors where supervisory failures have contributed to the commission of fraud.
   g. In conjunction with HR, taking appropriate disciplinary action against staff who knowingly fail to report fraud.
   h. Taking appropriate action to recover assets.

Line Managers

29. The prevention and detection of fraud lies primarily with Line Managers as they are responsible for many of the processes and controls operated by the HTA. In particular they are responsible for:

    a. Ensuring that an adequate system of internal control exists within their areas of responsibility and that controls operate effectively.
    b. Preventing and detecting fraud as far as possible.
    c. Assessing the types of risk involved in the operations for which they are responsible.
    d. Reviewing regularly and testing the control systems for which they are responsible.
    e. Ensuring that controls are being complied with and their systems continue to operate effectively, (this is key as most frauds occur because controls have not been enforced).
    f. Implementing new controls to reduce the risk of similar fraud occurring where frauds have taken place.

Internal and External Audit

30. The prevention and detection of fraud within the HTA is a management and staff responsibility. However, Internal and External Audit can assist by:

    a. Delivering an opinion to the CEO and the Board on the adequacy of arrangements for managing the risk of fraud and advising the HTA on how to promote an anti-fraud culture.
    b. Assisting in the deterrence and prevention of fraud by examining and evaluating the effectiveness of control commensurate with the extent of the potential exposure/risk in the various areas of the HTA's operations.
    c. Ensuring that management has reviewed its risk exposures and identified the possibility of fraud as a business risk.
    d. External audit may during the course of the final audits identify anomalies.

The DHSC Anti-Fraud Unit

31. The services of the DHSC Anti-Fraud Unit are available to the HTA on request. The unit provides advice, training about fraud prevention and investigation services. The Director of Resources or the Chief Executive will make the decision whether to call on this unit.

Staff

32. Every member of staff is responsible for:

    a. Acting with propriety in the use of HTA's resources and the handling and use of HTA funds whether they are involved with cash, receipts, payments, stock or dealing with contractors and suppliers.
    b. Conducting themselves in accordance with the seven principles of public life set out in the first report of the Nolan Committee "Standards

in Public Life". They are: selflessness, integrity, objectivity, accountability, openness, honesty, and leadership.

c. Being alert to the possibility that unusual events or transactions could be indicators of fraud.

d. Alerting their line manager when they believe the opportunity for fraud exists e.g., because of poor procedures or lack of effective oversight.

e. Reporting immediately, in accordance with the Fraud Response Plan (Appendix 1) and Whistleblowing policy, if they suspect that a fraud has been committed or see any suspicious acts or events.

f. Cooperating fully with whoever is conducting internal checks or reviews or fraud investigations.

Information Management and Technology

33. The Computer Misuse Act 1990 makes activities illegal, such as hacking into other people's systems, misusing software, or helping a person to gain access to protected files of someone else's computer a criminal offence.

34. The Head of IT will contact the Counter Fraud Lead in all cases where there is suspicion that IT is being used for offences under the Act or fraudulent purposes. Human Resources will also need to be informed if there is a suspicion that an employee is involved.

Procedures

35. The HTA has a Fraud Response Plan (Appendix 1) that sets out how to report suspicions and how investigations will be conducted and concluded.

Breach of the Policy

36. The HTA views fraud **EXTREMELY SERIOUSLY**. After proper investigation, the HTA will take legal and/or disciplinary action in all cases where it is considered appropriate. Where a case is referred to the police, the HTA will co-operate fully with police enquiries, and these may result in the offender(s) being prosecuted. In all cases the HTA will seek to recover assets where it can.

37. The consequences of breaching the Anti-Fraud Policy are set out in more detail in the Fraud Response Plan (Appendix 1).

Deterrence

38. There are a number of ways in which we deter potential fraudsters from committing or attempting fraudulent or corrupt acts, whether they are inside or outside of the HTA, and these include:

a. Publicising the fact that the Board is firmly set against fraud and corruption at every appropriate opportunity.

b. Acting robustly and decisively when fraud and corruption is suspected.

c. Prosecution of offenders.

d. Taking action to effect maximum recovery for the HTA.

e. Having sound internal control systems, that still allow for innovation and efficiency, but at the same time minimising the opportunity for fraud and corruption.

Sanction and Redress

39. This section outlines the sanctions that can be applied and the redress that can be sought against individuals who commit fraud, bribery and corruption against the Authority and should be read in conjunction with the HTA's Disciplinary Policy. Where staff are believed to be involved in any fraud, the Director of Resources will be informed and follow the HR Protocol.

40. The types of sanction which the HTA may apply when an offence has occurred are as follows:

   a. Civil – Civil sanctions can be taken against those who commit fraud, bribery, or corruption, to recover money and/or assets which have been fraudulently obtained
   b. Criminal – The Local Counter Fraud Specialist will work in partnership with the NHS Counter Fraud Authority, the police, and the Crown Prosecution Service, to bring a case to court against an offender. Outcomes, if found guilty, can include fines, a community order or imprisonment and a criminal record.
   c. Disciplinary – Disciplinary procedures will be initiated when an employee is suspected of being involved in fraudulent or illegal activity. Further information can be found in the HTA's Disciplinary Policy and Procedure.
   d. Professional body disciplinary – An employee may be reported to their professional body as a result of an investigation or prosecution.

Recovery of monies lost through fraud

41. One of the key aims of the HTA's Counter Fraud Strategy is to protect public funds, thus where there is evidence that fraud has occurred, it will seek to recover this. This will limit the financial impact, help to deter others from committing fraud and minimise any reputational damage to the HTA.

42. Recovery can take place in a number of ways:

   a. Through the Criminal Court by means of a Compensation Order;
   b. Through the Civil Courts or a local agreement between the HTA and the offender to repay monies lost;
   c. In cases of serious fraud, the DHSC Anti-Fraud Unit can apply to the courts to make an order concerning the restraint and confiscation of the proceeds of criminal activity. The purpose is to prevent the disposal of assets, e.g., abroad which may be beyond the reach of the UK criminal system; or
   d. For employees in the NHS Pension scheme, any benefits, or other amounts payable can be reduced. NHS Pensions guidance specifically states: *Where there is a loss to public funds as a result of a Scheme members' criminal, negligent or fraudulent act or omission, their NHS pension benefits may be reduced to recover the loss.*

Training Requirements

43. Training will be provided, as appropriate, to new members of staff as part of the induction process. The existence and scope of this Policy will be brought to the attention of all staff through staff newsletters and another method considered relevant, i.e., dedicated workshops/on-line/training events, or individual discussions.
44. Specific training will also be provided for managers to ensure they have the knowledge, skills, and awareness necessary to operate this policy and procedure efficiently and effectively and to communicate it to staff.

Monitoring and Compliance

45. The HTA will monitor policy effectiveness, which is essential to ensure that controls are appropriate and robust enough to prevent or reduce fraud, bribery, and corruption. Arrangements will include reviewing system controls on an on-going basis and identifying any weaknesses in processes.
46. Where deficiencies are identified as a result of monitoring, appropriate recommendations and action plans will be implemented and taken into consideration when this policy is reviewed.

Review

47. The Anti-Fraud, Corruption and Bribery Policy will be reviewed every two years and after any occasion of fraud has been identified.

Appendices

1. Fraud Response Plan

2. Helpful dos and don'ts

Related documents

- Counter Fraud Strategy
- Whistleblowing policy
- Bribery Act 2010
- Finance Procedures Manual
- Procurement and Tender Policy

APPENDIX 1

Fraud response plan

Introduction

48. The fraud response plan provides a checklist of actions and a guide to follow in the event that fraud is suspected. Its purpose is to define authority levels, responsibilities for action and reporting lines in the event of suspected fraud, theft, or other irregularity. It covers:

    a. notifying suspected fraud;
    b. the investigation process;
    c. liaison with police and external audit;
    d. initiation of recovery action;
    e. reporting process;
    f. communication with the Audit and Risk Assurance Committee.

Notifying suspected fraud

49. It is important that all staff are able to report their concerns without fear of reprisal or victimisation and are aware of the means to do so. The Public Interest Disclosure Act 1998 (the "Whistleblowers Act") provides appropriate protection for those who voice genuine and legitimate concerns through the proper channels. More details are set out in Appendix 3.

50. In the first instance, any suspicion of fraud, theft or other irregularity should be reported, as a matter of urgency, to your line manager. If such action would be inappropriate, your concerns should be reported upwards to one of the following:

    a. your Head;
    b. your Director;
    c. Chief Executive;
    d. Audit and Risk Assurance Committee Chair;

51. Additionally, all concerns must be reported to the Director of Resources who will also formally report to ARAC.

52. Every effort will be made to protect an informant's anonymity if requested. However, the HTA will always encourage individuals to be identified to add more validity to the accusations and allow further investigations to be more effective. In certain circumstances, anonymity cannot be maintained. This will be advised to the informant prior to release of information.

53. If fraud is suspected of the Chief Executive or Director of Resources, notification must be made to the Audit and Risk Assurance Committee Chair who will use suitable discretion and coordinate all activities in accordance with this response plan, appointing an investigator to act on their behalf. The Chair of Audit and Risk Committee will also inform the Chair of the Board.

54. If fraud by a Board Member is suspected, it should be reported to the Chief Executive and the Director of Resources who must report it to the Chair to investigate. If fraud by the Chair is suspected, it should be reported to the Chief Executive and Director of Resources who must report it to the Chair of the Audit and Risk Assurance Committee to investigate.

The investigation process

55. Suspected fraud must be investigated in an independent, open-minded, and professional manner with the aim of protecting the interests of both the HTA and the suspected individual(s). Innocence is assumed until guilt is proven.

56. The investigation process will vary according to the circumstances of each case and will be determined by the Chief Executive in consultation with the Director of Resources. The process is likely to involve the DHSC Anti-Fraud Unit, who have expertise and resources to undertake investigations. An "Investigating Officer" will be appointed to take charge of the investigation on a day-to-day basis.

57. The Investigating Officer will appoint an investigating team. This may, if appropriate, comprise staff from within the Resources Directorate but may be supplemented by others from within the HTA or from outside.

58. Where initial investigations reveal that there are reasonable grounds for suspicion, and to facilitate the ongoing investigation, it may be appropriate to suspend an employee against whom an accusation has been made. This decision will be taken by the Chief Executive in consultation with the Director of Resources, the Head of HR and the Investigating Officer who will consider alternatives before final decision. Suspension should not be regarded as disciplinary action, nor should it imply guilt. The process will follow the guidelines set out in HTA Disciplinary policy relating to such action.

59. It is important, from the outset, to ensure that evidence is not contaminated, lost, or destroyed. The investigating team will therefore take immediate steps to secure physical assets, including computers and any records thereon, and all other potentially evidential documents. They will also ensure, in consultation with the Director of Resources, that appropriate controls are introduced in prevent further loss.

60. The Investigating Officer will ensure that a detailed record of the investigation is maintained. This should include chronological files recording details of all telephone conversations, discussions, meetings, and interviews (with whom, who else was present and who said what), details of documents reviewed, tests and analyses undertaken, the results and their significance. Everything should be recorded, irrespective of the apparent insignificance at the time.

61. All interviews will be concluded in a fair and proper manner and as rapidly as possible.

62. The findings of the investigation will be reported to the Chief Executive and Director of Resources. Having considered, with the Head of HR, the evidence

obtained by the Investigating officer, the Chief Executive and Director of Resources will determine what further action (if any) should be taken.

Liaison with police & external audit

63. Some frauds will lend themselves to automatic reporting to the police (such as theft by a third party). For other frauds the Chief Executive, following consultation with the Director of Resources and the Investigating Officer will decide if and when to contact the police.

64. The Director of Resources will report suspected frauds to the police and external auditors at an appropriate time.

65. All staff will co-operate fully with any police or external audit enquiries, which may have to take precedence over any internal investigation or disciplinary process. However, wherever possible, teams will co-ordinate their enquiries to maximize the effective and efficient use of resources and information.

Reporting process

66. Throughout any investigation, the Investigating Officer will keep the Chief Executive and the Director of Resources informed of progress and any developments. These reports may be oral or in writing. All Personal data processed by the implementation of this document will be done so in accordance with HTA-POL-108 HTA HR Privacy Policy.

67. On completion of the investigation, the Investigating Officer will prepare a full written report to the Chief Executive and Director of Resources setting out:

    a. background as to how the investigation arose.
    b. what action was taken in response to the allegations;
    c. the conduct of the investigation;
    d. the facts that came to light and the evidence in support;
    e. recommended action to take against any party where the allegations were proved (see policy on disciplinary action where staff are involved);
    f. recommended action to take to recover any losses;
    g. recommendations and / or action taken by management to reduce further exposure and to minimise any recurrence.

68. In order to provide a deterrent to other staff a brief and anonymous summary of the circumstances will be communicated to staff.

69. The National Audit Office (NAO) are a prescribed person to whom disclosures can be made in cases of concerns about the proper conduct of public business, value for money, fraud, and corruption in relation to the provision of centrally funded public services. Their whistleblowing helpline is 020 7798 7999. Further advice is on the NAO website at www.nao.org.uk/about_us/contact_us/whistleblowing__concerns.aspx

Communication with the Audit and Risk Assurance Committee

70. Irrespective of the amount involved, all cases of attempted, suspected, or proven fraud must be reported to the Audit and Risk Assurance Committee by the Chief Executive or Director of Resources at the earliest opportunity.

71. The Audit and Risk Assurance Committee will notify the Board.

72. In addition, the Department of Health and Social Care requires returns of all losses arising from fraud together with details of:

   a. all cases of fraud perpetrated within the HTA by members of its own staff, including cases where staff acted in collusion with outside parties;
   b. all computer frauds against the HTA, whether perpetrated by staff or outside parties;
   c. all cases of suspected or proven fraud by contractors arising in connection with contracts placed by the HTA for the supply of goods and services.

73. The Director of Resources is responsible for preparation and submission of fraud reports to the Audit and Risk Assurance Committee and the Department.

Review

74. This policy will be reviewed every 3 years or where there has been an instance of fraud.

APPENDIX 2

Helpful dos and don'ts

DO	DON'T
Make a note of your concerns	**Be afraid of raising your concerns**
• Record all relevant details, such as the nature of your concern, the names of parties you believe to be involved, details of any telephone or other conversations with names dates and times and any witnesses. • Notes do not need to be overly formal, but should be timed, signed, and dated. • Timeliness is most important. The longer you delay writing up, the greater the chances of recollections becoming distorted, and the case being weakened	• The Public Interest Disclosure Act provides protection for employees who raise reasonably held concerns through the appropriate channels – whistleblowing. • You will not suffer discrimination or victimisation as a result of following these procedures and the matter will be treated sensitively. • Do not try to investigate the matter yourself, gather evidence or raise any issues with the person who is suspected of fraud.
Retain any evidence you may have	**Convey your concerns to anyone other than authorised persons**
• The quality of evidence is crucial and the more direct and tangible the evidence, the better the chances of an effective investigation.	• There may be a perfectly reasonable explanation for the events that give rise to your suspicion. Spreading unsubstantiated concerns may harm innocent persons.
Report your suspicions promptly	**Approach the person you suspect or try to investigate the matter yourself**
• In the first instance, report your suspicions to your line manager. If this action would be inappropriate, further guidance on disclosure can be found in the Fraud Response Plan and the Whistleblowing guidance. • Additionally, all concerns must be reported to the Director of Resources.	• There are special rules relating to the gathering of evidence for use in criminal cases. Any attempt to gather evidence by persons who are unfamiliar with these rules may destroy the case.

Revision history

Reference: 15.7

Author(s):   Morounke Akingbola

Reviewed by: Head of Finance

Approved by: SMT/Audit, Risk and Assurance Committee

Owner: Director of Resources
Distribution: All Staff

- Jan 2016/15.0   Reviewed by Head of Finance
- Jan 2016/15.1   Reviewed by Head of Finance
- Jan 2017/15.2   Reviewed by Head of Finance
- Jan 2018/15.2   Reviewed by Head of Finance
- Jan 2019/15.3   Reviewed by Head of Finance
- Feb 2019/15.4   Reviewed by Head of Finance
- Mar 2019/15.5   GDPR passage referring to the HTA's HR Privacy Policy inserted under Data Protection
- Dec 2019/15.6   Reviewed by Head of Finance
- Nov 2020/15.7   Reviewed by Head of Finance – minor amendments
- Dec 2021/15.7   No changes/next review date Dec 2024 (TBC by ARAC)

![HTA Human Tissue Authority logo]

Audit and Risk Assurance (ARAC) meeting

Date: 27 January 2022

Paper reference: 10/22

Agenda item: 11

Author: Morounke Akingbola
                    Head of Governance and Finance

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Whistleblowing Policy

Purpose of paper

1. The purpose of this paper is to present to the Audit, Risk and Assurance Committee the Whistleblowing Policy.

Decision making to date

2. None.

Action required

3. The Committee are requested to review and provide comment to changes or updates made to the Whistleblowing Policy.

Background

4. The Whistleblowing policy was last presented to the Committee in January 2020. Since then the policy has been reviewed and minor additions have been made as follows:
    a. Section on malicious whistleblowing has been added;
    b. Link to bribery and corruption has been made (para 41).

HTA Policy

Protective Marking: OFFICIAL

Whistleblowing Policy and Procedure

Purpose

1. The Public Interest Disclosure Act 1998 (PIDA) protects employees against detrimental treatment or dismissal as a result of any disclosure by them of normally confidential information in the interests of the public. The HTA's whistleblowing policy and procedure explains how concerns should be raised by staff and is in line with the Act.

2. This policy aims to mitigate the risk of inappropriate treatment of whistle-blowers.

3. In accordance with PIDA, this policy sets out a clear and fair procedure:

    a. That staff may use if they wish to make disclosures about the HTA that they feel are in the public interest; and
    b. which the HTA will use to investigate such disclosures.

4. This policy applies to all employees, permanent, fixed-term and any temporary/agency staff.

5. The policy does not form part of any employee's contract of employment. It may be revised or withdrawn at the HTA's absolute discretion and at any time.

6. Concerns that are raised about issues at other establishments should be handled under the relevant policy or SOP.

Introduction

7. The HTA is committed to high ethical standards and fosters an open culture.

8. Whistleblowing is when an individual reports suspected wrongdoing at work. This is also known as 'making a disclosure in the public interest'. Simply, it is raising concerns, usually acting from a feeling of fairness or ethics, rather than out of personal interest.

9. Whistleblowing is different to making a complaint or raising a grievance. Usually, these actions are taken when the individual is personally affected. The HTA has separate procedures for these.

10. Whistleblowing is important to safeguard the effective delivery of public services, and to ensure value for money. It serves to protect and reassure individuals, and to maintain a healthy working culture and an efficient organisation.

11. The sections below provide guidance to staff on the procedures to follow if they have concerns about improper behaviour that might indicate fraud or have serious implications for the HTA.

Data Protection

12. Personal data processed by the implementation of this document will be done so in accordance with HTA-POL-108 HTA HR Privacy Policy.

Raising concerns

13. A member of staff who has concerns should initially raise the matter with his or her line manager or Director. A concern should always be raised as soon as the whistle-blower becomes aware of it and they should gather no further information at this point.

14. Types of improper behaviours include actions that:

    a. are illegal;
    b. are in breach of a professional code or are otherwise unethical;
    c. make improper use of HTA funds;
    d. make improper use of HTA assets or sensitive data;
    e. involve maladministration;
    f. cause harm to another member of staff, HTA users or the general public;
    g. undermine the HTA's functions or reputation;
    h. attempt to cover up such malpractice.

15. If a member of staff feels unable to raise the matter through their line manager, they may do so through HR or their Director. If the Director is implicated the concerns should be raised with the CEO. This also applies if the member of staff is dissatisfied with the line manager's response to his or her concerns. The member of staff may seek the support of their trade union and choose to be accompanied by a trade union representative or work colleague at any stage of the procedure. Advice is also available from the charity Public Concern at Work.

16. When a member of staff continues to feel that there has not been a satisfactory response by HTA management or that there are compelling reasons that the matter cannot be raised with HTA management, he or she may contact one of the following people detailed at Annex A

      a. If staff feel that they cannot raise the matter with anyone associated with the HTA, then they may contact the sponsorship team at the **Department of Health and Social Care** (also at Annex A).

      b. HTA staff may also use the **Whistleblowing Helpline**, which offers free, confidential and anonymous advice to the health sector: http://wbhelpline.org.uk/ or People Concerns at Work whistle@protect-advice.org.uk formerly known as Public Concern at Work.

17. The National Audit Office (NAO) are a prescribed person to whom disclosures can be made in cases of concerns about the proper conduct of public business, value for money, fraud, and corruption in relation to the provision of centrally funded public services. Their whistleblowing helpline is 020 7798 7999. Further advice is on the NAO website at www.nao.org.uk/about_us/contact_us/whistleblowing__concerns.aspx.

18. Staff should not raise their concerns publicly unless in consideration of all the circumstances it is reasonable to do so (such as they receive an inadequate response through the proper channels). To do so may breach other legislation and leave an employee unprotected by PIDA.

Protected disclosures

19. Certain conditions must be met for a whistle-blower to qualify for protection under the Public Interest Disclosure Act 1998 (PIDA), depending on to whom the disclosure is being made and whether it is being made internally or externally.

20. Workers are encouraged to raise their concerns with the employer (an internal disclosure) with a view that the employer will then have an opportunity to address the issues raised. If a worker makes a qualifying disclosure internally to an employer (or another reasonable person) they will be protected.

21. No worker should submit another worker to a detriment on the grounds of them having made a protected disclosure.

22. Any colleague or manager (provided that they and the whistle-blower have the legal status of employee / worker) can personally be liable for subjecting the whistle-blower to detriment for having made a protected disclosure.

23. If a disclosure is made externally, there are certain conditions which must be met before a disclosure will be protected. One of these conditions must be met if a worker is considering making an external disclosure (this does not apply to disclosures made to legal advisors).

24. If the disclosure is made to a prescribed person, the worker must reasonably believe that the concern being raised I one which is relevant to the prescribed person.

25. A worker can also be protected if they reasonably believe that the disclosure is substantially true, the disclosure is not made for personal gain i.e., is in the public interest, it is reasonable to make the disclosure and one of the following conditions apply:

   a. At the time the disclosure is made, the worker reasonably believes that s/he will be subjected to a detriment by their employer if the disclosure is made to the employer; or
   b. The worker reasonably believes that it is likely that evidence relating to the failure/wrongdoing will be concealed or destroyed if the disclosure is made to the employer; or
   c. The worker has previously made a disclosure to his/her employer.

26. Additional conditions apply to other wider disclosures to the police, an MP, or the media. These disclosures can be protected if the worker reasonably believes that the disclosure is substantially true, the disclosure is of an exceptionally serious nature, and it is reasonable to make the disclosure.

Prescribed persons/organisations

27. Special provision is made for disclosures to organisations prescribed under PIDA. Such disclosures will be protected where the whistle-blower meets the tests for internal disclosures and additionally, honestly, and reasonable believes that the information and any allegation contained in it are substantially true. Contact details can be found [here](#).

28. The HTA is not a prescribed organisation under PIDA and as such can only take limited action in relation to whistleblowing concerns in respect of other external organisations.

Action on concerns

29. It is fundamentally important to the success of the "whistleblowing" arrangements that staff can have confidence that their concerns will be taken seriously and that their position at the HTA will not be prejudiced unfairly by their raising issues of improper conduct. Whistle blowers who have acted in good faith have guaranteed protection under the provisions of PIDA.

30. All staff are protected from victimisation, harassment, or disciplinary action as a result of any disclosure, where the disclosure is made in good faith and is not made maliciously or for personal gain.

31. There will be no adverse repercussions for an employee or other individual who raises a genuine concern in good faith, whether or not such a concern is

subsequently found to be justified. If any harassment, bullying or victimisation of such a whistle-blower arises, this will be regarded as a disciplinary matter.

32. Whistle blowers may wish their identity and or the information they provide to be treated confidentially. In some cases, this may be possible, although the nature of the matter may be such that the investigation cannot be made or will be restricted if this is the case. If concerns are raised anonymously, they will still be investigated, but this may restrict or prevent proper action.

33. As soon as a manager is made aware of a concern and he or she has checked that it is a matter where the interest of others or the organisation may be at risk, it must be reported upwards to the appropriate Head and the Director, as long as the Head and the Director is not the subject of the allegation. If so, the contacts in paragraph 15 should be used. The allegation must be reported upwards even if the matter is satisfactorily resolved by the manager who received the complaint. If necessary, the Head and Director will confirm the action to be taken and the likely timescales.

34. The member of staff who raised the issue must be given a report in writing of the outcome of the investigation. This report should be sufficiently detailed such that the member of staff has confidence that the investigation and any consequential actions were appropriate. If the investigations are lengthy, an interim oral report should be given to the member of staff to reassure him or her that appropriate action is being taken and appropriately documented that this has occurred.

35. Consideration should be given to referring an allegation to internal audit, either to conduct the investigation or to endorse the outcome. This should be discussed with the Director responsible for that area and the Director of Resources who is the HTA's principle point of contact with the internal auditors.

36. Raising a false allegation maliciously may lead to disciplinary action under the HTA's Disciplinary Procedure.

37. The nature of any whistleblowing allegation and the results of any investigation should be reported to the Audit and Risk Assurance Committee in order for the Committee to consider the impact on the HTA.

Malicious Whistleblowing

38. Where it is found that a whistle-blower makes an allegation maliciously, and:
    a. Does not act in the public interest;
    b. Makes an allegation without having reasonable grounds for believing it to be substantially true;
    c. Collects the information to support the allegations improperly, or;
    d. Makes an allegation for personal or 3rd party gain.

39. They will be subject to formal disciplinary action, up to and including dismissal and in some cases may be subject to criminal investigation where illegality has occurred in order to achieve those aims.

40. Additionally, where this criterion is met or the employee engages in improper conduct in relation to whistleblowing, they are unlikely to be protected as a whistle-blower under the PIDA Act.

Link to anti-bribery

41. The HTA recognises that bribery and corruption are both serious matters and may be the subject of whistleblowing activity.

Review

42. This policy will be reviewed by the Audit, Risk and Assurance Committee annually.

ANNEX A

a) **Chief Executive**
Colin Sullivan
020 7269 1901
colin.sullivan@hta.gov.uk

b) **Authority Chair**
Lynne Berry
0207 269 1970
Lynne.Berry@hta.gov.uk

c) **Audit and Risk Assurance Committee Chair (Board Champion)**
Professor Gary Crowe
0207 269 1925
gary.crowe@hta.gov.uk

d) **Staff Champion**
Clare Wend-Hansen
0207 269 1953
Clare.wend-hansen@hta.gov.uk

Department of Health and Social Care
e) Jacky Cooper (DHSC Sponsor Unit)
0113 254 5446 / jacky.cooper@dhsc.gov.uk

Protect (formerly People Concerns at Work)
https://protect-advice.org.uk/contact-protect-advice-line/

Revision history

Reference: HTA-POL-17

Author(s):   Morounke Akingbola

Reviewed by: **Head of Finance**

Approved by: SMT/ARAC

Owner: Director of Resources
Distribution: All Staff

Protective Marking: OFFICIAL

- Jan 2015/15.0: Reviewed by Head of Finance
- Jan 2016/15.1   Reviewed by Head of Finance
- Nov 2017/15.2   Reviewed by Head of Finance
- Jan 2018/15.3   Updated by Head of Finance
- Jan 2019/15.4   Reviewed by Head of Finance
- Mar 2019/15.5   GDPR passage added referring to HTA's HR Privacy policy – inserted under Data Protection
- Nov 2020/15.6   Reviewed by Head of Finance
- Dec 2021/15.7   Reviewed by Head of Finance – section on malicious whistleblowing (para 38-40) and Link to bribery (para 41) added.
- Dec 2022/   Next review date

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0207 269 1925
gary.crowe@hta.gov.uk

d) **Staff Champion**
Clare Wend-Hansen
0207 269 1953
Clare.wend-hansen@hta.gov.uk

Department of Health and Social Care
e) Jacky Cooper (DHSC Sponsor Unit)
0113 254 5446 / jacky.cooper@dhsc.gov.uk

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- Dec 2022/   Next review date

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Audit and Risk Assurance (ARAC) meeting

Date: 27 January 202

Paper reference: 11/22

Agenda item: 11

Author: Morounke Akingbola
                       Head of Governance and Finance

OFFICIAL

ARAC Handbook

Purpose of paper

1. The purpose of this paper is to present to the Audit, Risk and Assurance Committee its handbook.

Decision making to date

2. None.

Action required

3. The Committee are requested to review the handbook.

Background

4. The ARAC Handbook details the business of the Committee and is to be used as part of the induction of new members.

5. Since the last review, no changes have been proposed.

[Request front cover from the Comms Team]

Audit, Risk and Assurance Committee Handbook

Contents

Section 1

Introduction

1. The purpose of this handbook is to focus Committee business and to provide part of the mechanism for inducting new members.

2. The Audit & Risk Assurance Committee is a committee to the Human Tissue Authority's board (the Board) as defined by section 8 and Annex B of the Framework agreement between the DHSC and the HTA. The Committee's primary role is to advise the Board and the Accounting Officer on the exercise of their responsibilities, by concluding upon the adequacy and effective operation of the HTA's overall internal control system and ensuring there is an adequate and effective risk management and assurance framework.

3. It is the responsibility of the Accounting Officer (i.e. Chief Executive Officer) to ensure that the organisation properly exercises its obligations / responsibilities in relation to issues of risk, control, governance and associated assurances. As a result the Committee will review the Annual Governance Statement, - this being a primary disclosure statement within the final accounts - prior to signing by the CEO. The HTA assurance framework is illustrated below.

HTA ASSURANCE FRAMEWORK
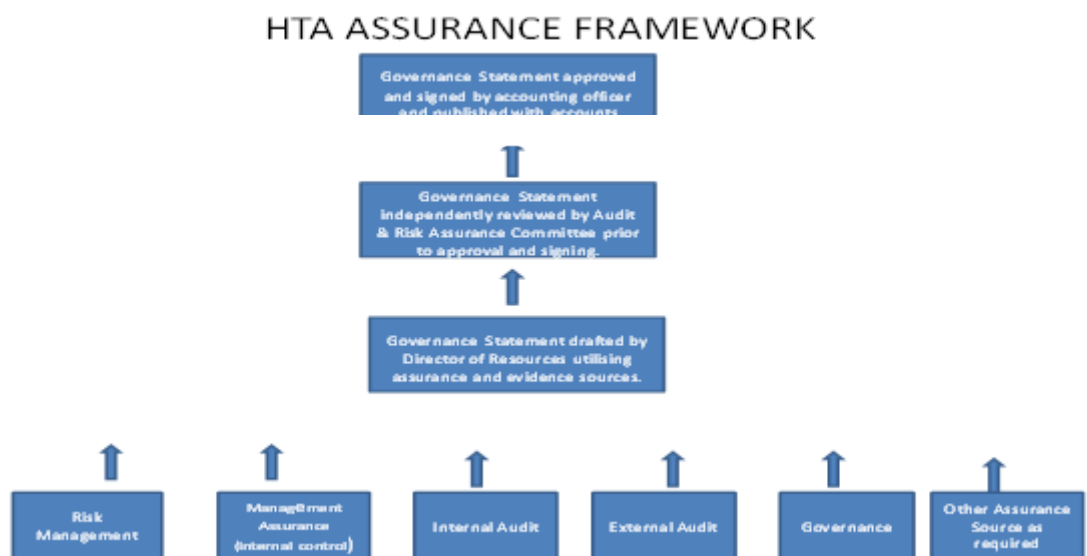
4. In discharging its duties, the Audit & Risk Assurance Committee will:

   a. Review the comprehensiveness of assurances in meeting the Board's / Accounting Officer's assurance needs
   b. Review the reliability and integrity of these assurances

   c. Review the adequacy of the Board and Accounting Officer in discharging their responsibilities (particularly in respect to Financial Reporting).

5. HM Treasury's Audit Committee Handbook provides further guidance on the role of audit committees, the role of the chair of the audit committee and good practice.

https://www.gov.uk/government/publications/audit-committee-handbook

6. In conducting their review the Committee will consider whether the Board and the Accounting Officer are:

   a. promoting the highest standards of propriety in the use of HTA funds and encourage proper accountability for the use of those funds

   b. improving the quality of financial reporting by reviewing internal and external financial statements on behalf of the Board

   c. promoting a climate of financial discipline and control which will help to reduce the opportunity for financial mismanagement

   d. identifying and managing risk and promoting the development of internal controls systems which will help satisfy the Board that the HTA will achieve its objectives and targets

   e. operating in accordance with any statutory requirements for the use of public funds, within delegated authorities laid down within the Human Tissue Authority's Standing Orders and the HTA's own rules on what matters should be referred to the Board and in a manner which will make most economic and effective use of resources available

Version history

7. The Handbook will be reviewed bi-annually by the ARAC and will be approved by the Board following that review.

Latest version	Date	Comments	Reviewed by	Approved by
15.0	24 February 2015	Updated to ensure factual accuracy, update membership information and add version control.	Sue Gallone / Amy Gelsthorpe-Hill	Authority Members
15.1	18 October 2016	Amendment to secretariat and updated forward plan as per May 2016 minutes	Sue Gallone / Morounke Akingbola	??
15.2	2 November	Updated per November 2016 minutes	Morounke Akingbola	ARAC Members 09-11-2017
15.3	18 September 2018	Amend role to Board Secretary	Morounke Akingbola	ARAC Members 23-10-2018
15.4	4 December 2020	Removed ToR; amend Authority to Board. Review period changed to bi-annually (TBA) by ARAC	Morounke Akingbola	ARAC Members 28-01-2021

Section 2

Audit & Risk Assurance Committee yearly work programme

Introduction

8. This programme of work has been developed taking into account the guidance in the HMT's Audit & Risk Assurance Committee handbook. It works on the basis of three meetings per annum with the timing of the second meeting of the year designed to link in with the requirement for the Committee to approve the Authority's accounts.

9. Audit & Risk Assurance Committee work programme

1. Winter meeting	
Regular items • Assurance reports from Internal Audit • Audit recommendations tracker report • Strategic risk register review • Polices/procedures updates • Anti-Fraud Policy (bi-annually) • Whistleblowing Policy • Schedule of policies	**Meeting specific** • Review and approval of the Internal Audit proposed Audit plan for the financial year • Review of the Audit & Risk Assurance Committee's performance including Members' skills and training • Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting)
2. Spring meeting	
Regular items • Assurance reports from Internal Audit • Audit recommendations tracker report • Strategic risk register review • Policies/procedures updates	**Meeting specific** • Receive Internal Audit Annual Report • Approval of the Annual Report and Accounts • SIRO Report • Review of the External Auditors ISA 260 report (management letter) • Consider key messages for the Audit & Risk Assurance Committee's report on its activity and performance (to the Authority)
3. Autumn meeting	
Regular items • Assurance reports from Internal Audit • Audit recommendations tracker report • Strategic risk register review • Policies/procedures updates	**Meeting specific** • Approval of External audit's planning report • Review of the Audit & Risk Assurance Committee's Governance including Handbook and Terms of Reference

Section 3

Role of internal audit

The role of internal audit at the Human Tissue Authority

10. The management of HTA is responsible for establishing and maintaining an appropriate system of internal control and for the prevention and detection of irregularities and fraud.

11. In fulfilling this responsibility, estimates and judgements by management are required to assess the expected benefits and related costs of control procedures.

12. The objectives of systems of internal control are to provide management with reasonable, but not absolute, assurance that the business is conducted in an orderly and efficient manner, that there is adherence to management policies and laws and regulation, that assets are safeguarded against loss or unauthorised use and that transactions are executed in accordance with management's authorisation and are accurately and completely recorded to permit, inter alia, the preparation of financial statements.

13. Internal audit is an element of the internal control framework established by management to examine, evaluate and report on accounting and other controls on operations. Internal audit assists management in the effective discharge of its responsibilities and functions by examining and evaluating controls. The objectives of internal audit include promoting effective control at reasonable cost and assisting management generally in the pursuit of value for money.

14. Internal Audit is an appraisal or monitoring activity established by management and directors to review and report on the adequacy and effectiveness of the system of internal control. This includes both financial and operational control and will encompass Risk Management, Governance, Accounting, Information Technology, Human Resources and Value for Money issues (VFM).

15. Effective internal audit requires the function to be a service to management at all levels, which identifies, evaluates and provides an opinion on the adequacy of the organisation's internal control framework with reference to achieving the organisation's objectives.

16. Internal Audit is a key part of the HTA's internal control system because it measures and evaluates the adequacy and effectiveness of other controls so that:

17. the Authority and senior management can know the extent to which they can rely on the whole system; and
18. individual managers can know how reliable the systems are and controls for which they are responsible, and any remedial action required.

Approach to internal audit

19. Internal Audit takes a risk-based approach to audit to comply fully with the requirements of the Public Sector Internal Audit Standards. This ensures compliance with best professional standards and makes a positive contribution to the Authority's Annual Governance Statement. In some areas, different approaches are required. Therefore, regularity, contract and VFM audit techniques are employed where appropriate.

Statement of assurance

20. In order to provide the required statement of assurance, the Internal audit service will undertake a programme of work, based on risk assessment, authorised by the Authority, to achieve the following objectives:

    a. to review and appraise the soundness, adequacy and application of the whole system of control;
    b. to ascertain the extent to which the whole system of internal control ensures compliance with established policies and procedures;
    c. to ascertain the extent to which the assets and interests entrusted to, or funded by, the Authority are properly controlled and safeguarded from losses of all kinds;
    d. to ascertain that management information is reliable as a basis for the production of financial and other returns;
    e. to ascertain the integrity and reliability of information provided to management including that which is used in decision-making; and
    f. to ascertain that systems of control are laid down and operate to achieve the most economic, efficient and effective use of resources.

21. In providing the annual assurance opinion, it should be noted that assurance can never be absolute. The most that the internal audit service can provide to the Accounting Officer and Audit & Risk Assurance Committee is a reasonable assurance that there are no major weaknesses in risk management, governance and control processes based on work undertaken during the year.

Reporting lines

22. Internal Audit is under the independent control and direction of the Audit & Risk Assurance Committee on behalf of the Authority. It is the responsibility of the Audit & Risk Assurance Committee to oversee the appointment and cost of internal audit provision, which is managed centrally by the DHSC.

23. The Audit & Risk Assurance Committee each year approves a rolling programme of audit work, which will be prioritised in line with an assessment of the Authority's key risks. The Director of Resources monitors progress against this programme in liaison with the Internal Auditors and they report regularly to the Audit & Risk Assurance Committee on this.

24. In respect of each internal audit assignment, the Internal Auditors present their findings to the Director of Resources who will, with the appropriate Director and/or Head of Service, co-ordinate a response. The Internal auditors then present their report and recommendations, together with management's response, to the next available meeting of the Audit & Risk Assurance Committee.

25. Management responses to internal audit findings identify responsibility for implementing recommendations and the line Director ensures that this is done within the agreed timescale. The Director of Resources reports to each meeting of the Audit & Risk Assurance Committee on progress with implementing recommendations.

26. Internal Audit submits an annual report to the Audit & Risk Assurance Committee that includes an overall assessment of Risk Management, Corporate Governance and the Control Environment for the year in question and a comparison of actual and planned activity for the period.

Rights of internal auditors

27. Internal Auditors have authority to:

    a. Enter (or require entry) into HTA premises at any time
    b. Access all records, documents and correspondence (including those held on computers) which may relate to financial or operational matters of the Board
    c. Require and receive from staff or Authority members such explanations as are necessary concerning any matter under review
    d. Require any staff or member to produce upon request any cash, stores, documents or other Authority property under his/her control

28. Staff and Board members will co-operate openly and honestly with reviews conducted by Internal Audit.

Section 4

Role of external audit

Introduction

29. The External Auditor for the HTA is a statutory appointment. The Comptroller and Auditor General (C&AG) is the auditor for the Human Tissue Authority under Section 16 of Schedule 2 of the Human Tissue Act 2004.

30. The C&AG is an officer of the House of Commons appointed by the Queen to report to Parliament on the spending of central government money. The C&AG is therefore independent of Government.

31. The C&AG is granted comprehensive audit and inspection rights and has appointed the staff of the National Audit Office (NAO) to act on his behalf.

32. The NAO conducts financial audits of all government departments and agencies and many other public bodies, and reports to Parliament on the value for money achieved by these bodies. Its relations with Parliament are central to our work, and we work closely with other public audit bodies that have a role in other areas of public expenditure. The NAO has three main work streams – Financial Audit, VFM audits and Investigations.

Financial audit

33. The NAO is responsible for auditing the accounts of all Government departments and agencies, and most 'arm's length' public bodies including HTA known as Non-Departmental Public Bodies. The NAO is also responsible for auditing all National Loans Fund accounts and has several International clients.

34. The C&AG is required to *form an opinion* on the accounts, as to whether they are free from material misstatement. The C&AG is also required to confirm that the transactions in the accounts have appropriate Parliamentary authority. If the NAO identifies material misstatements, the C&AG will issue a qualified audit opinion. Where there are no material misstatements or irregularities in the accounts, the C&AG may nonetheless prepare a report to Parliament on other significant matters. Such reports may be considered by the Committee of Public Accounts.

NAO timetable

35. Each year, the NAO is committed to presenting the following to the HTA:

36. Audit Planning Report (for the November Audit & Risk Assurance Committee) – This document outlines the risks identified during audit planning and the audit approach taken to address those risks

37. ISA 260 report (Management Letter), for June Audit & Risk Assurance Committee - This letter contains: unexpected modifications to the C&AG's certificate and report; unadjusted misstatements (other than those deemed to be trivial); material adjusted misstatements; material weaknesses in accounting and internal control systems identified; and NAO's views about the qualitative aspects of the Authority's accounting practices and financial reporting.

Section 5

Relationship of the Audit & Risk Assurance Committee with the HTA Executive

38. The Chief Executive of the HTA is the Accounting Officer and is responsible for ensuring that the HTA operates:

    a. sufficient and robust internal controls
    b. comprehensive financial reporting systems
    c. adequate systems for the identification and mitigation of risk
    d. adequate governance arrangements

39. The Accounting Officer will discharge these duties through the Director of Resources who will ensure that an adequate framework is in place so that suitable assurance and reliance can be derived. This is obtained through key documents submitted to the Committee such as financial / governance papers (e.g. accounts, policies), risk strategies / policies (e.g. risk register) and audit strategies / papers (e.g. audit plans, findings, reports), illustrated in the diagram in section 1.

40. The Accounting Officer will undertake the following activities:

Internal audit

41. Make recommendations to the Audit & Risk Assurance Committee to appoint the HTA's internal auditors.

42. Review their audit plan and agree with internal audit the plan to be presented for consideration by the Audit & Risk Assurance Committee.

43. Review the content / scope of each audit that makes up the yearly audit programme and includes an overall assessment of Risk Management, Corporate Governance and the Control Environment for the year in question and a comparison of actual and planned activity for the period. The annual audit programme will cover three areas: financial, governance and operational. These will be risk-based in nature.

44. Review and agree the audit findings prior to submission to the Audit & Risk Assurance Committee. If audit findings are not agreed with the Accounting Officer, internal audit have a right to report independently to the Committee.

45. Agree a response to audit findings with time frames for any actions necessary.

46. Present regular reports (audit tracker) to the Audit & Risk Assurance Committee.

Note. The Audit & Risk Assurance Committee can commission its own investigations / value for money studies.

External audit

47. Review external audit planning report and agree with the external auditors the plan to be presented for consideration by the Audit & Risk Assurance Committee.

48. Review the content / scope of each audit that makes up the yearly audit programme. These will be risk-based and may include national initiatives.

49. Review and agree the audit findings prior to submission to the Audit & Risk Assurance Committee. If audit findings are not agreed with the Accounting Officer, external audit has a right to report independently to the Committee.

50. Agree a response to audit findings with time frames for any actions necessary.

51. Present regular reports (audit tracker) to the Audit & Risk Assurance Committee.

Note. The Audit & Risk Assurance Committee can commission its own investigations / value for money studies.

Risk register

52. Produce risk strategy for review by Audit & Risk Assurance Committee.

53. Produce strategic risk register for review of Audit & Risk Assurance Committee.

Governance

54. Ensure financial / governance policies / systems are presented to the Audit & Risk Assurance Committee for approval.

Audit and Risk Assurance (ARAC) meeting

Date: 27 January 2022

Paper reference: AUD 12/22

Agenda item: 11

Author: Richard Sydee

OFFICIAL

ARAC Terms of Reference

Purpose of paper

1. To inform the Committee that its Terms of Reference are due for a review and will be brought to the Board for approval in February 2022.

Decision making to date

2. The terms of Reference have been reviewed by HTA staff who are proposing a few amendments to align them with other governance documents.

Action required

3. To note the proposed amendments.

Background

4. The ARAC's Terms of Reference were due for review in late 2021. The HTA staff has reviewed the terms of reference and will be proposing the following amendments to the Board:

   - Replace "the Authority" with "the Board" to align the Terms of Reference with HTA's Standing Orders.
   - Replace "the Board Secretary" with "the Executive Assistant" to reflect the staff changes at HTA.

5. The Terms of Reference are included for the Committee review and agreement to the amendments.

Terms of reference

Audit and Risk Assurance Committee (ARAC)

Reference number	HTA-TOR-001	**Version**	15.4
Owner	Resources Directorate	**Date approved**	*Insert date when approved 2022*
Author(s)	Head of Finance and Governance	**Next review date**	month 2023
Reviewed by	Head of Finance and Governance / Executive Assistant	**Distribution**	Internal and external
Approved by	HTA Authority		

Constitution

1. The Authority has established an Audit and Risk Assurance Committee (known to Human Tissue Authority (HTA) staff as ARAC) to support it in its responsibilities for risk management and governance. The ARAC will achieve this by advising the Board and the Accounting Officer on the exercise of their responsibilities, ensuring the comprehensiveness of assurances that these responsibilities are being met and reviewing the reliability and integrity of these assurances.

2. The ARAC will make recommendations to the Board regarding the adoption of the Annual Report and Accounts.

Duties and functions

3. The ARAC will advise the Accounting Officer and Board on:

    a. the strategic processes for risk, control and governance and the Annual Governance Statement;

    b. the accounting policies, the accounts, and the annual reports of the HTA. This includes the process for review of the accounts prior to

submission for audit, levels of error identified, and management's letter of representation to External Audit;

c. the planned activity and results of both Internal and External Audit;

d. adequacy of management response to issues identified by audit activity, including External Audit's audit completion report;

e. assurance relating to corporate governance requirements for the HTA;

f. ensure that the remuneration report for staff and Members in the annual report and accounts reflects the strategy (permanently delegated to ARAC by the Remuneration Committee);

g. (where appropriate) proposals for tendering for either Internal or External Audit services or for purchase of non–audit services from contractors who provide audit services; and

h. where necessary, anti–fraud policies, whistle–blowing processes, organisational culture and arrangements for special investigations.

Rights

4. The ARAC has the following rights:

a. it may co-opt additional participants, for a period not exceeding a year, to provide specialist skills, knowledge and experience (these additional participants must be recruited in line with paragraph 15 of this document);

b. it may procure independent specialist ad–hoc advice, at the expense of the HTA, subject to budgets agreed by the Board; and

c. it may seek any information it requires from HTA staff, who are expected to assist the Committee in the conduct of any enquiries.

Access

5. Internal and External Audit will have free and confidential access to the Chair of the ARAC. In addition, a confidential session with Internal and External Auditors for ARAC members will be scheduled each year.

Information requirements

6. As appropriate to the meeting the ARAC will be provided with:

a. a report summarising any significant changes to the organisation's Risk Register;

b. a progress report from Internal Audit summarising: work performed (and a comparison with work planned); key issues emerging from Internal Audit work;

c. management response to audit recommendations;

d. changes to the Internal Audit Plan;

e. details of any resourcing issues affecting the delivery of Internal Audit objectives. Requests for work and reports received will be channelled through the Accounting Officer, to whom Internal Audit reports;

f. a progress report from the External Audit representative summarising work done and emerging findings; and

g. progress reports from the Executive, including periodic in-depth reports on areas of potential uncontrolled risk as identified by the ARAC.

7. As and when appropriate the ARAC will also be provided with:

a. the Internal Audit Plan;

b. Internal Audit's annual opinion and report;

c. External Audit's annual report and opinion

d. the draft accounts of the organisation;

e. the draft Annual Governance Statement;

f. a report on any changes to accounting policies;

g. a report on any proposals to tender for audit functions;

h. a report on co–operation between Internal and External Audit; and

i. a report on any fraud or financial misdemeanour and any

whistleblowing.

Reporting to the Authority

8. The Board will receive the minutes of meetings of the ARAC for information. The circulation of any confidential minutes will be at the discretion of the Committee Chair.

9.   The ARAC will formally report back (either verbally or in writing) to the Board after each of its meetings.

10. The ARAC will provide the Board with an Annual Report, timed to support the finalisation of the accounts and the Annual Governance Statement. The report will summarise the conclusions from the work it has undertaken during the year.

Reviewing effectiveness

11. The ARAC will use the National Audit Office's self-assessment checklist for Audit Committees in order to undertake annual reviews of its own effectiveness and agree actions for improvement. The ARAC will report the results of the review to the Authority.

Recruitment and membership

12. The ARAC will be chaired by a lay Board Member, who is not the Authority Chair, and who preferably has relevant experience and expertise.

13. All other members of the Committee should be Board Members, but not the Board Chair. Including the ARAC Chair, there will be a minimum of three Board Members and a maximum of five Board Members on the Committee at any time.

14. At least one Board Member, who is not the ARAC Chair, must be a member of both the ARAC and the Remuneration Committee, to provide assurance over remuneration matters.

15. Recruitment of Board Members to the ARAC will be through 'expressions of interest' with personal statements in application. The applications will be reviewed by the Board Chair and the Chief Executive, who will decide on the appointments. Should an insufficient number of expressions of interest be received to fill an available role, the Board Chair will appoint the Member who has the most appropriate skills and experience to the role.

16. The ARAC Chair and the other ARAC members will be appointed for a set term of three years, which will not exceed their tenure as Board Members. It should be noted that Board Members may be reappointed to the ARAC in accordance with the HTA's business needs.

17. Members of the ARAC must disclose the existence and nature of any personal or material interest before the discussion of that interest at any meeting. They must be free of any relationship that may compromise their independence or interfere with the exercise of their judgement.

Attendance

18. A minimum of two members of the ARAC (excluding the ARAC Chair) will be present for the meeting to be deemed quorate.

19. Committee members will be expected to attend every meeting. If a member is not able to attend a meeting they must provide apologies to the Secretary in advance of the meeting if possible. If a member does not attend more than two consecutive meetings the Committee Chair will arrange a meeting with the member to discuss their attendance and whether they wish to continue their membership of the Committee.

20. Board Members who are not members of the ARAC have the right of attendance at Committee meetings. Authority Members attending meetings shall be entitled to speak with the permission of the Chair of the meeting, but in no case shall they be entitled to vote.

21. If the ARAC Chair is not present at a meeting, an alternative Board member will be co-opted to chair that meeting.

22. The Chair of the Board may attend Committee meetings, say once per year and not so frequently as to compromise the independence of the Committee. A Board Member who is not a member of the ARAC may be co-opted as a member of the ARAC for a specific meeting if necessary to ensure a meeting is quorate.

23. The Chief Executive in his or her role as Accounting Officer (as defined in the Framework Agreement), the Director of Resources, and any other officer (at the discretion of the Chair) and Internal and External Audit (or equivalents) will also attend meetings of the Committee.

24. Up to two observers from the Department of Health and Social Care will normally be invited to attend meetings of the Committee.

25. The ARAC may ask any other officials of the Board to attend to assist it with its discussions on any particular matter.

26. The ARAC may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters by the Committee.

Frequency of meetings

27. The ARAC will meet three times per calendar year, with meetings timed to ensure effective and timely conduct of business and reporting to the Board.

28. The Chair of the ARAC may convene additional meetings as they deem necessary.

29. External Audit may request a meeting of the Committee if they consider one necessary.

30. The Accounting Officer or the Board may ask the ARAC to convene further meetings to discuss particular issues on which the Committee's advice is sought.

Secretariat responsibilities

31. The Executive Assistant will have secretariat responsibility for the Committee.

32. The Secretary must ensure Committee meeting dates are scheduled, meeting venues are booked and that Committee members are invited to attend all meetings.

33. The Secretary will liaise with the Committee Chair to create the agenda and will be responsible for collating and distributing the papers relating to the meeting. The agenda, minutes from the last meeting and the meeting papers for consideration will be distributed to the Committee one week before each meeting.

34. The Secretary will be responsible for taking minutes of meetings and recording action points. The draft minutes and action points from each meeting will be circulated as soon as possible, within one month of the meeting. Committee members will be asked to provide any comments on accuracy of the minutes by email within a time frame set by the ARAC Chair. This will ensure the key areas of discussion and action points are captured accurately.

35. The minutes will be approved by the ARAC Chair prior to being published on the HTA website. The Secretary will be responsible for ensuring that minutes are published on the website no later than two months after each meeting.

36. The Secretary will write a short summary of the issues discussed at each meeting for publication in the next staff newsletter and e-newsletter. This note will be drafted within one week of each meeting and approved by the Committee's Chair prior to being sent to the Head of Communications for publication.

Version history

37. These Terms of Reference will be reviewed annually by the ARAC and will be approved by the Board following that review.

Latest version	Date	Comments	Reviewed by	Approved by
15.0	24 February 2015	Updated to ensure factual accuracy, update membership information and add version control.	Sue Gallone / Amy Gelsthorpe-Hill	Authority Members
15.1	18 October 2016	Amendment to secretariat and updated forward plan as per May 2016 minutes	Sue Gallone / Morounke Akingbola	
15.2	2 November 2016	Updated per November 2016 minutes	Morounke Akingbola	ARAC Members 09-11-2017
15.3	18 September 2018 (reviewed again 13 July 2020)	Amend role to Board Secretary	Morounke Akingbola	Board Members
15.4	January 2022	Updated to align with other governance documents	Morounke Akingbola	Board Members

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![HTA Human Tissue Authority logo]

Audit and Risk Assurance (ARAC) meeting

Date: 27 January 2022

Paper reference: 13/22

Agenda item: 12

Author: Morounke Akingbola
                     Head of Governance and Finance

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Gifts and Hospitality Register

Purpose of paper

1. To present the Gifts and Hospitality Register for the Committee to note.

Decision making to date

2. None.

Action required

3. The Committee are requested to note the two items on the attached register since it was tabled at the October 2021 meeting.

Register of Gifts / Hospitality Received and Provided

	Version:	HTAG0001
	Jan-22	

DIVISION / DEPARTMENT: HTA
FINANCIAL YEAR(s): 2017/18 - onwards

		Details of the Gift or Hospitality					Provider Details			Recipient Details	
Type	Brief Description of Item	Reason for Gift or Hospitality	Date(s) of provision	Value of Item(s)	Location where Provided	Action on Gifts Received	Name of Person or Body	Contact Name	Relationship to Department	Name of Person(s) or Body	Contact Name
Receipt	Lunch	Lunch provided on inspection	19/10/2021	Unknown	On site	Declined	London Bridge Hospital [L/N 11069}		Licenced establishment	H Tang/A Shackell	N/a
Receipt	Lunch	Lunch provided on inspection	07/12/2021	Unknown	On site	Accepted	CRF GMP Unit [l/n 22643]		Licenced establishment	H Tang	N/a

Audit and Risk Assurance (ARAC) meeting

Date: 27 January 2022

Paper reference: 14/22

Agenda item: 15

Author: Richard Sydee. Director of Resources

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Any Other Business

Purpose of paper

1. To provide the Committee with a brief overview of items under any other business

Decision making to date

2. None

Action required

3. ARAC Members are asked to note the papers enclosed in this section

Update

HTA Response to Public Accounts Committee request – Contingent Liabilities.

4. On 25 November 2021, the Permanent Secretary of the Department of Health and Social Care wrote to all ALB Accounting Officers requesting review and assurance relating to any contingent liabilities listed in the Departments register of Contingent Liabilities.

5. The HTA has one listed Contingent Liability, relating to the Department underwriting any losses due to professional negligence on the part of the HTA, it's

employees and other parties working on it's behalf. Although not strictly a contingent liability from an HTA accounting perspective this risk remains, and as such the HTA responded confirming that this was still extant.

6. The HTAs response is attached for reference and the Committee are asked to note the response.

Assessment of the Impact of IFRS16 - Leases

7. HM Treasury took the decision to defer the implementation of IFRS 16 across Government, delaying the start scheduled for this financial year until April 2022. The attached paper refreshes the position presented to ARAC previously on the impact of this new accounting standard on the HTA.

8. The Committee are asked to note the approach adopted by the HTA and the expected impact on our financial statements from the next financial year.

Accounting Officer Handover Letter

9. The attached letter represents a formal handover of accounting officer responsibilities from myself to Dr Colin Sullivan on 1 January 2022. This letter provides assurance to the incoming accounting officer that there are no known issues of regularity and propriety regarding the HTA's finances at the point of handover.   Also attached for information are the Accounting Officer appointment letter sent to The new HTA Chief Executive, and his response.

10. This will support the new Accounting Officers to sign off the 2021/22 Governance Statement in the HTA's Annual report and accounts later this year.

Contingent Liabilities

<u>Instructions</u>

Please complete the columns in the table in next tab as described below for existing contingent liabilities and, as far as possible, for any planned contingent liabilities.
Please also include full details of any contingent liabilities incurred in relation to the Covid-19 pandemic which have now expired.

1. **Contingent Liability –** provide the name of the contingent liability
2. **Details –** provide details of the nature of the contingent liability
3. **Start date –** provide the date the Department first incurred the contingent liability
4. **End date -** if the contingent liability is not indefinite, provide its end date
5. **Extensions –** if the contingent liability has an end date, please indicate whether it is likely that we will need to extend the term of the contingent liability and when this will happen
6. **HMT approvals –** please provide details of HMT approvals for this contingent liability and confirm the correct process was followed
7. **Parliamentary notifications –** please provide details and copies of parliamentary notification completed, including letters to the PAC & relevant departmental select committee; Written Ministerial Statement; and departmental Minute.
8. **Explanation and further actions required –** if the HMT approvals and parliamentary notifications processes were not correctly adhered to, please provide an explanation and details of any further actions required.
9. **Quantification (£) -** if unquantified, why is it not quantifiable?
10. **Confidentiality -** if confidential at the time that the contingent liability was incurred, please provide details and confirmation as to whether the details of this liability can now be disclosed publicaly and appear in a published document?

For further information on the approval and parliamentary notification of contingent liabilities, please consult:
Contingent Liability Approval Framework
Annex 5.4 of Managing Public Money

Contingent Liability	Details	Start date	End date	Extensions	HMT approvals	Parliamentary notifications	Explanation and further actions required (if applicable)	Quantification	Confidentiality
Professional idemnity	The Department, with Treasury approval, is bearing an insurable risk for professional indemnity, malpractice, etc on behalf of the Human Tissue Authority.	Jan-12	N/A	N/A	N/A	N/A	This is an financial indemnity in the event of a liability relating to negligence, malpractice or similar scenario by the HTA . There are no current actions or liabilities in relation to this area.	N/A	N/A

Human Tissue Authority
2 Redman Place
London, E20 1JQ

Tel: 020 7269 1900
Email: enquiries@hta.gov.uk
Web: www.hta.gov.uk

Date   25 November 2021

Sir Chris Wormald
Permanent Secretary
Department of Health and Social Care
39 Victoria Street
London
SW1H 0EU

Dear Sir Chris,

Review of Public Accounts Committee (PAC) business: accountability and governance

Thank you for your letter of 24 November 2021. In response I can confirm that the HTA executive have discussed the matter of contingent liabilities and can confirm:

- That the extant contingent liability contained in Annex B that relates to the HTA, *"The Department, with Treasury approval, is bearing an insurable risk for professional indemnity, malpractice, etc on behalf of the Human Tissue Authority.",* is ongoing, although there are no current actions in relation to this.

- That there are no new contingent liabilities identified for the HTA.

I enclose Annex A with updated information regarding the historic contingent liability relating to the HTA, please do contact me if further information or clarity is required.

Yours,

Richard Sydee
Director of Resources & Acting Accounting Officer for the HTA

Audit and Risk Assurance (ARAC) meeting

Date: 27 January 2022

Paper reference: 14b/22

Agenda item: 15

Author: Head of Finance and Governance

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Implementation of IFRS 16: Leases, impact on the Statement of Financial Position

Purpose of paper

1. To present to the Committee an update to the previous paper tabled in January 2020 on the impact of a change in accounting treatment of Leases

Decision making to date

2. None

Action required

3. The Committee are requested to note the update.

Background

4. IFRS 16 is applicable to most public sector organisations and for the HTA, and other ALBs, is effective from 1 April 2022. This new standard amends the accounting for leases, removing the distinction between recognising an operating lease (off balance sheet) and a finance lease (on balance sheet).

5. This new standard requires recognition of most leases, which last more than 12 months, to be recognised on the balance sheet.

6. There are exceptions where a lease need not be recognised and these are:

   a. Where the lease is of low value £5,000 has been used as a guide(i.e. tablet, personal computers, telephones, photo copiers)
   b. Where the lease term ends within 12 months of initial application of the standard (short term leases i.e. software licences, some property leases).

Definition of a lease

7. The standard defines a lease as a contract that 'conveys the right to control the use of an identified asset for a period of time in exchange for consideration'.

Assessment of current contracts at the HTA

8. An analysis was undertaken of existing contracts entered into by the HTA. The contracts can be categorised into three areas:

   - Software as a service (SaaS) – licensing and delivery model in which software is licenced on a subscription basis.
   - Licence agreements renewable annually
   - Contracts for service – such as Internal Audit
   - Contracts for support/maintenance

9. There were 20 contracts in total, of which one met the definition of a lease as per the standard. The remaining contracts were also of a low value and expired within 12 months, and therefore would not be included on the Statement of Financial Position (Balance Sheet).

Type	No.	Total value at 31/12/21	Lease agreement	Out of scope
Rental	1	£117k	Yes	N/a
Software/SaaS	4	£70k	No	Yes
Support	7	£55k	No	N/a
Service	3	£52k	No	N/a

10. The contract relating to the HTA's occupation of the second floor at 2 Redman Place meets the definition of a lease under IAS 17 guidance and is currently being treated as an operating lease therefore expensing the rent costs.

11. The new lease was signed by the DHSC on the 27 January 2021. For the accounting year ending 31 March 2022, the HTA will be required to disclose the

expected impact of introducing IFRS 16 from April 2022 onwards within its accounting policies.

12. From 1 April 2022, the HTA's Statement of Financial Position (Balance Sheet) will be impacted by the numbers below:

Lease term   -10 years
Annual Rent   - £107k (this figure is from the latest MOTO with DHSC, which also states that there is an 18 month rent-free period. This reduction is amortised over the 10 year lease period. *The reduction has not been factored into the below calculations.*
Discount rate -is per HM Treasury's PES paper and the DHSC Group Accounting Manual (GAM) which is 0.95%.

13. Impact on the balance sheet would be:

- Increase in non-current assets £1,016k - Present value of lease payments over 10 years (Right of Use Asset).
- Increase in long term liabilities £1,016k (Lease Liability)

14. Impact on the I&E (Profit and Loss account)
- Annual Depreciation charge £101.6k
- Annual Interest charge £9.7k.

15. In effect the above transactions eliminates the rental charge of £107k from the I&E account with the net impact being an increase in costs of c£4k in the first year.

16. For the 2021/22 business year, reporting bodies are only required to disclose how the standard would have impacted on the accounts were it applied in that year.

17. Committee members are requested to note the position.

HTA
Human Tissue Authority

Dr Colin Sullivan
CEO - Human Tissue Authority
2 Redman Place
London,
E20 1JQ

Human Tissue Authority
2 Redman Place
London, E20 1JQ

Tel: 020 7269 1900
Email: enquiries@hta.gov.uk
Web: www.hta.gov.uk

Date   12 January 2022

Dear Colin,

ACCOUNTING OFFICER LETTER OF ASSURANCE for the period from 22 October 2021 to 31 December 2021

As Interim Accounting Officer for the Human Tissue Authority, I write this letter to provide you with assurances as part of the handover of my responsibilities for safeguarding the public funds for which I have charge; for ensuring propriety, regularity, value for money and feasibility in the handling of those public funds; and for the day-to-day operations and management of the HTA.

I have also been responsible for ensuring that the HTA as a whole is run on the basis of the standards, in terms of governance, decision-making and financial management that are set out in Box 3.1 to Managing Public Money (Appendix A). Further details regarding my responsibilities are set out in the HTA Organisation Framework Documents.

I received a verbal handover and assurance from Allan Marriot-Smith, the outgoing Chief Executive and Accounting Officer, providing me with assurance relating to the position of the HTA from the beginning of this financial year to 21 October 2021. As such this letter should be read as providing assurance to you for the entire period 1 April 2021 to 31 December 2021

I confirm that for the period from 22 October 2021 to 31 December 2021:

- neither I nor any HTA staff authorised a course of action, the financial impact of which is that transactions infringe the requirements of regularity as set out in Managing Public Money;

- having considered and enquired as to HTA's compliance with the law and regulations, I am not aware of any actual or potential non-compliance that could have a material effect on the ability of the Human Tissue Authority to conduct its business;

- all accounting records are available to the 31st December 2021 and all transactions undertaken by the HTA have been properly reflected and recorded in the accounting records. All other records and related information, including minutes of all management meetings are also available to the 31st December 2021 and

- all staff are aware of their responsibility to provide any information required to undertake your responsibilities.

Key control information

The Treasury Officer of Accounts publication, *Regularity, Propriety and Value for Money* Chapter 12: Proper Conduct of Public Business, provides a checklist of the financial controls, including issues of regularity, propriety and value for money. I can confirm that the necessary financial controls have been in place for the period from 1 April 2021 to 31 December 2021.

Internal Control

As Accounting Officer, I confirm that I have diligently delivered my responsibility for the design and implementation of internal controls to prevent and detect error. I confirm that I have reviewed the effectiveness of the system of internal control and confirm that I am not aware of any material risk to disclose.

Fraud

I am not aware of any fraud or suspected fraud affecting HTA and no allegations of fraud or suspected fraud affecting HTA financial records have been communicated to me by employees, former employees, analysts, regulators or others.

Assets

All assets have been accurately recorded in the asset register, and are free from any lien, encumbrance or charge.

Liabilities

All liabilities have been accurately recorded in HTA financial systems. There were no significant losses in the period from 1 April 2021 to 31 December 2021.

Contingent liabilities

I am not aware of any pending litigation, which may result in significant loss to HTA, and I am not aware of any action that is or may be brought against HTA under the Insolvency Act 1986.

Other disclosures

I confirm that I am not aware of any transactions of a sort not usually undertaken by HTA, or circumstances of an exceptional or non-recurring nature.

Management of Personal data

There have been no personal data related incidents reported in the period from 22 October 2021 to 31 December 2021.

Accounting Officer responsibilities

With the transfer of Accounting Officer responsibilities, this letter should provide you with assurance for the period from 1 April 2021 to 31 December 2021. This will enable you to take up your duties as Accounting Officer for the HTA.

Signed,

Richard Sydee
Director of Resources, HTA

From the Permanent Secretary
Sir Chris Wormald

**Department
of Health &
Social Care**

Colin Sullivan
Chief Executive
Human Tissue Authority
2 Redman Place,
London,
E20 1JQ
Sent via email to: Colin.Sullivan@hta.gov.uk

39 Victoria Street
London
SW1H 0EU
permanent.secretary@dhsc.gov.uk

December 2021

Dear Colin

Accounting Officer for the Human Tissue Authority

Your role as Chief Executive carries with it the responsibility of Accounting Officer for the Human Tissue Authority (HTA). This letter confirms your appointment as Accounting Officer, with effect from 01 January 2022.

As Principal Accounting Officer, I am accountable for the Department of Health and Social Care Account. This includes monies paid from that resource for the HTA and I must satisfy myself that the resources authorised by Parliament are used for the purposes intended by Parliament. You will be personally responsible and accountable to Parliament for the use of public money and stewardship of public assets.

You will be required to input towards a governance statement as part of the HTA's annual report and accounts. The statement should give assurances about performance and insight on the HTA's risk profile, the responses to the identified and emerging risks and how any risks have been successfully managed.

As an accounting officer, you must be able to assure Parliament and the public of high standards of probity in the management of public funds and assets. This will include the HTA's governance statement; your organisation's governance, decision-making and financial management assurances when considering, promoting and safeguarding regularity, propriety, affordability, feasibility, sustainability, risk, and value for money across the whole of the public sector and not just your organisation; and accounting accurately and transparently for your organisation's financial position and transactions. It is important that you appreciate that if you do not meet the standards required of accounting officers, your accounting officer designation can be withdrawn.

From the Permanent Secretary
Sir Chris Wormald

**Department
of Health &
Social Care**

You will wish to note the matters set out in Chapter 3 in Managing Public Money on Arm's Length Bodies. In the event you were to be overruled by your Board on a matter of propriety, regularity value for money, or feasibility, you should inform me of any issues in the first instance. However, in the event of a written direction from the Board, you will need to inform the Comptroller and Auditor General.

Managing Public Money sets out the principles and high standards expected for handling public resources and Chapter 3 focuses on the main responsibilities of an accounting officer.

Your accountability will be subject to my overall responsibilities for the Department of Health and Social Care. As part of these responsibilities, the Committee of Public Accounts may invite you to attend as a witness at its evidence sessions. Appearing as a witness before the Committee is not optional. It is only with specific agreement of the Chair of the Committee that an accounting officer may defer their attendance or send a substitute.

You should also look at the guidance on the accountability framework for public spending
available on gov.uk. It contains links to the following Treasury issued handbooks:

- The accounting officer's survival guide which draws out the main accounting officer's responsibilities;
- Guidance on accounting officer assessments which are recommended for assessing significant or complicated policy initiatives; and
- Parliamentary scrutiny of public spending which provides practical guidance on engagement with the National Audit office and the Committee of Public Accounts.

The Civil Service Leadership Academy provides a full training package for newly appointed accounting officers, namely, the Accounting Officer's Responsibilities Roundtable which is held in the Treasury (or virtually if appropriate), and covers the concepts of regularity, propriety, value for money and feasibility as they affect public service delivery. I recommend that you contact the Leadership Academy to arrange this training: csleadershipacademy@cabinetoffice.gov.uk

The Treasury Officer of Accounts team can offer further advice in your accounting officer capacity. You may also wish to arrange a discussion with staff at the National Audit Office.

Finally, may I take this opportunity to wish you well in your new appointment as an accounting officer.

From the Permanent Secretary
Sir Chris Wormald

**Department
of Health &
Social Care**

I am copying this letter to the Comptroller and Auditor General, the Clerk of the Committee of Public Accounts, the Treasury Officer of Accounts and the Civil Service Leadership Academy.

Yours sincerely,

**SIR CHRIS WORMALD
PERMANENT SECRETARY**

AUD 14c/22

Human Tissue Authority
2 Redman Place
London, E20 1JQ

Tel: 020 7269 1900
Email: enquiries@hta.gov.uk
Web: www.hta.gov.uk

Date   14 January 2022

Sir Chris Wormald
Permanent Secretary
Department of Health and Social Care
39 Victoria Street
London
SW1H 0EU

Dear Chris

Re: HTA Accounting Officer role

Thank you for your letter of 7 December 2021 and your best wishes.

I write both to acknowledge receipt of the letter and to highlight my recognition of the importance of the Accounting Officer role, which I will wish to discharge to the high standards expected and required of senior officials in public service.

Thank you for outlining in your letter the support available as I assume the AO role at the Human Tissue Authority. To-date, I have enlisted with the Accounting Officers Responsibilities Roundtable and completed relevant pre-employment training with Civil Service College.

I have also sought and received the attached assurance letter from my predecessor which I draw to your attention as the Principal Accounting Officer for the DHSC Account.

Yours sincerely

Dr Colin Sullivan
Chief Executive

cc William Vineall, Director - NHS Quality, Safety, Investigations, DHSC

Appendix A – Managing Public Money

Box 3.1: standards expected of the accounting officer's organisation

Acting within the authority of the minister(s) to whom they are responsible, the accounting officer should ensure that the organisation, and any ALBs it sponsors, operates effectively and to a high standard of probity. The organisation should:

governance

- have a governance structure which transmits, delegates, implements and enforces decisions
- Have trustworthy internal controls to safeguard, channel and record resources as intended
- Work cooperatively with partners in the public interest
- Operate with propriety and regularity in all its transactions
- Treat its customers and business counterparties fairly, honestly and with integrity
- Offer appropriate redress for failure to meet agreed customer standards
- Give timely, transparent and realistic accounts of its business and decisions, underpinning public confidence;

Decision-making

- Support its ministers with clear, well reasoned, timely and impartial advice
- Make all its decisions in line with the strategy, aims and objectives of the organisation set by ministers and/or in legislation
- Take a balanced view of the organisation's approach to managing opportunity and risk
- Impose no more than proportionate and defensible burdens on business;

Financial management

- Use its resources efficiently, economically and effectively, avoiding waste and extravagance
- Plan to use its resources on an affordable and sustainable path, within agreed limits
- Carry out procurement and project appraisal objectively and fairly, using cost benefit analysis and generally seeking good value for the Exchequer as a whole
- Use management information systems to gain assurance about value for money and the quality of delivery and so make timely adjustments
- Avoid over defining detail and imposing undue compliance costs, either internally or on its customers and stakeholders
- Have practical documented arrangements for controlling or working in partnership with other organisations, as appropriate
- Use internal and external audit to improve its internal controls and performance.

HTA Governance & Assurance framework map

Purpose

1.   HM Treasury defines an Assurance Framework as:

     '… a structured means of identifying and mapping the main sources of assurance in an organisation, and co-ordinating them to best effect.'
     - Assurance Frameworks, HM Treasury December 2012

2.   In line with this definition the purpose of HTA's Assurance Framework is to:

     • Provide a clear shared corporate understanding of what assurance means for HTA;

     • Identify the areas the business is seeking assurance on;

     • Identify the sources of assurance that meet the requirement;

     • Set out the process whereby assurance is provided and the key principles, accountabilities and responsibilities to ensure this is effective; and

     • Provide sufficient, continuous and reliable assurance on corporate stewardship and the management of the major risks to successful delivery of strategic aims and objectives and achieving value for money.

3.   HTA's Assurance Framework is part of the organisation's governance documentation.

What is meant by Assurance?

4.   The Institute of Internal Auditors define assurance as:

     '… an objective examination of evidence for the purpose of providing an independent assessment on governance, risk management, and control processes for the organisation.'
     - Institute of Internal Auditors Practice Advisory 2050-2

5.   For HTA assurance is required in respect of assessing the planned delivery of our strategic aims and objectives, the effectiveness of control frameworks associated with key business processes, and the operation of governance and risk management arrangements.

Assurance Principles

6.   The following principles are applied to the delivery of assurance activity within HTA:

- Assurance will be risk based;

- Assurance will reflect accountabilities set out in HTA's scheme of delegation;

- HTA's assurance arrangements will reflect accepted good practice (e.g. built around the 'three lines of defence' assurance model).
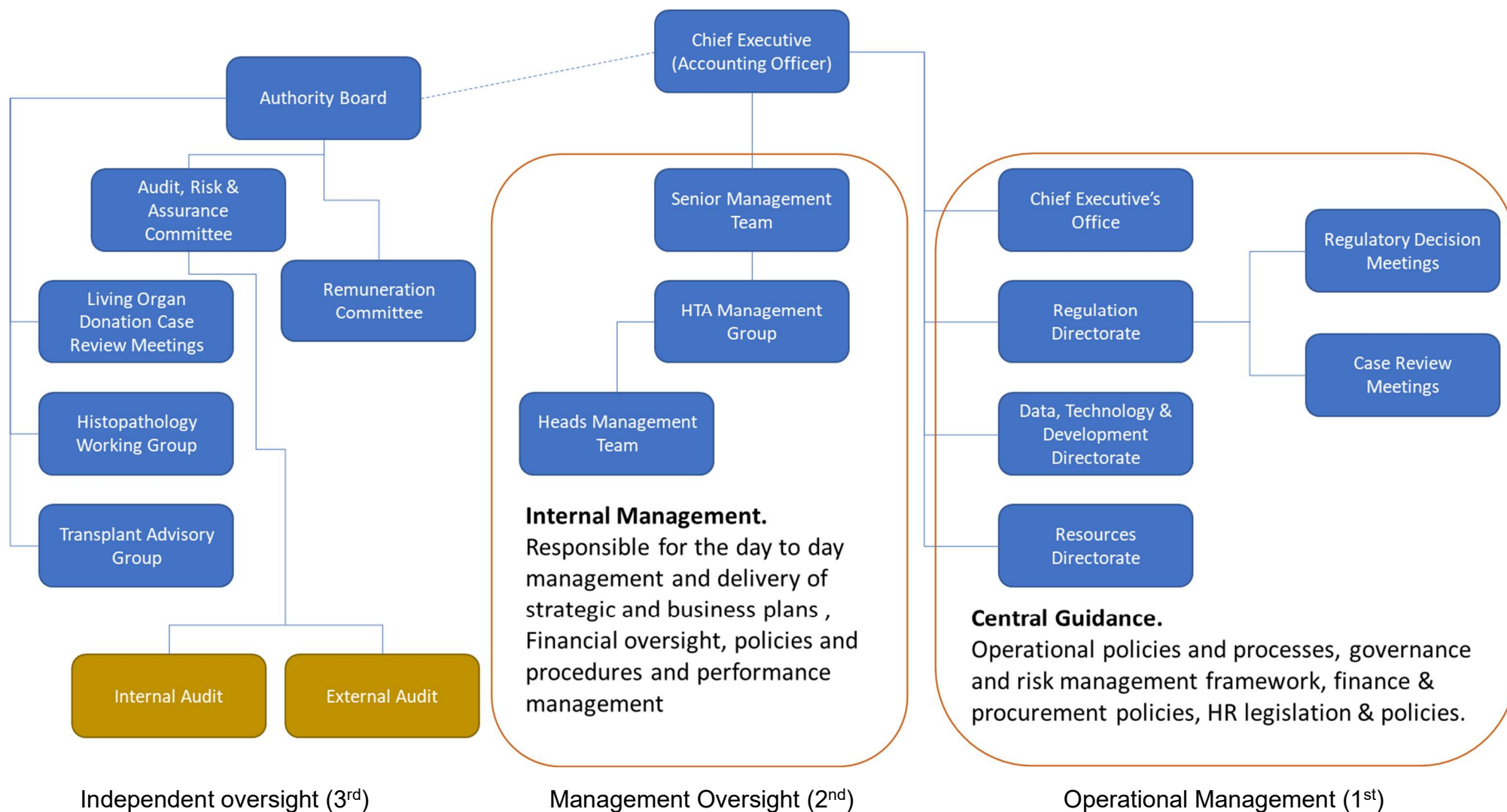
Sources of Assurance

7.   Assurance is taken from performance reporting, assessing the operation of key processes and their controls, and the management of risks and issues as they arise.

8.   In line with Cabinet Office and Treasury guidance on control and assurance frameworks HTA operates the 'three lines of defence' approach to the provision of assurance. These are set out in the table below:

First line: Management Stewardship (operational delivery)	Second line: Management Oversight	Third Line: Independent Assurance	Other Assurance Outside the 'Three Lines of Defence' Model
Description: The processes in place at the 'front line' of the business that can be used to derive assurance on how well objectives are being met and risks managed.	**Description**: The processes associated with the oversight of management activity. Provides management insight into how well work is being carried out in line with set expectations and policy or regulatory considerations.	**Description**: Independent assurance conducted to provide an Accounting officer with an opinion on the framework of governance, risk management and control.	**Description**: External Audit (for HTA the NAO). External to the organisation with a statutory responsibility for certification audit of the financial statements.
Examples: Documented business process controls, management information, risk registers.	**Examples**: Compliance assessments, reviews of policy implementation, setting and monitoring	**Examples**: Primarily Internal audit but also provided by other independent bodies (e.g. Investors in People).	

	internal guidelines		
Pros/Cons: May lack independence and objectivity, but value lies in coming from those who know the	**Pros/Cons**: Separate from those responsible for delivery. More objective than first line, but not	**Pros/Cons:** Independent/objective assurance. Reliance placed on assurance mechanisms in first and second lines to target effectively	
business, culture and day to day challenges.	independent of the management chain.	areas of highest risk or gaps/weaknesses in control framework.	

9.   Within HTA there are a number of sources of assurance operating across the three lines of defence that, combined with our approach to managing and mitigating strategic risk in line with these principles, deliver assurance sufficient to meet the needs of the business. These are set out in the diagram below:

HTA Governance and Assurance Map

Chief Executive (Accounting Officer)

Authority Board

Audit, Risk & Assurance Committee

Remuneration Committee

Living Organ Donation Case Review Meetings

Histopathology Working Group

Transplant Advisory Group

Internal Audit

External Audit

Senior Management Team

HTA Management Group

Heads Management Team

Internal Management. Responsible for the day to day management and delivery of strategic and business plans , Financial oversight, policies and procedures and performance management

Chief Executive's Office

Regulation Directorate

Data, Technology & Development Directorate

Resources Directorate

Regulatory Decision Meetings

Case Review Meetings

Central Guidance. Operational policies and processes, governance and risk management framework, finance & procurement policies, HR legislation & policies.

Independent oversight (3rd)

Management Oversight (2nd)

Operational Management (1st)

Roles & Responsibilities

10. **Chief Executive Officer as Accounting Officer** - Supported by the Board and the Senior Management Team, is responsible for ensuring that there are robust governance, risk management and internal control arrangements in place across the whole organisation. Providing the Principal Accounting Officer of the Department of Health and Social Care with assurance on the effective delivery of HTA's planned aims and objectives, financial stewardship and probity.

11. **The Board -** To ensure that the HTA's statutory responsibilities are met. It achieves this by setting the HTA's strategic direction and providing both support and challenge on delivery, including routinely monitoring the mitigation of strategic risks. This supports the Accounting Officer in ensuring that there transparent, regular and timely assurance.

12. **The Audit and Risk Assurance Committee** examines the arrangements in place to provide comprehensive and reliable assurance. This involves:

    - Identifying the assurance need;

    - How it will be met;

    - Whether there are any assurance gaps or overlaps and how these can best be filled; and

    - Whether this will provide sufficient, relevant reliable assurance.

13. **Senior Management Team (SMT)** - Responsible for ensuring the business operations within their responsibilities are subject to effective and documented control frameworks as part of their core operating processes, that these are routinely tested and outcomes reported, with issues identified and managed. Specifically, each Directorate/Director oversees the following areas:

    - Chief Executives Office – HR Policies, Board Governance, Business Planning
    - Director of Resources – Financial control, procurement and contracting, Risk and Assurance, SIRO
    - Director of Regulation – Operational policy, assurance on regulatory oversight, coverage and compliance with Act requirements
    - Director of Data, Technology & Transformation – Cyber Security

14. **Internal Audit** - Independent assurance on the adequacy of compliance with the internal control and governance frameworks,

15. **External Audit** - Independent scrutiny of the effectiveness of the financial control environment including financial reporting, regularity and propriety. Ensuring the Governance Statement is consistent and in accordance with HM Treasury Guidance