

## **Audit and Risk Assurance Committee (ARAC)**

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**Date:** 14 October 2021

**Time:** 9.30 – 10.00 (Private Members session)  
10.00 – 12.00 (Main meeting)

**Venue:** Zoom

**Protective Marking:** OFFICIAL

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### **Agenda**

1. Welcome and apologies **(10 mins)**
2. Declarations of interest
3. Minutes of Meeting 17 June 2021 meeting (AUD 12/21)
4. Matters arising from 17 June 2021 meeting (AUD 13/21)

### **Internal Audit (15 mins)**

5. Item 5 is confidential and not included.

### **Audit Tracker (15 mins)**

6. Audit Tracker Update (AUD 15/21)

**External Audit (15 mins)**

7. Update report and introduction to HTA's new auditors (Oral)

**Risk Update (25 mins)**

8. Risk Update (AUD 16/21)

Annex A – Strategic Risk Register Summary

Annex B – Strategic Risk Register

Deep dive discussion around Strategic Risk Four

**Change Programme (10 mins)**

9. Development Programme Update (AUD 17/21)

**Cyber Security (10 mins)**

10. Cyber Security Update (AUD 18/21)

Annex A - Dashboard Report

**Policies and Procedures (10 mins)**

11. Policy and Procedure (AUD 19/21)

Fraud Strategy (AUD 20/21)

Reserves Policy (AUD 21/21)

Declaration of Interests (AUD 22/21)

12. Gifts and Hospitality Register (Oral update)

**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. Any Other Business (Oral)

## Minutes of the Audit and Risk Assurance (ARAC) meeting

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**Date:** 17 June 2021

**Time:** 10.00- 12.00

**Venue:** Zoom

**Protective Marking:** OFFICIAL

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### Attendees:

#### ARAC Members

Professor Gary Crowe (Chair)  
Dr Charmaine Griffiths  
Dr Stuart Dollow  
Glenn Houston  
Jan Williams

#### Apologies

Louise Dineley, Director of Data,  
Technology and Development  
Nicky Harrison, Director of Regulation

#### Observers

Lynne Berry, HTA (Human Tissue  
Authority) Chair  
Dylan Parrin, DHSC (Department of  
Health and Social Care)  
Amy Parsons, DHSC (Department of  
Health and Social Care)

#### Attendees

Allan Marriott-Smith, CEO  
Richard Sydee, Director of Resources  
Morounke Akingbola, Head of Finance  
David Thomson, Head of Business  
Technology  
Mike Surman, National Audit Office  
(NAO)  
Laura Fawcus, NAO  
Jo Charlton, Government Internal  
Audit Agency (GIAA)

### **Item 1 – Welcome and apologies (Oral)**

1. The Chair welcomed Members, the Executive and colleagues from Government Internal Audit Agency and the National Audit Office.
2. Apologies were noted from Nicky Harrison, Director of Regulation and Louise Dineley, Director of Data, Technology and Development.
3. The Chair also welcomed Lynne Berry, HTA Chair and colleagues from the Department of Health and Social Care as observers.

### **Item 2 – Declarations of interest (Oral)**

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

### **Item 3 – Minutes of 28 January 2021 meeting (HTA 01/21)**

5. The Chair asked the Committee if there were any comments in relation to the previous meeting's minutes; there were none.
6. The minutes from the meeting were accepted as an accurate record of the meeting.

### **Item 4 – Matters arising from the 28 January 2021 meeting – (AUD 02/20)**

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

8. It was agreed during the meeting that deep dive and training topics would be discussed with Members in preparation for the meeting in October, outside of this meeting.
9. The Committee noted the audit plan for the business year 2021/22 had been endorsed out of committee.
10. The Chair highlighted that he had meet with the Staff Forum representative. There had been positive discussion about the current appraisal process as well as the revised HTA contractual arrangements. However, there had been some indication that staff felt over-stretched by current workloads.
11. The Chair had also asked about Virtual Regulatory Assessments (VRAs) and there was broad staff consensus that while they were a useful tool, there was more to do to ensure they work as effectively as they could.
12. The Chair informed the Committee that there was training on 18 March at GIAA which ARAC members attended, and that he had attended an ALB Audit Chairs' meeting on 26 March.

## **Item 5 – Internal Audit Reports (AUD 03/21)**

13. Jo Charlton presented this paper and audit reports to the Committee.
14. The Committee was informed that draft internal audit opinion concluded a moderate assurance, in keeping with previous years. She asked the Committee to note that the area of improvement required related to the implementation of recommendations by the Executive. The Committee was asked to note that both GIAA and the Executive have been working collaboratively to ensure recommendations are fully agreed. Members asked whether GIAA colleagues were confident that all issues in the management of audit recommendations had been reviewed. It was confirmed that the Executive had a clear understanding of improvements to be made.
15. With regard to audits carried out, it was confirmed that three reports had been issued, these were: risk management; accounts payable and the development of VRAs. There would be an effectiveness review of VRAs in 2021/22.

16. It was agreed that the proposed amendments to the 2021/22 audit plan would be agreed by correspondence and that data protection security toolkit would be included on the plan. The ARAC agreed that there would be no requirement for this to be presented at the meeting but that an update could be provided at a future meeting.

## **Item 6 – Audit Tracker (AUD 04/21)**

17. Morounke Akingbola presented the audit tracker to the Committee.
18. The Committee was asked to comment on the adequacy of this new format and were provided an update on actions.
19. The following update was provided to the Committee:
- An update paper on the progress with meeting the Records Management recommendations was provided to the Committee. The Committee was reminded that although the Records Management Policy was in place, the systems requirements to adopt the policy could not be implemented at the time. Cloud migration and the upgrade of the Electronic Document and Records Management System (EDRMS) means that the Executive is now able to implement the policy. The recommendations as they stand are now out-dated and it was agreed that the current recommendations should be removed and for GIAA to audit this area in 2022/23.
  - For the Utilisation of Capabilities audit there was one outstanding recommendation to be completed by quarter two of this year.
  - The recommendations arising for the payroll expenses and anti-fraud audit recommendations link in with the work being undertaken on the staff handbook and would be dealt with as part of this piece of work.
  - There were two recommendations outstanding in relation to the Cyber Security Essentials Audit.

- There were two recommendations in progress in relation to the Incident Response and Business Continuity plan which had gone to SMT for sign off.
- UK Transition training will be taking place for staff on the 25 June.
- It was proposed for the risk management training recommendation to be closed off.
- For the Development of VRAs audit, there are no outstanding recommendations on this at present.

## **Item 7 – Approval of 2020/21 Annual Report and Accounts (AUD 05/21)**

20. Richard Sydee presented the report to the Committee.
21. National Audit Office colleagues thanked the Executive for their patience and understanding during the audit and highlighted that the scrutiny applied to NAO audits has increased in the last year.
22. The Committee was referred to page four of the papers, where three significant risks were highlighted. The Committee was also asked to note the confirmation of no evidence of fraudulent activity.
23. Of the three risks, risk three (relating to the move to Stratford) had required some consideration of the HTA's assessment of the treatment of the new office lease as an operating lease. Mike Surman confirmed that although work was ongoing, that he was content that this was an operating lease.
24. The Committee was informed that there were no audit adjustments and that the annual opinion was good. The Committee could now advise the CEO to sign the accounts to be laid before parliament.
25. The NAO noted that working with the HTA had proved a positive experience.



## **Item 8 - Risk Update (AUD 06/21)**

26. Richard Sydee presented this paper to the Committee.
27. He informed the Committee that since the Board meeting, further narrative had been added to the Risk Summary sheet. He highlighted that the risks remained stable and that risk six now focussed only on the Development Programme and that the office move had been moved from its scope. Furthermore, risk four had been updated to reflect the impending departure of the CEO.
28. There were questions around risk four in relation to ensuring that the HTA is recruiting from a diverse talent pool. The Committee was informed that the HTA uses NHS Jobs which has a wide reach. However, the Executive would welcome any ideas on improving its recruitment practices in this regard.
29. The Committee noted that there were some residual risk scores above tolerance. The Executive assured the Committee that these would continue to be monitored by the full Board either for tolerance levels to be reviewed or to agree prioritisation of action to reduce risk to within existing tolerance.
30. The Committee noted the amendments to the policy attached to this paper.

## **Item 9 - Development Programme (AUD 07/21)**

31. The Committee were presented this update for information.
32. The Committee was informed that there had been progress with the Programme. The ARAC Chair had met with Louise Dineley about the reporting of progress with this Programme to ensure that key milestones are reported into ARAC. Louise had confirmed that she would continue to report on success, measures and milestones with the Programme.
33. Questions were raised about the relationship between the Enterprise content management system and EDRMS. The Committee were informed

that both systems would have interoperability and to integrate in a single way.

34. The Committee noted the update.

### **Item 10 - Cyber Security and Dashboard report (AUD 08/21)**

35. Dave Thomson provide an update to the Committee.

36. The Committee was asked to note that although the dashboard had not changed since the last meeting, there had been a lot of work undertaken on monitoring cyber threats. The additional data produced from recently deployed systems provided the opportunity for richer reporting at the next ARAC meeting.

37. The Committee was assured that there is an appropriate level of oversight in relation to cyber security threats posed to the HTA. The Committee also noted that a number of items in the audit tracker had not been updated and that this should be rectified by the next meeting.

**Action 1:** To present an updated dashboard report at the October 2021 ARAC meeting with a particular focus on threats.

### **Item 11- SIRO (Senior Information Risk Owner) Report (AUD 09/21)**

38. Richard Sydee presented the SIRO report to the Committee.

39. Richard Sydee informed the Committee that the paper provides a standard report with an assessment against the National Cyber Security Centre standards and forms part of the Annual Governance statement. He also highlighted that there had been no fundamental changes since the update last provided at the June 2020 meeting.

40. The Committee was assured by the report, however, highlighted the importance of ensuring staff awareness and training is in place to prevent against cyber-attacks. The Executive reassured the Committee that there had been a lot of communication with staff to ensure good practice is in place to reduce vulnerabilities of an attack, with a focus on targeted conversations with staff members whose systems may not yet have received security updates.
41. The Committee requested for further information to be provided on staff awareness and training at the next ARAC meeting.

**Action 2:** An update to be provided on staff awareness and training of cyber security.

## **Item 12 Summary of Policies (AUD 10/21)**

42. Morounke Akingbola presented this report to the Committee.
43. It was confirmed that most documents listed within the paper are reviewed annually.
44. As a result of the move in premises, there had been a review of the Business Continuity plan (BCP) and Critical Incident Response plan (CIRP) and views of the Committee were sought on the changes made.
45. The Committee suggested that every role should have a nominated deputy if someone is absent. The plan might also give advice on what types of events could trigger a critical incident and which would be managed as a business continuity issue.
46. The Executive informed the Committee that best practice on developing both the CIRP and BCP had been sought and shared with other Arm's Length Bodies and that testing of each would take place annually where there had not been cause to test either plan in an actual incident.

### **Item 13 Gifts and Hospitality Register (AUD 11/21)**

- 47. Morounke Akingbola presented Gifts and Hospitality Register to the Committee.
- 48. There were no changes to the register.
- 49. The Committee agreed that it would be appropriate to see the register in full once and otherwise to have additions reported at each meeting.
- 50. The Committee noted the policy; there were no comments.

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

- 51. The Committee noted that since the January 2021 ARAC meeting there had been one grievance from a staff member which was not upheld.
- 52. An update was provided on some work that had been carried out into concerns about the HTA's culture and working environment. This work had been sponsored by the ARAC Chair and had concluded that there were no systemic problems to be addressed.
- 53. There was nothing to report to the Committee under fraud or dispute.

### **Item 15 Topics for future discussion (Oral)**

- 54. The Chair proposed to the Committee that a deep dive around risk four could be undertaken at the October meeting.
- 55. The Chair also highlighted anti-Fraud training as a potential target for future ARAC training.

### **Item 16 Any Other Business (Oral)**

- 56. The Chair asked if the Committee had any other business; none was raised.

# AUD 13/21 - Matters Arising from 17 June 2021 Meeting

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.	Live
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	Live
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	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

## AUD 13/21 - Matters Arising from 17 June 2021 Meeting

### Risk exploration topics

Topic	Meeting	Progress
<b>Topics covered</b>		
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. <b>Complete.</b>
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. <b>Complete.</b>
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 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 2018 ARAC Meeting, the Committee elected to explore the risks and assurance associated with the HTA's staff induction process. <b>Complete.</b>
Risks posed by sectors and the HTA's approach to protect public confidence.	TBC	<b>HA and PM done.</b> Poor risk profile with some of the other sectors.
<b>Outstanding Topics</b>		
Risks associated with the HTA's Licensed Establishment Relationship programme	TBC	As agreed at the 1 February 2018 ARAC Meeting. At 19 June 2018 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	<b>HA and PM done.</b> Poor risk profile with some of the other sectors.
Fraud in Public Sector and lack 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 13/21 - Matters Arising from 17 June 2021 Meeting

Future training			
Topic	Meeting	Provider	Progress
<b>Training completed</b>			
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. <b>Complete.</b>
Value for money auditing and the optimal deployment of resources		NAO	NAO have been invited to host a training session on 18 May 2017. <b>Complete.</b>
A NAO perspective on the risks emerging within the health sector	February 2018	NAO Catherine Hepburn	<b>Complete.</b>
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. <b>Complete.</b>
IFRS training	January 2020	NAO	Complete.
<b>Outstanding training</b>			
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. <b>Postponed</b>
Fraud Awareness	June 2020	TBC	TBC

\* No training since January 2020

# AUD 13/21 - Matters Arising from 17 June 2021 Meeting

## Forward plan - AUD 13/21

Standing items	Assurance reports from Internal Audit Audit recommendations tracker report Risk update includes strategic risk register review and update on UK transition Policies/procedures updates Cyber security	Meeting Specifics to be covered
Meeting		
<b>January 2021</b>	Assurance reports from Internal Audit  Audit recommendations tracker report  Strategic risk register review  Policies/procedures updates  Anti-Fraud Policy (bi-annually) Whistleblowing Policy Schedule of policies	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)
<b>June 2021</b>	Audit recommendations tracker report Strategic risk register review  Policies/procedures updates	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)
<b>October 2021</b>	Assurance reports from Internal Audit  Audit recommendations tracker report  Strategic risk register review Policies/procedures update	Approval of External audit's planning report  Review of the Audit & Risk Assurance Committee's Governance including Handbook and Terms of Reference  Operational Risk Register review (not standing agenda item)



AUD 13/21 Matters Arising from 17 June 2021 Meeting

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		
Antifraud Policy HTA/POL/050	Policy states the minimum level of cash reserves that the HTA should ideally keep as a contingency	Annual
Whistle-blowing Policy HTA/POL/017	Policy covers definitions of fraud, responsibilities of HTA employees	Annual
Declaration of Interest, Gifts and Hospitality Policy	Policy covers procedure to be followed if they have concerns about improper behaviour	Annual
	Policy covers the procedure for receiving/declining gifts	Annual

**Internal Audit - Confidential**

## **Audit and Risk Assurance (ARAC) meeting**

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**Date:** 14 October 2021

**Paper reference:** 15/21

**Agenda item:** 6

**Author:** Morounke Akingbola

### **OFFICIAL**

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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 23 September 2021.

### **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 one new audit conducted which was a Staff Wellbeing Audit in July. This audit was completed in August. Our internal auditors (GIAA) agreed that this could be closed in August.

6. Below is a summary of the audits and the number that have been completed in the last 3 months. The discrepancy (38 vs 42) was due to 3 recommendations that were marked as closed and therefore not picked up in the June report. These were:
- a. Critical Incidents recommendation 1.2.
  - b. Business Continuity recommendation 1.6.
  - c. Risk Management (EU Transition) recommendation 2.1.
7. The Staff Wellbeing audit brings the total back to 42.

### Summary of audits

FY	Audit	Total (June)	Closed Jul-Sept	Total (Sept)	
2018/19	Records Management	8	N/a	8	
2019/20	Utilisation of Capabilities	2	1	1	
	Critical Incidents	6	3	3	
	Business Continuity	7	3	4	
	Payroll and Expenses	1	0	1	
2020/21	Anti-Fraud Controls	1	0	1	
	Cyber Security Essentials	6	4	2	
	Risk Management (EU Transition)	4	4	0	
	Payables and Receivables	3	2	1	
	Development of the inspection process during COVID-19	3	2	1	
2021/22	Staff Wellbeing	1	1	0	
	<b>Totals:</b>	<b>42</b>	<b>20</b>	<b>22</b>	

**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 experience 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.	<p><b>October 2019</b> Further work has not yet commenced. An SMT discussion will be scheduled to agree what further action should be taken in light of our comments in Agreed Actions.</p> <p><b>January 2020</b> Head of HR and SMT will review all Key Roles and Key People with a view to Succession Planning during Q1 2020/21 (Subject to relative prioritisation) The number of stand-alone roles and small teams reduces the opportunity for meaningful internal succession planning, however to better support this a recruitment strategy will be developed which will include a Preferred Supplier List of Agencies that can help to build the right skill set as it evolves across the HTA. This work will not be completed until end of Q1 2020/21.</p> <p><b>June 2020</b> 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.</p> <p><b>October 2020</b> As of June update</p> <p><b>January 2021</b> 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.</p>	Head of HR/SMT	Nov-19	No		<p>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.</p> <p>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.</p>	
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 as part of our annual review of the operational risk register	<p><b>June 2020</b> Not due.</p> <p><b>October 2020</b> Not due</p> <p><b>January 2021</b> We will feed these recommendations into any work we may undertake as part of our annual review of the operational risk register.</p> <p><b>June 2021</b> See rec 1.4</p>	Quality and Gov Manager	01/12/2020	No			
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	<p><b>June 2021</b> The ORR was revised back in Dec-20. We have taken the action that we agreed to undertake.</p>	Quality and Gov Manager Head of Finance	01/12/2020	No			
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	<p><b>June 2020</b> 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.</p> <p><b>October 2020</b> 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.</p> <p><b>December 2020</b> Training was been identified however, the time required (20 hours) is proving prohibitive.</p> <p><b>June 2021</b> We have identified some training and are looking for a suitable time to implement, which we expect in the 2021/22 business year.</p>	Director of Resources/Head of HR	01/06/2020	No			

**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	1.2	We recommend that the HTA review the BCP elements of the CIRP against the Civil Contingencies Secretariat's toolkit to strengthen HTA's approach to business continuity planning. In particular, HTA would benefit from undertaking a business impact analysis, and refining and clarifying the documentation of its communication strategy within the CIRP	Medium	Agreed – Previously our CIRP was developed in line with the relevant Civil Contingencies Secretariat's toolkits extant in 2012. We will review the new standards for material changes	<b>June 2020</b> Again, events have overtaken us. In line with recommendation 1.1 we will consider this as part of a review of BC and CIP ahead of our relocation. <b>October 2020</b> Not due <b>January 2021</b> This will be factored in when the BCP is revised at the end of Q4	Director of Resources	Mar-20	No	31/05/2021	Copy of plan shared with GIAA	09/06/2021
Business Continuity	2019/20	1.5	We recommend that HTA formalise the process to record lessons learned and follow-up of actions by management	Low	Agreed – will be detailed in the new BC plan	<b>June 2020</b> As outlined above this work will be delayed and considered as a part of the policy revision ahead of our relocation. <b>October 2020</b> Not due <b>January 2021</b> Lessons learned and follow-up actions will be added to the SOP	Director of Resources	01/03/2020	No	31/05/2021	Copy of plan shared with GIAA	09/06/2021
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		Head of HR	30/06/2020	No			
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	<b>June 2020</b> Not due. <b>October 2020</b> Not due <b>January 2021</b> This will be actioned after the office relocation is completed. <b>June 2021</b> 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			
Payroll and Expenses	2019/20	4	The existing code of conduct to be reviewed and where appropriate updated and communicated to all staff.	Low	Agreed. Code to be reviewed and link to revised values will be conducted	<b>June 2020</b> Not due <b>October 2020</b> Update to be provided at meeting <b>July 2021</b> Will be incorporated into the HTA Staff Handbook	Head of HR	Sep-20	No			
Anti-Fraud Controls	2019/20	1.2	HTA should agree a set of expected values and behaviours consistent with the Nolan Principles and the Civil Service Code of Conduct and promote and communicate them to staff.	Medium	Not agreed – the HTA has a set of values which were recently reviewed. Agree that the Staff Code of conduct should be updated and aligned with updated values.	<b>June update</b> A HTA Handbook will be designed and delivered by later in the year due to the impact of COVID-19. <b>June 2021</b> Will be incorporated into the HTA Staff Handbook Will be incorporated into the HTA Staff Handbook. Work has begun on this and will be completed in this financial year, but has been de-prioritised as a result of high volume of recruitment	Head of HR	Jun-20	No			
Cyber Security Essentials	2020/21	1.4	Document the approach to privileged user access to ensure that the knowledge is retained and stakeholders are aware and agree.	Low		<b>June update</b> Addressed through the Consolidated Audit Log in MS365. There is no policy document.	Head of IT	Dec-20	No	23/08/2021	Sent copy of email containing MS365 Console Log to GIAA	03/09/2021
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		<b>June update</b> 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	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		Director of Resources	31/03/2022	No			

### 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
Development of the inspection process during COVID-19	2020/21		1.1 The Board should consider its assessment of risk one – “failure to regulate appropriately” – considering so few inspections have taken place and should discuss the risk appetite on a regular basis. Changes to the risk appetite may be applicable due to red	Medium	<p>The HTA Senior Management Team has actively reviewed the strategic risk register monthly, which has also been considered at all ARAC and Board meetings.</p> <p>The HTA has annually reviewed its risk policy, including our risk appetite statement. This has now been enhanced, with a risk appetite applied to each of our strategic risks.</p> <p>A revised strategic risk register, including risk tolerance levels aligned to the Board's risk appetite, will be considered by the Board at their meeting on 6 May, this is the only action proposed in response to this recommendation.</p>	N/a	Director of Regulation	31/05/2021	No	31/05/2021	Strategic risk register reviewed at Board meeting on 6 May 2021	10/06/2021

## **Audit and Risk Assurance (ARAC) meeting**

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**Date:** 13 October 2021

**Paper reference:** AUD 16/21

**Agenda item:** 8

**Author:** Richard Sydee, Director of Resources

### **OFFICIAL**

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## **Risk Update**

### **Purpose of paper**

1. To provide ARAC with an update on HTA's strategic risks and proposed mitigations as of 6 October 2021.

### **Decision-making to date**

2. This paper was approved by the Director of Resources on 6 October 2021.

### **Action required**

3. ARAC Members are asked to comment on the strategic risks and assurances within the HTA Strategic Risk Register attached to this paper at Annex A.

### **Background**

4. The strategic risks are reviewed by the SMT monthly, and the summary risk paper and register are updated. The summary risk paper and strategic risk register that were updated on 6 October 2021 are at Annex A and B.



## Risk assessment

5. **Risk 1 – Failure to regulate appropriately (10 – Medium, at tolerance).** The risk level was raised to 5/3 in March in response to the escalating COVID-19 position but has since returned to 5/2 and a medium scoring. Activity in the PM sector is now stable, although many emergency mortuary licences are being renewed and there is a limited expansion of licencing for funeral directors' premises to support national public health COVID-19 surveillance.
6. A full schedule of regulatory assessments and site visits has commenced from the beginning of quarter 3, retuning broadly to levels of pre-pandemic activity. We continue to monitor SAEARS and HTARIs and manage a small number of specific regulatory matters with establishments.
7. **Risk 2 – Failure to manage an incident (12 – High, above tolerance).** The HTA believes that our incident management response plans were well tested and found to be robust and effective through their deployment in managing the impact of the pandemic and related restrictions over the past 15 months; as well as their adaptation for use in managing the potential impacts of the European Union (EU) Exit at the end of the Transition Period.
8. In response to a confidential matter, the SMT increased the likelihood of this risk materialising from 3 to 4, resulting in an increased residual risk level of High (12). Although additional resources have been acquired to prepare for this matter, we do not believe the residual risk level is reduced and it is likely to remain at High for the third quarter of the business year.
9. **Risk 3 – Failure to manage regulatory expectations (9 – Medium, at tolerance).** Following the end of the Transition Period for the UK's exit from the EU on 31 December 2020, the HTA's UK Transition Project has been proactively managing the regulatory changes, some of which did not take effect until 1 July 2021. Resources have remained in place throughout the second quarter to the business year to further support changes.
10. 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. Work has also commenced to convene round table discussions to understand and address perceived and actual barriers to innovation in the life sciences and the role of regulation in addressing them.

11. **Risk 4 - Failure to utilise capabilities effectively (High – 12, above tolerance).**  
A number of posts across the organisation have been successfully filled throughout the second quarter of the business year. Plans are in place to fill the few remaining vacancies across the third quarter
12. Although there has been significant successful recruitment some key vacancies remain. Capability gaps will exist during quarter 3 as a result of the vacancy of the Portfolio and Business Planning Manager, the pending departure of the Chief Executive and the resignation of the Head of Business Technology. As a result, SMT assess the current residual risk as High.
13. **Risk 5 – Insufficient, or ineffective, management of financial resources (6 – Medium, above tolerance).** Quarter 2 finances are in line with the budgeted position and, although some risks for additional expenditure have been highlighted, we are forecasting to spend within budget for the financial year
14. We await the outcome of SR21, although we do not anticipate any material reductions on our current level of GIA and hope to finalise budgets and fees for discussion at the November Board meeting.
15. **Risk 6, failure to achieve the benefits of the organisational transformation programme (Paused).** As discussed previously, this risk has been suspended from active management and will be redrafted in line with revised Development Programme delivery timelines.

Latest review date – 09/09/2021

## 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	<b>10 – Medium</b>	At tolerance	↔ ↔ ↔ ↔
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	<b>12 - High</b>	Above tolerance	↔ ↔ ↑ ↔
R3: Failure to manage expectations of regulation	Delivery e) and Development c)	<b>9 - Medium</b>	At tolerance	↔ ↔ ↔ ↔
R4: Failure to utilise our capabilities effectively	Delivery, Development and Deployment (a, c, and d)	<b>12 - High</b>	Above tolerance	↔ ↔ ↔ ↔
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	<b>6 - Medium</b>	Above tolerance	↔ ↔ ↔ ↔
R6: Failure to achieve the benefits of the organisational Development Programme	Development (a-d) objectives	<b>6 - Medium</b>	Below 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
<p><b>At tolerance.</b></p> <p>We have a good regulatory framework, with a strong assured position on our key regulatory processes from an Internal Audit review within the past 18 months. Activity in the PM sector is now stable, with some emergency mortuary licences having been renewed. We are expecting a further expansion of licencing of funeral directors' premises to support national public health Covid surveillance. We have also dealt with around forty new import / export licences (or licence variations) in the HA sector because of licensing changes following EU Exit. We have adopted a proportionate approach to these new licences and SMT have agreed the longer-term regulatory approach to be adopted in relation to these new licences.</p> <p>At the start quarter 3 we have initiated a full schedule of regulatory assessments and site visits in line with pre-pandemic activity.</p> <p>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 throughout the pandemic restrictions. We continue to actively manage a small number of regulatory matters with establishments</p> <p>SMT believes this risk is stable, at tolerance, in September 2021.</p>

**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	4	3	12 -High
Tolerance threshold:					6 - Medium

### Commentary

#### At tolerance.

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 also used these arrangements more recently in preparing for the potential consequences of an incident which occurred at an establishment that, although not a regulatory matter, may lead to a significant impact on the HTA.

Having increased the risk scoring in July we are of the opinion that the likelihood of this risk materialising remains high. Further clarity on the timelines for managing the confidential matter has been provided and we have put in place additional resource, both internal and external, to help manage this matter as it crystallises. We also note the likely continued demands on senior management in dealing with these matters and the stretch on the remaining members of the SMT with the departure of the CEO at the end of October 2021

SMT believe this risk remains high and although further mitigation actions and resources have been deployed that this will remain above tolerance for the next quarter.

**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	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 about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit, but which may adversely impact on public confidence, is challenging. 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 proactive approach went live in quarter four of 2020/21 and will continue to be embedded in 2021/22.

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. Work has also commenced to convene a round table discussion to address the issues associated with the use of tissue blocks and slides from coronial post-mortems for research, teaching and clinical audit.

Work has continued to support the Public Health England initiated pilot project to undertake post-mortem surveillance sampling for COVID-19 through the licensing of Funeral Directors. The future demand for these licenses is currently uncertain and we are seeking further clarity on the next phase of the project.

All these matters are being actively managed, and there has been no detrimental impact on the HTA's reputation.

SMT believe this risk remains 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	4	3	12 – High
Tolerance threshold:					9 - Medium

Commentary
<p><b>Above tolerance.</b></p> <p>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.</p> <p>Key vacancies remain relating to the planning and portfolio manager, with plans for an interim appointment to be made during October, and with the pending departure of the Head of Business Technology in November 2021 recruitment for a replacement has commenced.</p> <p>The HTA's new Chief Executive, Dr Colin Sullivan, will begin his new role on 1 January 2022, with the current Chief Executive departing at the end of October plans have been agreed to distribute activities and responsibilities temporarily to other members of SMT.</p> <p>SMT believe that the risk tolerance has not changed and remains above tolerance, although significant progress has been made several vacancies gaps relating to planning and the pending departure of both the CEO and Head of Technology leave the organisation facing critical short-term pressures through quarters 3 and 4 of this business year.</p>

**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
<p><b>Above tolerance.</b></p> <p>Planning for 2021/22 is now complete. DHSC has confirmed GIA funding for the new financial year, and we expect additional funding for ongoing EU transition activities. With anticipated cost reductions from our estate, and the impact of ongoing restrictions on normal site visit and meetings/events likely to continue to reduce expenditure, we have allocated funds for the continuation of our development activities.</p> <p>As we approach the mid-year point our expenditure is in line with budgets and we forecast a balanced year end position whilst acknowledging some potential additional costs in relation to recruitment and specialist support.</p> <p>We expect the outcome of the 2021 Spending Review towards the end of the 2021 calendar year, we do not anticipate specific savings measures but are mindful that some small reductions in our Grant in Aid could be required.</p> <p>We expect to finalise recommendations on 2022/23 fees for the November Board meeting and subject to a settlement on GIA would expect to finalise budgets for 2022/23 and reach tolerance for this risk towards the end of Quarter 3.</p>



**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	2	6- Medium
Tolerance threshold:					9 - Medium

Commentary
<p><b>At tolerance.</b></p> <p>As previously advised the risk has been suspended</p>

**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.

## 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:

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

IMPACT	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%)

## 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 I L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION													
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: Alan Marriott-Smith	Causes	5	3	Ongoing	Regulatory model	5	2	10	1	2	3	Preventative	Board developed and approved the current HTA Strategy and is aware of the risks and opportunities associated with the suspension of routine site visit inspections during Covid restrictions and how VRAs are being incorporated into BAU. Board 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. 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 pandemic, including use of virtual assessment techniques. Development and use of funeral director licensing regime to support PHE-sponsored project of post-mortem public health surveillance for Covid-19.	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. VRAs being incorporated into BAU in HA sector from Quarter 4 2020/21, with plans to expand into all sectors during Quarters 1 and 2 or 2021/22, as evidenced in Business Plan. Internal Audit late Quarter 3 / early Quarter 4 2020/21 on 'Inspection Process during Covid-19' - draft report agreed late May 2021; Moderate assurance; to be considered by ARAC early June 2021. Renewal of emergency mortuary licences and expansion of Funeral Director licensing for removal of issue for PHE post-mortem public health surveillance for Covid-19. Police referral made late 2019/20 being actively investigated by the police, with ongoing input (Witness Statements) from HTA.										
		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. Internal collection of compliance updates data from other sectors.																							
		Regulation is not transparent, accountable, proportionate, consistent and targeted				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 of key decisions in Board Reporting.	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.						
		Regulation is not sufficiently agile to respond to changes in sectors				Annual scheduled review of Strategy										X	X	Preventative	Outputs from annual strategy review translate into revised annual Strategy	Latest update of HTA Strategy published November 2020. Annual Board Strategy session 27 April 2021 to consider annual strategy refresh.					
		Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IAs)).				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.	Following the departure of the Head of Planning and Performance, SMT and their Heads have ensured there is regular review and updating of the operational business plan and monthly performance pack.  Plans to be put in place to re-introduce KPIs and PIs for internal decision making and external transparency and accountability.									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 was produced in Quarter 1 2020/21 and published during Quarter 2 (delayed by Covid).  2021/22 narrative Business Plan is currently under development.	Progress on the Portfolio Management approach being developed is a regular item of business at SMT meetings (most recently July 2021). SMT receives monthly reports of Management Information for review and action (most recently in July 2021).					
		Inadequate adherence to agreed policies and procedures in particular in relation to decision making				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.  Detailed evaluation carried out prior to adoption and expansion.  Following Internal Audit on the Inspection Process during Covid, some further management actions are being undertaken, principally to ensure other regulatory processes and documentation (SOPs) are updated to take account of VRAs.											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 largely complete - to be considered by ARAC June 2021.	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.				
		Poor quality or out of date policies and procedures				Quality management systems										X			Preventative/ Monitoring	Management oversight and reporting through the monthly performance pack. This work is expected to transfer to a newly created role during Quarter 2 2021/22.	Limitations in QMS still remain. Scheduled reviews have now been re-instated following the departure of the quality manager with a schedule of activity in place. QMS and monthly performance reporting pack includes evidence of degree to which the documents are current.				
		Failure to identify new and emerging issues within HTA remit				People										X			Preventative	Management information and assessment presented to the Board quarterly.	HR report included in Chief Executive's report to the Board at the July 2021 meeting. End-of-year reviews completed during Quarter 1 2021.				
		Failure to properly account for Better Regulation				Adherence to the HTA People Strategy which has been substantially amended and approved by the Board										X			Preventative	Annual PDPs, Corporate Training Programme (led by Head of HR), RM Training programme, Career Investment Scheme proposals to SMT	Evidence of corporate training programme, including quarterly mandatory training. Regulation-led Training sessions focusing on Change and VRAs. 'Lunch and Learn' programme.				
		Insufficient funding in regulated sectors				Training and development of professional competence										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.				
		Failure to deal with regulatory consequences of the Transition Period and the period after 31 December 2020.				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 / 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.				
		Failure to properly manage the business impact of the coronavirus pandemic.				EU Exit (End of Transition period and HTA Exit Sls 'vacca period')	Fortnightly Transition Period oversight meetings from February 2020 with H-Q16-H-Q15									X	X		Preventative / 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.				
		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																							

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	<p><b>Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:</b></p> <ul style="list-style-type: none"> <li>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)</li> <li>caused by deficiency in the HTA's regulation or operation</li> <li>where we need to regulate, such as with emergency mortuaries</li> <li>that causes business continuity issues</li> </ul> <p>(Risk to all Delivery Development and Deployment objectives)</p> <p>Risk owner: <b>Nicky Harrison</b></p>	<p><b>Cause</b></p> <ul style="list-style-type: none"> <li>Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)</li> <li>Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)</li> <li>Failure to work effectively with partners/other organisations</li> <li>Breach of data security</li> <li>IT failure or attack incident affecting access to HTA office</li> <li>External factors such as terrorist incident, large scale infrastructure failure or pandemic</li> </ul> <p><b>Effect</b></p> <ul style="list-style-type: none"> <li>Loss of public confidence</li> <li>Reputational damage</li> <li>Legal action against the HTA</li> <li>Intervention by sponsor</li> </ul>	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	4	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. 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	2	3		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.					X				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.
						Availability of legal advice					X				Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy					X				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. Engagement with NHS Counter Fraud Authority (CFA) on a matter where there appears to have been HTA regulatory breaches and offences as well as potential fraud offences, which NHS CFA are investigating.
						Onward delegation scheme and decision making framework, agreed by the Board					X	X			Standing Orders and Board minutes	Standing Orders published May 2017, due to be updated before Board meeting in November 2021.
						Regulatory decision making framework					X				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			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					X	X			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.
						Evaluate test exercise of incident and feedback to all staff.					X				SMT content that activation and use of CIRP during first wave and first lockdown superseded the need for a test.	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.					X				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.	Findings at inspection (onsite or VRAs).  Minutes of quarterly meeting with NHSBT to review SAEARs cases in ODT sector - latest meeting was 24 March 2021.  Most recent SARE report submitted June 2020.  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.
						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.									Annual SARE (Serious Adverse Reactions and Events) HA SAEARs data reported to European Directorate for the Quality of Medicines (EDQM).	
						Publication of quarterly incident numbers in the professional e-newsletter may remind establishments to report.									Monitoring establishments' reporting of incidents through the HTARI, HA SAEARs and ODT SAEARs groups and advice, guidance and CAPAs regarding those incidents.	
						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.									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. Smooth management of the end of the transition period at 31/12/20 through the regular stand-ups (based on the CIRP) through the defined UK Transition project oversight. SMT paper 14 January agreed scope of next phase to 30 June 2021 with project closure expected by 31 July 2021. Internal Audit 2019/20 (Moderate assurance and most management actions completed by the end of May 2021).  Rapid replacement of contractor project manager following departure of former incumbent to ensure continued rigour in approach to project management.



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			I	L			I	L			1	2	3					
3	<p><b>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</b></p> <p><b>(Risk to Delivery objective e, and Development c)</b></p> <p>Risk Owner:</p> <p><b>Louise Dineley</b></p>	<p><b>Cause</b></p> <p><b>External factors</b></p> <ul style="list-style-type: none"><li>No scheduled review of Human Tissue Act and associated regulations, or Quality and Safety Regulations (other than for EU Exit)</li><li>Rapidly advancing life sciences</li><li>Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates</li><li>Introduction of deemed consent for Organ donation in England</li><li>Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario</li></ul> <p><b>Matters which certain stakeholder groups believe require review</b></p> <ul style="list-style-type: none"><li>Scope of relevant material e.g. waste products</li><li>Licensing requirements e.g. transplantation research</li><li>Regulation relating to child bone marrow donors</li><li>Issues raised by emergence of social media e.g. non-related donors</li><li>Strengthening of civil sanctions for non-compliance</li></ul> <p><b>Matters which stakeholders/public may expect to be inside regulatory scope</b></p> <ul style="list-style-type: none"><li>Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure</li><li>Police holdings</li><li>Products of conception and fetal remains</li><li>Data generated from human tissue</li><li>Funeral directors</li><li>Forensic research facilities</li><li>Cryonics</li><li>Body stores / Taphonomy</li><li>Imported material</li><li>Clinical waste</li><li><b>Other</b></li><li>Inadequate stakeholder management</li></ul> <p><b>Effect</b></p> <ul style="list-style-type: none"><li>Diminished professional confidence in the adequacy of the legislation</li><li>Reduced public confidence in regulation of matters relating to human tissue</li><li>Reputational damage</li></ul>	5	4	Ongoing	<p>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</p>	3	3		9	1	2	3		Ongoing log	<p>Log in place and shared with Board in outline at the Strategic planning session in 2021.</p>		
														X	Monitoring			
							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 May 2019. Professional newsletters issued regularly - last one May 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 July 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.
							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 also published. These publications reflect the importance of ongoing publications and updates to specific conditions.	Update to the Board and DHSC at Board meeting July 2021.  Professional newsletter May 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.
							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.
							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



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			I	L			I	L			1	2	3			
4	<p><b>Failure to utilise people, data and business technology capabilities effectively</b></p> <p><i>(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)</i></p> <p>Risk Owner: <b>Louise Dineley</b></p>	<ul style="list-style-type: none"> <li><b>Cause</b> Lack of knowledge about individuals' expertise</li> <li>Poor job and organisational design resulting in skills being under used</li> <li>Poor line management practices</li> <li>Poor project management practices</li> <li>Poor leadership from SMT and Head</li> <li>Loss of productivity as a result of the effects of changes to ways of working</li> <li>Data holdings poorly managed and under-exploited</li> <li>Inadequate business technology or training in the technology available</li> <li>Lack of ring-fenced resource for 'no-deal' EU Exit</li> </ul> <p><b>Effect</b></p> <ul style="list-style-type: none"> <li>Poor deployment of staff leading to inefficient working</li> <li>Disaffected staff</li> <li>Increased turnover leading to loss of staff</li> <li>Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed</li> <li>Poor use of technology resulting in inefficient ways of working</li> <li>Inadequate balance between serving Delivery and Development objectives</li> </ul>	3	4		People capability	3	4	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.
						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.	

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			I	L			I	L			1	2	3						
5	Insufficient, or ineffective management of, financial resources  (Risk to Deployment objective b  Risk Owner:  Richard Sydee	<p><b>Cause</b></p> <ul style="list-style-type: none"><li>Fee payers unable to pay licence fees -</li><li>The number of licenced establishments changes, leading to reduced fee income</li><li>Management fail to set licence fees at a level that recover sufficient income to meet resource requirements</li><li>Failure to estimate resource required to meet our regulatory activity</li><li>Poor budget and/or cash-flow management</li><li>Unexpected increases in regulatory responsibilities</li><li>Unforeseeable price increases / reductions in GIA</li><li>Fraudulent activity detected too late</li></ul> <p><b>Effect</b></p> <ul style="list-style-type: none"><li>Payments to suppliers and/or staff delayed</li><li>Compensatory reductions in staff and other expenditure budgets</li><li>Increased licence fees</li><li>Requests for further public funding</li><li>Draw on reserves</li><li>Failure to adhere to Cabinet Office Functional Standards</li></ul> <p><b>Leading to:</b></p> <ul style="list-style-type: none"><li>Inability to deliver operations and carry out statutory remit</li><li>Reputational damage and non payment of fees</li></ul>	5	4	Ongoing	Budget management framework to control and review spend and take early action	2	3		3	1	2	3	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		X						Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report to Board in May 2021
						Licence fee modelling											Preventative	Annual update to fees model	No change to fees agreed by the Board November 2020 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	Will go to the Board November 2021
						Annual external audit						X					Detective	NAO report annually	Unqualified Accounts produced June 2021
												X					Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report July 2021
									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.

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			I	L			I	L			1	2	3			
6	<b>Failure to achieve the full benefits of the HTA Development Programme</b>  <b>(Development objectives a-d)</b>  <b>Risk owner</b>  <b>Louise Dineley</b>	<b>Causes</b> <ul style="list-style-type: none"> <li>Uncertainty of funding</li> <li>Programme and project benefits poorly defined and understood</li> <li>Inadequate programme and project governance arrangements</li> <li>Poorly specified programme and projects</li> <li>Insufficient programme, project and change management skills</li> <li>Inadequate leadership of change</li> <li>Inability to access the necessary skills required at a affordable cost</li> <li>Lack of staff buy-in to change</li> <li>Management and Head stretch of delivering transformation alongside business as usual and other development activity</li> <li>Insufficient agility in (re)deploying people to change projects</li> <li>Poorly specified procurement and inadequate contract management</li> <li>Realisation of single points of failure for DDAT and People Strategy</li> </ul> <b>Effects</b> <ul style="list-style-type: none"> <li>Wasted public money</li> <li>Failure to achieve the central strategic intent of the Authority</li> <li>Distracts senior management from operations at a time when demands have increased</li> <li>Reputational damage</li> <li>Unaffordable cost over run</li> <li>Staff demotivation</li> <li>Data remains under-utilised</li> <li>Technology inadequate to meet future needs (cost, functionality)</li> <li>Limited ability to achieve improvements in efficiency and effectiveness</li> <li>Pace of change is inadequate and impacts negatively on other work</li> </ul>	3	3		SMT experience of organisational change, programme and project management.	2	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	Programme 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 2021
									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		

## **Audit and Risk Assurance (ARAC) meeting**

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**Date:** 14 October 2021

**Paper reference:** AUD 17/21

**Agenda item:** 9

**Author:** Louise Dineley  
Director of Data, Technology and Development

**OFFICIAL**

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### **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 two deliverables.
  - ii. Note the deliverables for quarter three.

#### **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.
5. In parallel to the HTA's Development Programme we have continued to contribute to a number of external projects over the last quarter. These have included Data Collaboration Partnership, the development and progress of the Life Sciences vision and exploring the development of a regulators map.

#### **Quarter two 2021/22 – update on deliverables**

6. The deliverables for the three priority projects and the programme overall in the quarter are outlined below along with a forecast assessment.
7. *Completion of “as is” and “to be” business process mapping including data flows to support and inform future system and data architecture.*  
 Status: AMBER  
 The business process mapping of the “as is” and “to be” has not been completed in quarter 2. The revised commission set in August failed to deliver to the requirements set for the Development Programme. Key gaps included the omission of data flows, a lack of consistency in the level of mapping with no high level map at the domain level produced, and missed or incomplete processes. A recovery plan is in place to complete the mapping of the “as is” by the end of the quarter. The plan for delivery of the “to be” maps has been reframed and will extend into early quarter three.
8. *Development and roll out of a data collection pilot and a test version of the Regulatory Insight Model and Index (RIMI)*  
 Status: AMBER  
 There is a critical dependency between the data flow mapping and the data collection pilot. The delay in the production of the data flow maps is having a knock on effect on the design and roll out of the data collection pilot. The aim of

this pilot was to test an updated data set with operational teams. To mitigate the impact we have reviewed additional actions that can replicate, in part, the pilot. These actions include the implementation of the proof of concept model developed last year, the development of a revised, updated set of data indicators (to be tested) and plans for an initial engagement event with external stakeholders.

9. *Develop the transition architecture for the Enterprise Content Management System to be built in quarter three*

Status: AMBER

Collection of the business requirements for the transition architecture has commenced with the aim of a draft specification produced by the end of the quarter. This draft specification will be used to engage developer resource for the design and development of the architecture. The output of the transition architecture has been reframed as an early quarter 3 deliverable due to the dependency with the “to be” output.

10. *Agree and commence targeted developments of the Target Operating Model*

Status: GREEN

Over the last quarter the Operating Model has evolved to provide a vision for a Target Operating Model (TOM) including opportunities for improvements and developments. The draft TOM will be used as the basis of the “to be” mapping with opportunities for improvements signed off via the SMT as initial priorities and future opportunities assessed against resource investment and benefits to be realised.

11. *A first draft of future workforce requirements to inform wider organisational preparedness and the options to develop or access core skill sets.*

Status: AMBER / GREEN

As each of the projects progress we need to consider the impact of any change or development has on the current and future skills required from the HTA workforce. In conjunction with the Head of HR, these skills will be collected and added to the skills mapping tool. An early draft is on track for delivery by the end of the quarter. In addition to the above actions work has also progressed to support the organisation and its preparedness for the future changes and development. The recruitment of a Change Manager is underway. This role will focus on the implementation of change.

### **Quarter Three 2021/22 Deliverables**

12. By the end of quarter three we aim to have delivered:

- An updated version of the Regulatory Insight & Index Model (RIMI).

- The design phase of the transition architecture with development progressing and delivered in full by the end of quarter four.
  - 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
  - Future workforce skills map to inform workforce development and future operating model
  - Engagement with stakeholders (internal and external)
13. The planning of deliverables in quarter three is currently under review to take into consideration changes to staffing planned at the end of quarter two and in the middle of quarter three. The roles impacted include the Business Analyst scheduled to leave the HTA at the end of quarter two. The Head of Technology will also be leaving at the HTA at the end November. At the time of writing this report the programme and its deliverables are being reviewed and reprioritised to the resources available.

### **Measuring Success**

14. The timing of this report means that the quantification of the success measures with the reframing of the programme and the end of the quarter is outstanding. A verbal update on the measures will be provided as part of the presentation of this paper at the meeting.



Cybersecurity Dashboard



## Metrics

### Potentially malicious events

0

*When traffic is detected from sources that are known to be malicious, alerts are created in Azure Sentinel. Alerts are created distinctly for inbound traffic: someone is trying to access the organisation from a known malicious IP address, and outbound traffic: data from our network is being streamed out of the organisation to a known malicious IP address.*

### Indicators of adversary

- 197 queries
- 11 investigated
- 0 compromise

Several threat hunting queries only alert a cyber security analyst to the possibility of a MITRE tactic or technique being deployed but are not absolute and require further analysis to determine the true nature of the alert. Of the 11 investigated, 10 were determined to be false positives and not a true indication of an adversarial attack. One alert did prove to be a genuine threat.

Multiple attempts were made to login to one current and one past staff member account from Mexico, Ukraine, Brazil and India. All of these anomalous login attempts failed and our cloud application security (CAS) alerted these to us as failed login attempts and impossible travel. An impossible travel alert is raised when CAS detects activities from the same user in different locations within a time period that is shorter than the expected travel time between the two locations.

These activities were consistent with a threat actor attempting to gain initial access to our systems. If this had succeeded, they would then attempt to find a vulnerability they could exploit to raise their level of access and traverse across systems and execute their intended attack. The SMT were notified of these initial access attempts on 22 July 2021.

*Threat hunting in Azure Sentinel enable us to proactively hunt for security threats. Threat hunting queries are aligned with MITRE tactics and techniques. MITRE ATT&CK® is a globally accessible knowledge base of adversary tactics and techniques based on real-world observations. The ATT&CK knowledge base is used as a foundation for the development of specific threat models and methodologies in the private sector, in government, and in the cybersecurity product and service community.*

### Mailboxes accessed by non-owners

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Microsoft Exchange logs occurrences of mailboxes that have been accessed by someone other than the person who owns the mailbox. A non-owner accessing a mailbox may be an indication of a compromised account or potentially an insider threat.

### Changes to administrator role groups

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Administrator role groups are used to assign administrative permissions to users. These permissions allow users to perform administrative tasks in your organization, such as resetting passwords, creating or modifying mailboxes, and assigning administrative permissions to other users. Unexpected changes to administrator role groups may be an indication of a compromised account or potentially a privileged user insider threat.

#### **Email auto-forwarding**

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Auto-forwarded emails pose a potential data leak risk when people in the organisation automatically forward email messages to an external domain, such as a personal email address.

#### **Account provisioning**

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*User accounts being created outside of a new starter process may be an indication that we have been successfully infiltrated and an adversary is creating accounts for malicious ends. Each of the 10 user accounts created have been the result of a new starter process.*

#### **Users with restricted email privileges**

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*Users who are detected and marked as a suspicious or restricted will have their email privileges restricted. A user is considered suspicious when the user has sent suspicious email and is at risk of being restricted from sending mail; this user's activities might need to be monitored. A restricted user is a user that has been restricted from sending mail due to highly suspicious patterns associated with that user's activities due to a possible compromise*

#### **High/medium infrastructure vulnerabilities**

- 0 High
- 9 Medium

*Infrastructure vulnerabilities could be exploited by a determined attacker. We scan our infrastructure monthly for vulnerabilities and prioritise high and medium impact issues for remediation. New vulnerabilities are being discovered by security researchers all the time so it is unlikely that these numbers will ever be zero.*

## **Threat Intelligence and Cyber Security alerts**

Through the NHS Cyber Security Operations Centre instance of Microsoft 365 Defender, we are monitoring 131 threats.

- 30 Ransomware campaigns

- 9 Phishing campaigns
- 50 Vulnerability exploitation campaigns
- 40 Activity Groups

The NHS Cyber Alerts Service has issued two high severity alerts\* since the last report.

The first high severity alert was for the PrintNightmare Remote Code Execution vulnerability. The alert was issued at 23.05 on 6 July. The alert was acknowledged on the **Respond to an NHS Cyber Alert service** (RTANCA) at 23.14 on 6 July. The available patches were applied to HTA servers by 18.32 on 7 July. The Microsoft developed patches did not fully address the vulnerability and further mitigations were implemented at 10.32 on 8 July.

The second high severity alert was issued at 13.45 on 4 September. The alert was acknowledged on RTANCA at 14.02 on 4 September. In this case the alert did not apply to the HTA and no remediation activity was required.

NHS Digital require high severity alerts to be acknowledged within 48 hours and any applicable updates or mitigations to be implemented within 14 days. Our average time to acknowledge was **13 minutes** and our time to mitigate was **19 hours and 27 minutes**.

Active monitoring of communications on the **NHS Cyber Associates Network** meant that we were aware of the developing threat before it was issued as a high severity alert. It also allowed us to be ready when Microsoft released their patches and to respond rapidly when it became clear that the patches were only partially successful.

*\* Issuing a high severity alert is a significant decision. The decision-making process involves many different people at NHS Digital in the Cyber Security Operations Centre as well as other organisations before approval is given. Once the decision is made, thousands of hours of work begin for people at many different levels, from the people fixing machines to the executive decision-makers in each area of the NHS and the wider system, to the people who must write the reports days, weeks, and months later. Issuing a high severity alert is a necessarily complex decision, made jointly with NHS Digital, NHSX, NCSC, and NHS England.*

## Incidents

We have responded to a single information security incident, which occurred in July. The incident was logged in the Data Security and Protection Toolkit with reference 24896.

### Summary of the incident

A member of staff accidentally included an external recipient when forwarding an email to an internal audience. The email contained the email addresses of several members of staff and a link to an internally hosted document detailing summer leave arrangements. The individual who made the mistake reported the incident when they became aware.

### Action taken

The external recipient was contacted, and they confirmed that they permanently deleted the email received in error and that they were not able to access any HTA staff data at any time.

To help reduce instances of emails being sent externally that were intended for HTA staff only we introduced MailTips to warn when sending an email to an external recipient. This warning is configured to appear in Outlook on HTA PCs and Outlook for iPhone and Android mobiles. The introduction of MailTips was communicated to all staff via the HTA Staff Newsletter on 27 July.

### **Conclusion of the incident**

This information security incident had the potential to become a breach of personal data of 27 members of HTA staff however at no time were the rights and freedoms of any individual violated due to the fact the personal data was included in an internal file that could not be accessed by the external recipient. The incident did not require reporting to the Police or the Information Commissioners Office.

## Benchmarking

In August we secured access to BitSight, a security performance management rating system. Our entitlement to access to BitSight came through our relationship to NHS Digital and DHSC and is free of charge to the HTA.

BitSight adopts an outside-in approach to assessing the effectiveness of security management at an organisation and this assessment can be carried out without the organisation being assessed knowing about it. BitSight suggest that their security rating be interpreted in a similar way to a credit rating.

BitSight ratings are banded into Basic, Intermediate and Advanced. Ratings for the Basic band range from <410 - 630, Intermediate is 640 - 730 and Advanced is 740 - > 800.

BitSight have been rating the HTA since September 2020 and at that time we had an Intermediate rating of 670. Our rating has steadily increased over the 12 months since and is now in the Advanced range at 780.

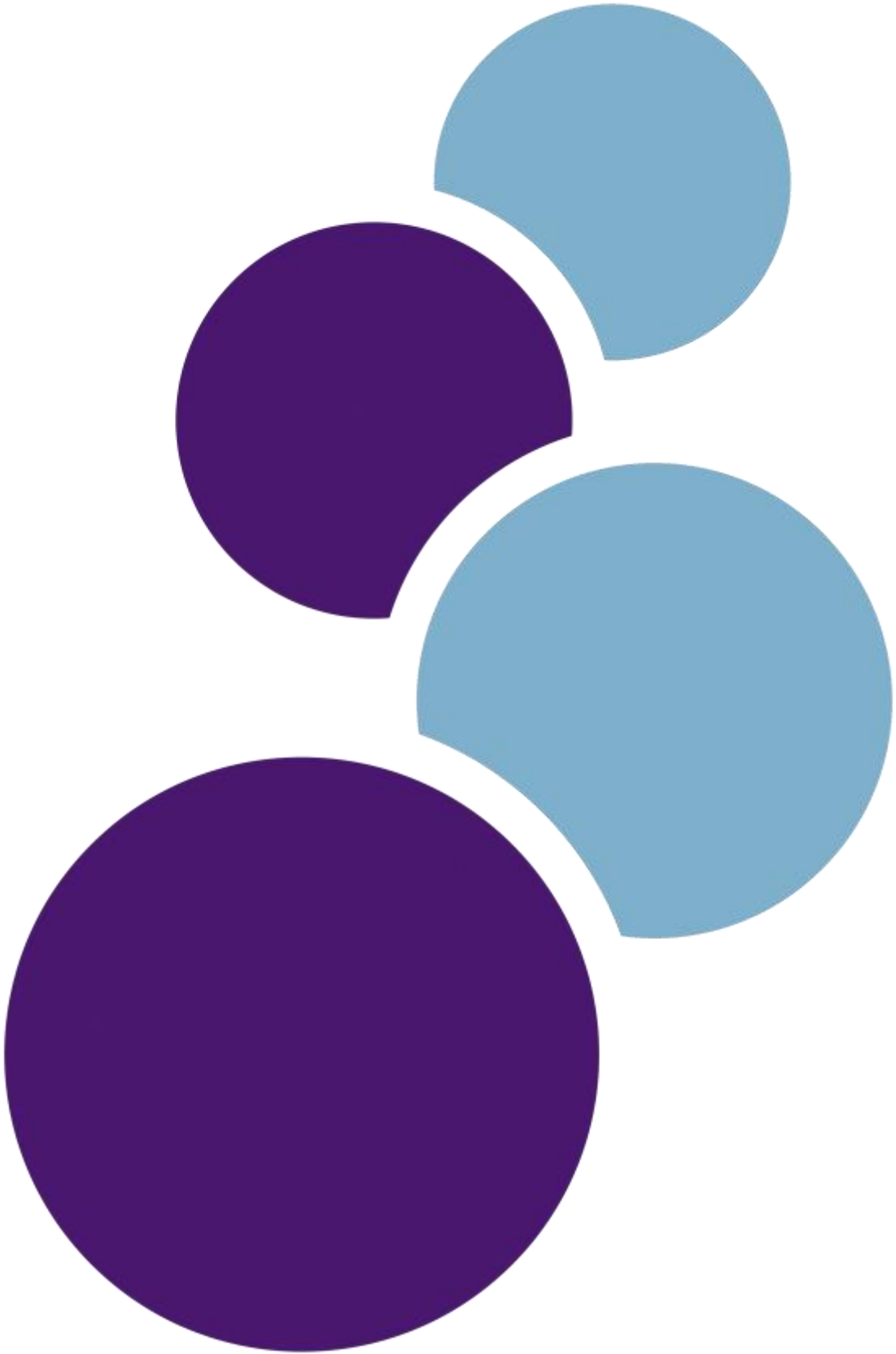
Due to the way BitSight has been procured and deployed by NHS Digital it has already mapped a peer relationship between DHSC, CQC, HFEA, HTA, NICE, and Public Health England. The system allows us to benchmark ourselves against this peer network and, in an assessment against 20 different risk vectors, the HTA are rated the highest.

BitSight have also included the HTA in a wider peer group consisting of 20,272 Healthcare/Wellness organisations and has rated us as better than 99% of this peer group.

## Next steps

- We will be developing further reporting and metrics around threats and vulnerability management specifically for HTA end user computers. This will be informed largely by intelligence collected from the NHS CSOC Microsoft 365 Defender.
- We will develop solutions to support or capabilities in:
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## **Audit and Risk Assurance (ARAC) meeting**

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**Date:** 14 October 2021  
**Paper reference:** 19/21  
**Agenda item:** 11  
**Author:** Morounke Akingbola

### **OFFICIAL**

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## **HTA Counter Fraud**

### **Purpose of paper**

1. The purpose of this paper is present to the Committee the updated Counter Fraud Strategy and feedback from Cabinet Office in relation to the Functional Standard: Counter Fraud assessments conducted in August 2019.

### **Decision making to date**

2. The updated Strategy was reviewed by SMT (Senior Management Team) on 9<sup>th</sup> September. Feedback from Cabinet Office was shared with SMT and noted.

### **Action required**

3. The Committee are requested to approve the strategy; fraud risk assessment and note the Counter Fraud, Functional Standards Assessment (CFFS).

### **Background**

4. The Committee are reminded that in August 2019 as part of the Governments drive to embed counter-fraud within public sector organisations, we assessed

ourselves against the Government Functional Standard: Counter Fraud. At this point we assessed we had met the 'basic' standard.

5. We submitted various documents to the Cabinet Office on the 30<sup>th</sup> of August 2019 and were awaiting their feedback. An early-stage review by the Department of Health and Social Care Anti-Fraud Unit (DHSC AFU) has now been received (see annex A) where it shows whether the HTA has been compliant with the Government Counter Fraud Function Standards (GCFFS).
6. The overall position is a positive one, and we will continue to refine our processes and documentation in order that we can achieve full compliance.
7. One area of the standard requires us to develop and implement our Counter-Fraud Strategy. Attached at annex B is the latest version of our strategy.
8. The areas marked as 'partially met' are being addressed and below are updates to each area:
  - a. **4.2/4.3 Annual Action plan** – this is being amended to include mitigations for actions that have not been completed or are delayed and the quantifiable metrics to be added/amended.
  - b. **5.1 Fraud Risk Assessment** – this document will be shared annually with the Committee for approval with this meeting being the first. Committee to agree delegation to Director of Resources.
  - c. **5.6 Proactive detection activity** – whilst reviews are conducted quarterly and reported to Cabinet Office, the Fraud Risk Assessment will be amended to include dates of actions/controls and address actions that are overdue.
  - d. **5.7 Fraud awareness training** – we currently use Astute as our training platform that does have some relevant training modules. Training for the finance team is to be sourced. The recommendation that 3<sup>rd</sup> parties working for the HTA require training will be addressed by including PowerPoint slides or videos during the induction process.
9. The Committee are requested to note/comment on the attached documents and approve the Fraud Risk Assessment which is at Annex C.

## HTA Strategy

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### HTA Counter Fraud, Bribery and Corruption Strategy 2021-2024

#### Introduction

1. This strategy has been produced in order to promote and support the framework within which the HTA tackles fraud and theft and makes reference to the Bribery Act 2010. It sets out the aims and objectives of the Authority with respect to countering fraud and theft, whether it is committed externally or from within.
2. Awareness of, and involvement in, counter-fraud and anti-theft work should be a general responsibility of all, and the support of all staff is needed with clear direction from the CEO that there will be a zero-tolerance attitude to fraud with the HTA.

#### Purpose

3. The HTA is a small organisation with a less public-facing role than some other regulators, nevertheless our activities can expose us to inherent risk of fraud from both external and internal sources. Our commissioning and procurement of goods and services, our granting of Licences and site visits also presents inherent risks of corruption and bribery.
4. As well as financial loss, fraud and corruption also detrimentally impacts service provision, morale and undermines confidence in the HTA and public bodies more generally.
5. To date there is little evidence that these risks ('fraud risk') are a material risk for the HTA. This may be due to the established counter fraud arrangements as set out in the "Anti-fraud Policy", although such evidence can, of course, only be based on what is known. There is, however, robust evidence that overall, fraud risk in the public sector is increasing, due partly to more sophisticated methods of fraud but also diverse ways of delivering service and revised management arrangements.

6. It is therefore essential that the HTA regularly assesses its exposure to fraud risk and ensures that its counter fraud arrangements and the resources allocated to managing the risks are appropriate – that the controls are effective and aligned to best practice. Overall, the Anti-Fraud Policy commits the HTA to achieving an anti-fraud and theft culture that promotes honesty, openness, integrity, and vigilance in order to minimise fraud, theft, and its cost to the HTA.
7. This Strategy therefore sets out what the HTA will need to do over the period 2021 to 2023 to successfully fulfil this commitment.
8. Many controls to manage fraud risk are already in place but these need to be maintained and where necessary, improved to help keep pace with the increased level of perceived risk. There are also other controls that either are needed or may be needed, depending on the overall assessment of fraud risk and the resources available.
9. Implementation of the Strategy will help the HTA to achieve its strategic objective of improving standards through intelligence and meet the Cabinet Office Functional Standards released in 2018.

## **Scope**

10. All references to fraud within this Strategy include all types of fraud-related offence, i.e., theft, corruption, and bribery.
11. The Strategy covers all business, activities and transactions undertaken by the HTA or on its behalf, and therefore applies to all Members and all who work for the HTA<sup>1</sup>.

## **Basis – What has informed the Strategy**

12. The HTA's counter-fraud arrangements are based on the Cabinet Office Government Functional Standard for Counter Fraud. These Standards set the expectations for the management of fraud, bribery, and corruption risk in all government organisations.
13. This standard sets out key principles:

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<sup>1</sup> Employees including casual staff and agency staff, consultants, contractors, and partners.

<b>Strategic Governance</b>	Accountabilities and responsibilities for managing fraud, bribery and corruption risk are defined across all levels of the organisation
<b>Inform and Involve</b>	Staff have the skills, awareness, and capability to protect the organisation against fraud
<b>Prevent and deter</b>	Policies, procedures, and controls are in place to mitigate fraud, bribery and corruption risks and are regularly reviewed to meet evolving threats
<b>Investigate and sanction</b>	Thoroughly investigate allegations of fraud and seek redress
<b>Continuously review and hold to account</b>	Systems in place to record all reports of suspected fraud, bribery and corruption are reviewed, intelligence feeds into the wider landscape

14. This Strategy has been informed by a detailed assessment against these principles using the Functional Standards Maturity model and an organisational fraud risk assessment. The HTA has assessed itself as being non-compliant against the standard currently.
15. The basis of this Strategy is therefore to address those areas of the standard that must be met and developed in order that the HTA can move towards embedding the counter-fraud culture envisaged by the functional standards.
16. Not all areas of the standard are relevant to the HTA as the standard applies to organisations of varying sizes and type within the UK, and not all recommendations are therefore proportionate to the risks faced.
17. Detailed fraud assessments have been carried out during the period of this strategy. The outcome of these assessments has highlighted those areas of our organisation that are susceptible to fraud. The main area identified is within Travel and Subsistence and actions are being taken to mitigate the risk.
18. There are other areas of fraud risk, such as Cyber risk, mandate fraud and procurement which are considered to be business as usual and therefore are managed via the operational and strategic risk registers.



## **Objectives – Where the HTA needs to be**

19. Based on the five principles of the Counter Fraud Functional Standards above, the objectives below set out what the HTA will need to be achieving by 2022 in order to fully have met the basic standard.

- a) Conduct fraud risk assessment of existing and new fraud threats to ensure appropriate actions are taken to mitigate identified risks.
- b) Creation of a counter-fraud culture across the organisation through training and communication.
- c) Maintain effective systems, controls, and procedures to facilitate the prevention and detection of fraudulent and corrupt activity.
- d) Effective response and investigation of suspected cases of fraud and corruption and pursue redress and effective sanctions, including legal action against people committing fraud.
- e) Implement reporting of counter-fraud performance by establishing key metrics for reporting on counter-fraud activity and fraud cases.

## **Implementation**

20. Implementation of this Strategy takes account of the controls that are already in place to mitigate fraud risk. High-level actions that are complete or to be completed to achieve the above objectives are at Annex A.

## **Accountability**

21. The Director of Resources is the SMT (Senior Management Team) member responsible for counter fraud and has delegated responsibility for maintaining, reviewing, and implementing this Strategy to the Head of Finance and Governance.

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

23. A report on progress on implementing this Strategy will be provided to the Audit, Risk and Assurance Committee (ARAC) in addition to the Department of Health and Social Care Anti-Fraud Unit (DHSC AFU).

24. The effectiveness of counter fraud controls is assessed in part by Internal Audit reviews, and an overview of the effectiveness of our mitigating controls are

contained in the Internal Audit reports submitted to ARAC. Any strategic concerns could be raised in these reports.

### **Measures of success**

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

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

### **Reporting and review**

26. The HTA's approach to suspected fraud can be demonstrated in its Fraud Response Plan contained in the [Anti-Fraud Policy](#)

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

28. The Chief Executive and the Director of Resources are responsible for ensuring the HTA has a robust anti-fraud and corruption response.

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

**Annex A: Strategic Action plan FY 2021-23**

<b>Strategic Governance</b>					
<b>Action</b>	<b>Description</b>	<b>Core Discipline</b>	<b>Due date</b>	<b>Outcome</b>	<b>Owner</b>
Roles and responsibilities	Assign accountable individual responsible for delivery of counter-fraud strategy, senior lead for counter-fraud activity	Leadership, Management and Strategy	Agreed June 2019	Director of Resources assigned as Accountable individual	Head of Finance and Governance
Annual Action Plan	Produce annual action plan that includes actions to mitigate high risk areas	Prevent	Created July 2019 then annually	Delivery of strategy	Head of Finance and Governance
Strategy	Develop Strategy for counter fraud, bribery, and corruption which will detail our arrangements for counter fraud, bribery, and corruption	Leadership, Management and Strategy	Developed August 2019 and updated August 2021	Embed counter fraud	Director of Resources

<b>Inform and Involve</b>					
<b>Action</b>	<b>Description</b>	<b>Core Discipline</b>	<b>Due date</b>	<b>Outcome</b>	<b>Owner</b>
Risk Assessment	Identify and assess HTA's fraud risk exposure affecting principle activities in order to fully understand changing patterns in fraud and corruption threats and potential harmful consequences to the authority	Risk Assessment	Complete July 2019 then annually July 2020 Aug 2021	Controls implemented for fraud risks identified	Head of Finance and Governance
Awareness	Raise awareness of fraud and corruption by running awareness campaigns, staff surveys	Culture	Ongoing throughout the duration of the strategy 'Fraud' page on WAVE	Improved staff awareness	Head of Finance and Governance
Training	Actively seek to increase the HTA's resilience to fraud and corruption through fraud awareness by ensuring that all existing and new employees in all directorates undertake a fraud and corruption e-learning course	Culture	November through January annually Astute Training platform	All staff have undertaken fraud awareness training via e-Delta	Heads of Finance and Governance and HR

<b>Prevent and Deter</b>					
<b>Action</b>	<b>Description</b>	<b>Core Discipline</b>	<b>Due date</b>	<b>Outcome</b>	<b>Owner</b>
Policies	Refresh and promote the HTA's suite of anti-fraud related policies and procedures to ensure that they continue to be relevant to current guidance.	Leadership, Management and Strategy	Annually, each September	Updated policies.	Head of Finance and Governance
Internal Audit	Use of Internal Audit review to identify further weaknesses	Prevent	February Payables and Receivables audit Cyber Security Audit conducted in 2020/21	Assurance to ARAC	Director of Resources
Intelligence	Use of information and intelligence from external sources to identify anomalies that may indicate fraud	Prevent	January 2022 subject to agreement with DHSC AFU	Increased awareness, additional controls implemented	Head of Finance and Governance

<b>Investigate and sanction</b>					
<b>Action</b>	<b>Description</b>	<b>Core Discipline</b>	<b>Due date</b>	<b>Outcome</b>	<b>Owner</b>
Reporting	Produce fraud investigation outcome reports for management which highlight the action taken to investigate the fraud risks, the outcome of investigations e.g., sanction and recommendations to minimise future risk of fraud	Leadership, Management and Strategy	November, then quarterly as standing item on ARAC agenda	Management feels assured and sighted on any actual fraud and resulting investigations	Director of Resources
Recording	System for recording of and progress of cases of fraud to be utilised where practicable	Leadership, Management and Strategy	On-going and when necessary HTA has access to DHSC AFU team	Database of intelligence that feeds into DHSC AFU's benchmarking data	Director of Resources

<b>Review and held to account</b>					
<b>Action</b>	<b>Description</b>	<b>Core Discipline</b>	<b>Due date</b>	<b>Outcome</b>	<b>Owner</b>
Embedding the standard (GovS 013)	Maintaining staff awareness through consistent sharing of information.	Culture	On-going	100% of staff complete fraud training, survey results positive	Head of Finance and Governance
Sharing	Reporting quarterly to Cabinet Office' Consolidated Data Requests	Leadership, Management and Strategy	Commenced in Sept 2019 and quarterly thereafter	Basic to maturing standard met	Director of Resources

## Revision history

**Reference:** HTA-STR-001

**Author(s):** Head of Finance and Governance

**Reviewed by:** SMT

**Approved by:** ARAC

**Owner:** Director of Resources

**Distribution:** All staff, Board, ARAC

**Protective Marking:** OFFICIAL

- (30/08/2019 / Version 1.0: Strategy created and approved by ARAC)
- (31/08/2021 / Version 1.1: Reviewed, updated with actions)



Department  
of Health &  
Social Care

## **Government Functional Standard GovS 013: Counter Fraud**

### **Human Tissue Authority (HTA) Review 2021**



Overall Rating .....	3
Executive Summary .....	4
Accountable Individual .....	5
Strategy .....	6
Annual action plan .....	8
Outcome based metrics .....	10
Fraud Risk Assessment .....	12
Policy and Response Plan .....	14
Reporting routes .....	15
Loss reporting routes .....	17
Fraud awareness training .....	21
Polices and registers for gifts and hospitality and conflicts of interest .....	24
Contacts.....	26

## Overall Rating

GovS 013 element	Standard	Rag rating
4.4.2	Accountable Individual	Met
4.1	Strategy	Met
4.2	Annual action plan	Partially met
4.3	Outcome based metrics	Partially met
5.1	Fraud risk assessment	Partially met
5.2	Policy and response plan	Met
5.3	Reporting routes	Met
5.4	Loss reporting	Met
5.5	Access to trained investigators	Met
5.6	Proactive detection activity	Partially met
5.7	Fraud awareness training	Partially met
5.8	Policies and registers for gifts and hospitality and conflicts of interest.	Met

Overall: Based upon information reviewed, 7 standards are met and 5 standards are partially met.

# Executive Summary

The DHSC Anti-Fraud Unit (AFU) agreed to conduct an early stage review of HTA's compliance with the Government Counter Fraud Functional Standards (GCFFS). This desktop analysis is to help identify any gaps in adherence to Government Functional Standard GovS 013: Counter Fraud.

In order to demonstrate full adoption of the remaining 5 "partially met" standards recommendations need to be implemented as detailed under each standard.

# Accountable Individual

4.4.2: Organisations shall have an accountable individual at board-level who is responsible for counter fraud, bribery and corruption.			
RAG	Not Met	Partially met	Met
Criteria	No accountable individual for counter fraud, bribery and corruption (DG / FD grade or equivalent).	N/A	Accountable individual in post for counter fraud, bribery and corruption (DG / FD grade or equivalent).
Rating			X
Comments			
<p>The HTA Director of Resources is listed as the accountable individual - Richard Sydee.</p> <p>Evidence and supporting documents:</p> <p>HTA Counter Fraud Strategy 2019-2022.</p> <p>Areas for improvement:</p> <p>Rating: Met</p>			
Date Reviewed	13/07/21	Reviewed By	Mark Richardson.

# Strategy

4.1: The organisation has a counter fraud strategy that has been approved by the board or executive risk committee.			
RAG	Not Met	Partially met	Met
Criteria	<p>The organisation does not have a counter fraud strategy or;</p> <p>the counter fraud strategy is not informed by a fraud risk assessment (to ensure the strategy is relevant to the organisation's context and key fraud risks it faces).</p>	<p>The organisation has a counter fraud strategy that partially meets some of the elements in GovS 013:</p> <p>Limitations include – not assessing the main fraud risks and challenges facing the organisation;</p> <p>Not assessing how the fraud landscape may change (how wider macro trends will change the organisation's fraud risk profile or its operating environment);</p> <p>Not articulating where the organisation wants to be in the next 2-5 yrs (how it will adapt and develop its counter fraud arrangements);</p> <p>Not detailing counter fraud activity for the period of the strategy; and/or,</p> <p>Not having a counter fraud strategy that has been approved by the organisation's board or executive risk committee.</p>	<p>The organisation has a counter fraud strategy in place that meets all aspects of GovS 013.</p> <p>The organisation's board and/or executive risk committee have approved the counter fraud strategy.</p>
Rating			X
Comments  HTA have a Counter Fraud Strategy which meets the key areas set out above and has been approved by their Audit, Risk and Assurance Committee.			

<p>Evidence and supporting documents:</p> <p>HTA Counter Fraud Strategy 2019 - 2022</p> <p>Areas for improvement:</p> <p>The next iteration of the strategy should explicitly state the organisation's board and/or executive risk committee have approved the counter fraud strategy.</p> <p>Rating: met</p>			
Date Reviewed	14/07/21	Reviewed By	Mark Richardson

# Annual action plan

4.2: The organisation has an annual action plan that summarises key actions to improve capability, activity and resilience in that year.			
RAG	Not Met	Partially met	Met
Criteria	No annual action plan in place.	<p>The organisation has an annual action plan, but the actions do not align to the counter fraud strategy.</p> <p>Some actions do not have responsible owners or timescales for delivery.</p> <p>Progress against the action plan is not tracked and managed.</p>	<p>The organisation has an annual action plan that meets all aspects of GovS 013.</p> <p>The action plan is linked to the counter fraud strategy.</p> <p>The action plan is tracked and managed (progress against the plan is monitored and reviewed).</p>
Rating		X	
<p>Comments</p> <p>HTA has an action plan, but is not clear what mitigating action is or will be taken for actions that are delayed. Column B of the action plan suggests "actions" but these appear to be "themes" rather than actions?</p> <p>Evidence and supporting documents:</p> <p>HTA Action Plan and Metrics.</p> <p>Areas for improvement:</p> <p>It is recommended that the action plan includes mitigating activity for actions which are off track.</p> <p>Rating: Partially met</p>			

**HTA Counter Fraud Functional Standards Review**

Date Reviewed	13/07/21	Reviewed By	Mark Richardson.
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## Outcome based metrics

4.3: The organisation has outcome based metrics summarising what outcomes they are seeking to achieve that year. For organisations with 'significant investment' in counter fraud or 'significant estimated' fraud loss, these should include metrics with a financial impact.			
RAG	Not Met	Partially met	Met
Criteria	<p>No metrics in place or defined outcomes against counter fraud activity / initiatives or investments.</p> <p>No financial metrics (where there is a 'significant investment' in counter fraud or 'significant estimated' fraud loss).</p>	<p>The organisation has metrics against counter fraud activity / initiatives or investments but no evidence of tracking or monitoring to ensure the outcome and/or benefit is realised.</p> <p>No financial metrics (where there is a 'significant investment' in counter fraud or 'significant estimated' fraud loss).</p>	<p>The organisation has metrics against counter fraud activity / initiatives or investments.</p> <p>Activities are monitored / reviewed to ensure the potential benefit is realised.</p> <p>The organisation has financial metrics (where there is a 'significant investment' in counter fraud or 'significant estimated' fraud loss).</p>
Rating		X	
<p>Comments</p> <p>To move this rating to "met" more quantifiable targets/metrics should be included within the Action Plan. For example, at present the workplan refers to "Staff to undertake awareness training" - but the metric should include a target %. Also, it is not clear what the difference between Refs 5 and 6 of the plan is - are the two training packages referred to different?</p> <p>Evidence and supporting documents:</p> <p>Annual Action Plan.</p> <p>Areas for improvement:</p>			

Clear and SMART targets need to be introduced. It is recommended that metrics are detailed, showing regular monitoring and progress across the financial year and new actions added as appropriate to demonstrate the current and emerging fraud landscape.

Rating: Partially met

Date Reviewed	15/07/21	Reviewed By	Mark Richardson.
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# Fraud Risk Assessment

5.1: The organisation has a fraud risk assessment that is submitted to the centre.			
RAG	Not Met	Partially met	Met
Criteria	No fraud risk assessment in place (high level or detailed).	<p>The organisation has undertaken a high-level or detailed fraud risk assessment however its effectiveness is limited:</p> <ul style="list-style-type: none"> <li>• Fraud risks are not fully identified;</li> <li>• Fraud risks have not been assessed and carry an inherent risk rating;</li> <li>• Existing fraud controls are not detailed (where they exist);</li> <li>• The effectiveness of each control is not considered;</li> <li>• Residual fraud risks have not been assessed (rated or described).</li> <li>• No consideration given to additional controls in response to unacceptable levels of residual fraud risk.</li> <li>• The fraud risk assessment has not been reviewed within the last year.</li> </ul>	<p>The organisation has undertaken a high-level or detailed fraud risk assessment that meets all of the following:</p> <ul style="list-style-type: none"> <li>• Fraud risks are clearly identified and carry an inherent risk rating;</li> <li>• Existing fraud controls are detailed, with narrative on how they mitigate the risk;</li> <li>• Residual fraud risks have been assessed / rated with a narrative on the risk that remains;</li> <li>• Additional fraud control activity is considered where existing control activity does not reduce residual risk to an acceptable level.</li> <li>• The fraud risk assessment is regularly reviewed (e.g. within the last year).</li> </ul>
Rating		X	
Comments			

A clear Fraud Risk Assessment has been provided but it is not clear if it was approved by the HTA Audit and Risk Assurance Committee (ARAC) or the date of its creation/date of next update. Minutes from the HTA ARAC on 12 June 2019 suggest counter fraud issues were discussed in some detail but approvals appear to have been delegated or are not clearly set out.

Evidence and supporting documents:

HTA Fraud Risk Assessment

Areas for improvement:

Further information is needed on the Fraud Risk Assessment and whether it has been delegated from, for example the ARAC, to an individual Director?

needs to be explicitly approved by the HTA ARAC.

Rating: Partially met

Date Reviewed	15/07/21	Reviewed By	Mark Richardson
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# Policy and Response Plan

5.2 : The organisation has a policy and response plan for dealing with potential instances of fraud.			
RAG	Not Met	Partially met	Met
Criteria	No policy or response plan in place.	The organisation has a policy and response plan that partially meets GovS 013.	The organisation has a policy and response plan that fully meets GovS 013.
Rating			X
<p>Comments</p> <p>Whilst a HTA Whistleblowing Policy was provided and the HTA Anti-Fraud, Bribery and Corruption Policy.</p> <p>Evidence and supporting documents:</p> <p>HTA Whistleblowing Policy</p> <p>HTA Anti-Fraud, Bribery and Corruption Policy</p> <p>Areas for improvement:</p> <p>Rating: Met.</p>			
Date Reviewed	15/07/21	Reviewed By	Mark Richardson

# Reporting routes

5.3 : The organisation has well established and documented reported routes for staff /contractors and members of the public to report fraud and a system for recording referrals and allegations.			
RAG	Not Met	Partially met	Met
Criteria	No reporting routes, whistleblowing lines or systems for recording referrals or allegations of suspected fraud.	<p>The organisation has some reporting routes in place, but not across all channels.</p> <p>The organisation does not have a case management system or tool for recording referrals or allegations of suspected fraud.</p>	The organisation has reporting routes across all channels and systems / tools in place for recording referrals and allegations of suspected fraud.
Rating			X
<p>Comments:</p> <p>Evidence and supporting documents:</p> <p>HTA Anti-Fraud, Bribery and Corruption Policy</p> <p>HTA Whistleblowing Policy</p> <p>Areas for improvement:</p> <p>Evidence is needed of the HTA policy and response plan</p> <p>Rating: Met</p>			
Date Reviewed	15/07/21	Reviewed By	Mark Richardson

# Loss reporting routes

5.4 : The organisation reports quarterly identified loss from fraud and error, alongside associated recoveries and prevented fraud to Cabinet Office in line with the agreed government definitions.			
RAG	Not Met	Partially met	Met
Criteria	<p>The organisation does not report identified loss to Cabinet Office in line with the agreed government definitions.</p> <p>Fraud losses are not disclosed or reported.</p>	<p>Fraud losses are disclosed, but are not reported to the Cabinet Office in line with the agreed government definitions / CDR process.</p>	<p>The organisation reports losses to Cabinet Office in line with the agreed government definitions / CDR process.</p> <p>Quarterly CDRs are supplied.</p>
Rating			X
<p>Comments</p> <p>2020/21 CDR for HTA received, this was first year ALBs had to submit CDR.</p> <p>Areas for improvement:</p> <p>Rating: Met</p>			
Date Reviewed	15/07/21	Reviewed By	Mark Richardson



## Access to Trained Investigators

5.5 : The organisation has access to trained Investigators that meet the public sector skill standard.			
RAG	Not Met	Partially met	Met
Criteria	The organisation does not have access to trained Investigators that meet the public sector skill standard.	The organisation has a plan in place to up skill its Investigators to meet the public sector skill standard within the next year.	The organisation has access to trained investigators (via another government Dept /approved supplier or GIAA) or employs Investigators that meet the public sector skill standard.
Rating			X
<p>Comments:</p> <p>HTA Anti-Fraud, Bribery and Corruption Policy makes clear investigations will be referred to the DHSC AFU.</p> <p>Evidence and supporting documents:</p> <p>HTA Whistleblowing Policy</p> <p>HTA Anti-Fraud, Bribery and Corruption Policy</p> <p>Areas for improvement:</p> <p>Evidence is needed of the HTA fraud policy, any DHSC AFU involvement and response plan.</p> <p>Rating: not met</p>			
Date Reviewed	15/07/21	Reviewed By	Mark Richardson

## Proactive detection work

5.6 : The organisation undertakes activity to try and detect fraud in high-risk areas where little is known of current fraud levels. This can include loss measurement activity (FMA) or the use of data sharing and analytics.			
RAG	Not Met	Partially met	Met
Criteria	<p>No attempt to detect fraud or measure loss levels in high risk areas.</p> <p>No provision in the use of data or fraud data analytics to detect fraud.</p>	<p>The organisation undertakes some activity to detect fraud in some high risk areas.</p> <p>Some use of data and exception reporting to flag anomalous transactions.</p>	<p>Fraud loss measurement exercises are undertaken across high risk areas (via the FMA programme or other)</p> <p>The organisation is proactive in using fraud data analytics to detect fraud.</p>
Rating		X	
<p>Comments</p> <p>Fraud Risk Assessment (FRA) provided, however, it would benefit from "due dates" for risks.</p> <p>Evidence and supporting documents:</p> <p>HTA FRA</p> <p>Areas for improvement:</p> <p>Review FRA and address any overdue areas.</p> <p>Rating: Partially met.</p>			

Date Reviewed	15/07/21	Reviewed By	Mark Richardson
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# Fraud awareness training

5.7 : Staff have access to and undertake fraud awareness training as appropriate to their role.			
RAG	Not Met	Partially met	Met
Criteria	<p>Fraud awareness training is not available</p> <p>Fraud awareness training is not undertaken by staff (annually and/or as part of the induction programme).</p>	<p>Some evidence of fraud awareness training, but undertaken by all staff</p> <p>No provision for role specific training.</p>	<p>Fraud awareness training is available to all staff.</p> <p>Staff undertake role specific training in roles that have greater exposure to fraud risk.</p>
Rating		X	
<p>Comments</p> <p>Some evidence of access to a training package provided such as relevant emails and a requirement for staff to complete generic counter fraud training. To raise this area to fully met more information and work is needed on the following areas:</p> <p>* what fraud awareness training is required and undertaken by 3rd parties working for the organisation; and</p> <p>* what role specific fraud awareness learning is completed by staff in roles where there is a greater exposure of risk, for example Finance.</p> <p>Evidence and supporting documents:</p> <p>HTA emails as set out above.</p> <p>Areas for improvement:</p> <p>It is recommended further that evidence is provided to demonstrate the standard.</p> <p>Rating: Partially met</p>			

Date Reviewed	15/07/21	Reviewed By	Mark Richardson

# **Policies and registers for gifts and hospitality and conflicts of interest**

5.8 : The organisation has policies and registers for gifts and hospitality and conflicts of interest.			
RAG	Not Met	Partially met	Met
Criteria	<p>No policies or registers in place.</p> <p>Staff members are unaware of responsibilities to declare gifts, hospitality or conflicts of interest.</p> <p>No management of conflicts of interest.</p>	N/A	<p>The organisation has registers and policies in place.</p> <p>Staff members declare gifts and hospitality and conflicts of interests in line with the agreed policy.</p> <p>Conflicts of interest are managed by the organisation.</p>
Rating			X
<p>Comments</p> <p>Comprehensive gifts and hospitality register in place and evidence of how conflicts of interest are managed by HTA.</p> <p>Evidence and supporting documents</p> <p>HTA Gifts and Hospitality Register</p> <p>Register of staff interests</p> <p>Register of members interests</p> <p>Areas for improvement</p> <p>Evidence should include a conflicts of interest register.</p> <p>Rating: Met.</p>			

Date Reviewed	15/7/21	Reviewed By	Mark Richardson
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# Contacts

Name	Job Title	Contact details (telephone number & Email)
Mark Richardson	AFU Senior Policy Manager	Email: <a href="mailto:mark.richardson@dhsc.gov.uk">mark.richardson@dhsc.gov.uk</a> T: 020 7972 1044

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## HTA Fraud Risk Assessment

Ref 1	Ref 2	Business Area	Process Area	Risk Identified	Likelihood	Impact	Inherent Risk Rating	Risk Response	Existing Controls	Likelihood	Impact	Residual Risk Rating	Residual Risk Rating (H/M/L)	Residual Risk	Risk Owner	Further Mitigating Action	Due Date
R11	INFORM	IT	Access to applications	Unauthorized access to applications - cyber-attacks	4	5	20	Mitigate	Permissions to applications controlled according to role within the organisation.	2	2	4	L		Head of IT	None	On-going
RF1	FINSUP	Finance	Suppliers	Account details changed without confirmation with supplier	4	4	16	Mitigate	Great Plains (GP) Audit trail reviewed and signed off by Head of Finance	2	3	6	M	Small number of changes to supplier details which may not be checked regularly	Head of Finance and Governance	Internal Audit review and follow-up (2021-22 date TBC)	End 2021/22
RP1	PRCCON	Procurement	Contract management	Change in delivery address diverting consumables	3	5	15	Avoid	Contracts agreed where delivery is automated and agreed delivery address is never amended from 2 Redman Place unless authorised by Director of Finance and Resources	2	4	8	M	If attempted, cannot be certain supplier will not comply with both HTA and their own policy to confirm change.	Director of Resources	None	On-going
RF2	FINEXP	Finance	Expense claims	Claiming for private expenses - by adding to legitimate expense claims	3	5	15	Mitigate	Expenses are checked by Finance and other staff within teams prior to payment	1	4	4	L		Head of Finance and Governance	Low value, a review of previous quarters submissions as cut-off is 3 months	Monthly 2021/22 Jul-21 Oct-21 Jan-22
RF3	FINEXP	Finance	Expense claims	Multiple claims for the same expense	3	5	15	Mitigate	Expenses are checked by finance team prior to payment	2	3	6	M	A few could slip through due to the manual process	Head of Finance and Governance	Periodic check of stock by IT and Finance	Jan-22 Jan 2021 Jan 2022
R12	INFORM	IT	Asset tracking	Theft of IT equipment (not fraud)	3	5	15	Mitigate	Staff responsible for ensuring security of equipment Spare kit is kept securely in one location	2	3	6	L	??	Head of IT		
R13	INFORM	REGS	Expense claims	Claiming for private expenses - by adding to legitimate expense claims	3	4	12	Mitigate	Expenses checked/approved by Heads	2	4	8	M	Further check/challenge by payment authorisers which includes senior staff	All Heads of Service	Finance conduct final check before payment; HoF conducts audit periodically; payment approval by other senior staff	On-going/weekly till 31/03/22
R14	INFORM	REGS	Expense claims	Multiple claims for the same expense	3	4	12	Mitigate	Expenses checked/approved by Heads. Periodic check via Smart List in Great Plains against each employee	2	4	8	M	Finance conduct checks at point expense presented for payment. Period review against License number by running Smart List in Great Plains	Head of Finance	Finance conduct audit periodically; payment approval by other senior staff	On-going/monthly
R15	INFORM	REGS	Inspection	Inflated travel over-time claims	3	4	12	Accept	Prior approval to additional hours	1	3	3	L	Number of hours employee claimed to travel for work can be tracked using Google Maps, Trainline	Heads of Regulation	Possibility of refusal if employee cannot clearly demonstrate the hours were necessary	On-going prior to payroll cut-off 10th of each month
RF4	FINREC	Finance	Receipts	Depositing cheques into a third party account without authority	2	5	10	Mitigate	Bank reconciliations conducted.	1	3	3	L	Cheque depositor and reconciliation carried out by same person due to size of the team	Head of Finance and Governance	Cheques to be passed to HoF and confirmed when cleared at bank	Each month end
RP2	PRCPUR	Procurement	Purchases	C/Card used for personal purchase	2	5	10	Mitigate	Authorisation of usage (form) signed by budget-holder includes detail of required purchase	1	3	3	L		Head of Finance and Governance		On-going
RH1	HRPAY	HR	Payroll	Unauthorised change of account details	2	5	10	Mitigate	Segregation of duties; Expense check with member of staff to which account relates	1	4	4	L		Head of Finance and Governance		On-going
RH2	HRPAY	HR	Payroll	Use of ghost employees	2	5	10	Mitigate	Audit trail in place. Senior sign-off on any changes and the controls as in the above risk	1	4	4	L		Head of HR		On-going
RP3	INFORM	REGS	Inspection	Favourable inspection reports in return for financial inducement or gifts	2	5	10	Mitigate	Reports are moderated. Q&A carried out by senior staff	1	3	3	L		Director of Regulation	Raise awareness of staff through training; updated policies	Jun-21
RP4	PRCCON	Procurement	Contract management	Non-competitive bids to secure contract	3	3	9	Mitigate	Panel convened to review bids/tenders	1	3	3	L	Information gap could mean that an invoice for a contractor could be paid at higher hours but rate	Director of Finance and Resources	None at present as no tender process	N/A
RH3	PCRINV	Procurement	Invoicing	Inflated invoice for services (contingent labour)	2	4	8	Mitigate	Process of PO matching and sign-off on where invoice value differs to the Purchase Order Invoice approver differs from PO approver	1	3	3	L		Head of HR	None	On-going
RH7	HRPAY	HR	Payroll	Inproper changes to salary levels	2	4	8	Mitigate	Payments Policy in place, audit trail, senior sign-off on changes to salaries New supplier form signed off by senior member of staff	1	3	3	L		Head of HR	None	On-going
RF5	FINPAY	Finance	Payments	Payments fraudulently made to an account not related to a bonafide supplier or staff member	2	3	6	Mitigate	Dual authorisation of payments made Bank flags change in details	1	2	2	L		Head of Finance and Governance	None	On-going
RF6	FINTRAN	Finance	Transactions	Numerous journal entries without explanation	2	3	6	Mitigate	Journals are checked to the accounts and signed off by HoF. Annual audits (interim/final) Director review	1	1	1	L	Increase the frequency of review of journals	Head of Finance and Governance	None	On-going, end of the month
RH4	HRPAY	HR	Payroll	Inflated over-time claims	2	3	6	Mitigate	Line manager approval. Staff aware of anti-fraud policy and HTA's zero tolerance Mandatory training	1	3	3	M	Number of hours employee claimed to work cannot always be easily verified	All Line Managers	Possibility of refusal if employee cannot clearly demonstrate the hours were necessary	On-going each month end
RH5	HRDATA	HR	Recruitment	False qualifications	2	3	6	Mitigate	Checks made with issuing body if role requires a professional qualification such as Finance	1	2	2	L		Head of HR	None	On-going
RH6	HRDATA	HR	Absence management	Staff working whilst on sick leave (moonlighting)	2	3	6	Mitigate	Staff keep Line Manager informed. Certification/Dr sign-off is required. Dependent on length of absence. Occupational Health assessment SMT review of assumptions; disclosures in annual report; ARAIC oversight of Governance Statement Challenge by External Audit	1	2	2	L		Head of HR	None	On-going
RF7	FINMGT	Finance	Management estimates	Change in underlying assumptions in estimating liabilities to hide the truth	2	5	10	Mitigate		1	4	4	L		Director of Finance and Resources	None	Apr-21
RF8	FINPAY	Finance	Payments	Theft of HTA cheques	1	5	5	Mitigate	Cheques kept securely, access only via keypad	1	5	5	L		Head of Finance and Governance	None	On-going
RP5	PCRINV	Procurement	Invoicing	Invoice issued but service not delivered	2	2	4	Mitigate	PO must state period of which goods/service given. Contracts in place that will stipulate period. Challenge existence of goods/service from senior staff Procurement Policy; preferred suppliers via Crown Civil Service framework	1	2	2	L	If CCSS database does not provide the type of supplier needed there is currently no further check to ensure suggested supplier is not an employee who has a side business.	Head of Finance	Delay paying invoice until confirmation received	On-going
RP6	PRCPUR	Procurement	Purchases	Use of own company to purchase goods at inflated cost	1	4	4	Mitigate	New supplier form sign-off Declaration of interest; policy awareness	1	2	2	L		Director of Finance and Resources	Generate more awareness through all-staff meetings	TBC
R17	INFORM	REGS	Compliance	Use of HTA Logo without permission by establishments to attract funding	1	4	4	Accept	Regulation Teams relationship with Establishments are likely to result in them being made aware of unlicensed organisations	1	2	2	L	Yes - reliance on transparency of Establishments	Director of Regulation		On-going
R18	ITDATA	IT	Data	Personal data being utilised to impersonate	3	4	12	Mitigate	Check this with DT before submitting			0		MS 365 components can be used but requires updating our licences to the next level	Data Protection Officer?		
							0					0					
							0					0					TBC
							0					0					
							0					0					
							0					0					

# HTA Fraud Risk Assessment

Ref 1	Ref 2	Business Area	Process Area	Risk Identified	Likelihood	Impact	Inherent Risk Rating	Risk Response	Existing Controls	Likelihood	Impact	Inherent Risk Rating	Residual Risk Rating (H/M/L)	Residual Risk	Risk Owner	Further Mitigating Action	Due Date
R03	INFORM	REGS	Expense claims	Claiming for private expenses - by adding to legitimate expense claims	3	4	12	Mitigate	Expenses checked/approved by Heads	2	4	8	M	Further check/challenge by payment authorisers which includes senior staff	All Heads of Service	Finance conduct final check before payment; HoF conducts audit periodically; payment approval by other senior staff	On-going/weekly till 31/03/22
R04	INFORM	REGS	Expense claims	Multiple claims for the same expense	3	4	12	Mitigate	Expenses checked/approved by Heads. Periodic check via Smart List in Great Plains against each employee	2	4	8	M	Finance conduct checks at point expense presented for payment. Period review against Licence number by running Smart List in Great Plains	Head of Finance	Finance conduct audit periodically; payment approval by other senior staff	On-going/monthly
RP1	PRCCON	Procurement	Contract management	Change in delivery address diverting consumables	3	5	15	Avoid	Contracts agreed where delivery is automated and agreed delivery address is never amended from 2 Redman Place unless authorised by Director of Finance and Resources	2	4	8	M	Finance do not comply with both HTA and their own policy to confirm change	Director of Resources	None	On-going
RF1	FINSUP	Finance	Suppliers	Account details changed without confirming with supplier	4	4	16	Mitigate	Great Plains (GP) Audit trail reviewed and signed off by Head of Finance	2	3	6	M	Small number of changes to supplier details which may not be checked regularly	Head of Finance and Governance	Internal Audit review and follow-up (2021-22 date TBC)	End 2021/22
RF3	FINEXP	Finance	Expense claims	Multiple claims for the same expense	3	5	15	Mitigate	Expenses are checked by finance team prior to payment	2	3	6	M	A few could slip though due to the manual process	Head of Finance and Governance	Low value; a review of previous quarters submissions as cut-off is 3 months	Jul-21 Oct-21 Jan-22
RH4	HRPAY	HR	Payroll	Inflated over-time claims	2	3	6	Mitigate	Line manager approval. Staff aware of anti-fraud policy and HTA's zero tolerance Mandatory training	1	3	3	M	Number of hours employee claimed to work cannot always be easily verified	All Line Managers	Possibility of refusal if employee cannot clearly demonstrate the hours were necessary	On-going each month and
R02	INFORM	IT	Asset tracking	Theft of IT equipment (no fraud)	3	5	15	Mitigate	Staff responsible for ensuring security of equipment. Spare kit is kept securely in one location	2	3	6	L	??	Head of IT	Periodic check of stock by IT and Finance	Jan 2021 Jan 2022
RF8	FINPAY	Finance	Payments	Theft of HTA cheques	1	5	5	Mitigate	Cheques kept securely, access only via keypad	1	5	5	L		Head of Finance and Governance	None	On-going
RF2	FINEXP	Finance	Expense claims	Claiming for private expenses - by adding to legitimate expense claims	3	5	15	Mitigate	Expenses are checked by Finance and other staff within teams prior to payment	1	4	4	L		Head of Finance and Governance	None	Monthly 2021/22
RF7	FINMGT	Finance	Management estimates	Change in underlying assumptions in estimating liabilities to hide the truth	2	5	10	Mitigate	SMI review of assumptions; disclosures in annual report; ARAC oversight of Governance Statement	1	4	4	L		Director of Finance and Resources	None	Apr-21
RH1	HRPAY	HR	Payroll	Unauthorised change of account details	2	5	10	Mitigate	Challenge by External Audit	1	4	4	L		Head of Finance and Governance	None	On-going
RH2	HRPAY	HR	Payroll	Unauthorised access to applications - cyber-attacks	2	5	10	Mitigate	Segregation of duties. Finance check with member of staff to which account relates	1	4	4	L		Head of HR	None	On-going
R11	INFORM	IT	Access to applications	Use of absent employees	4	5	20	Mitigate	Audit trail in place; Senior sign-off on any changes and the controls as in the above risks	2	2	4	L		Head of IT	None	On-going
RF4	FINREC	Finance	Receipts	Unauthorised access to applications - cyber-attacks	4	5	20	Mitigate	Permissions to applications controlled according to role within the organisation.	2	2	4	L		Head of IT	None	On-going
RH3	PCRINV	Procurement	Invoicing	Depositing cheques into a third party account without authority	2	5	10	Mitigate	Bank reconciliations conducted. Annual audit testing	1	3	3	L	Cheque depositor and reconciliation carried out by same person due to size of the team. Information gap could mean that an invoice for a contractor could be paid at higher hours but rare.	Head of Finance and Governance	Cheques to be passed to HoF and confirmed when cleared at bank	Each month and
RH7	HRPAY	HR	Payroll	Inflated invoice for services (contingent labour)	2	4	8	Mitigate	Process of PO matching and sign-off on where invoice value differs to the Purchase Order	1	3	3	L		Head of HR	None	On-going
RH7	HRPAY	HR	Payroll	Invoice approver differs from PO approver	2	4	8	Mitigate	Payments Policy in place, audit trail, senior sign-off on changes to salaries	1	3	3	L		Head of HR	None	On-going
R05	INFORM	REGS	Inspection	Incorrect changes to salary levels	2	4	8	Mitigate	Prior approval to additional hours	1	3	3	L	Number of hours employee claimed to travel for work can be tracked using Google Maps, Trainline	Heads of Regulation	Possibility of refusal if employee cannot clearly demonstrate the hours were necessary	On-going prior to payroll cut-off 10th of each month
RP2	PRCPUR	Procurement	Purchases	Inflated travel over-time claims	3	4	12	Accept	Prior approval to additional hours	1	3	3	L		Head of Finance and Governance	None	On-going
RP2	PRCPUR	Procurement	Purchases	C/Card used for personal purchase	2	5	10	Mitigate	Authorisation of usage (form) signed by budget-holder includes detail of required purchase	1	3	3	L		Director of Finance and Resources	Raise awareness of staff through training, updated policies.	Jun-21
RP3	INFORM	REGS	Inspection	Favourable inspection reports in return for financial inducement or gifts	2	5	10	Mitigate	Reports are moderated. O&A carried out by senior staff	1	3	3	L		Head of Finance and Governance	None at present as no tender process	N/A
RP4	PRCCON	Procurement	Contract management	Non-competitive bids to secure contract	3	3	9	Mitigate	Panel convened to review bids/tenders	1	3	3	L		Head of Finance and Governance	None	On-going
RF5	FINPAY	Finance	Payments	Payments fraudulently made to an account not related to a bonafide supplier or staff member	2	3	6	Mitigate	New supplier form signed off by senior member of staff - Dual authorisation of payments - Dual review of payments made - Bank flags change in details	1	2	2	L		Head of Finance and Governance	None	On-going
RH5	HRDATA	HR	Recruitment	Checks made with issuing body if role requires a professional qualification such as Finance	2	3	6	Mitigate		1	2	2	L		Head of HR	None	On-going
RH6	HRDATA	HR	Absence management	False qualifications	2	3	6	Mitigate	Staff keep Line Manager informed. Certification/Dr sign-off is required. Dependent on length of absence. Occupational Health assessment	1	2	2	L		Head of HR	None	On-going
R17	INFORM	REGS	Compliance	Staff working whilst on sick leave (moonlighting)	2	3	6	Mitigate	Regulation Teams relationship with Establishments are likely to result in them being made aware of unlicensed organisations	1	2	2	L	Yes - reliance on transparency of Establishments	Director of Regulation	Delay paying invoice until confirmation received	On-going

**HFEA 5 Point Risk Scoring Matrix**

Inherent Risk Rating:

	Impact	Score				
Potential Impact	5	5	10	15	20	25
	4	4	8	12	16	20
	3	3	6	9	12	15
	2	2	4	6	8	10
	1	1	2	3	4	5
	1	2	3	4	5	
	Very Low	Low	Medium	High	Very High	
	Likelihood					

**Risk Prioritisation****Score**

Priority 1: Immediate Priority	20-25
Priority 2: High Priority	12-16
Priority 3: Medium Priority	5-10
Priority 3: Low Priority	3-4
Priority 4: Low Priority Very I	1-2

**Residual Risk Rating (After the risk response is applied)**

<b>VH</b>	=>90% likelihood of risk occurring
<b>H</b>	68-89% likelihood of risk occurring
<b>M</b>	34-67% likelihood of risk occurring
<b>L</b>	11-33% likelihood of risk occurring
<b>VL</b>	=<10% likelihood of risk occurring

## **Audit and Risk Assurance (ARAC) meeting**

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**Date:** 14 October 2021

**Paper reference:** 20/21

**Agenda item:** 12

**Author:** Morounke Akingbola

### **OFFICIAL**

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## **Reserves Policy**

### **Purpose of paper**

1. To provide the Committee with an update on the HTA's Reserves Policy.

### **Decision making to date**

2. The policy was last reviewed by the Committee in October 2020. The Committee agreed that the HTA (Human Tissue Authority) should maintain an ongoing minimum cash balance of £900k to facilitate its usual cash flow requirements plus a £600k buffer for exceptional events. Since then, the HTA has relocated to new offices where the overall accommodation costs are significantly lower compared to those of 151 Buckingham Palace Road, however our staff costs have increased due to pension increases.
3. Taking into account our updated accommodation costs, the original £600k buffer for exceptional events has reduced to £530k. It is recommended the minimum cash balance remains unchanged at £900k, therefore maintaining a reserves balance of £1.4m.
4. There have been previous discussions pertaining to a reduction in our cash reserves. Recently we have obtained a soft agreement from DHSC, (Department of Health and Social Care), Finance to utilise our reserves through overspending against budget. This will need to be factored into the budget setting process in the autumn and any fees review.

5. A summary of cashflow to the end of this financial year is attached for information. Based upon our projections where we have been very prudent as to cash collection and the fact that we are yet to see the effect of September's billing run, the attached policy has remained the same.
6. The Reserves Policy was reviewed and agreed by the SMT (Senior Management Team) on 9 September.

### **Action required**

7. ARAC Members are required to approve the attached policy.

## Cashflow for the year ended 31 March 2022



HTA  
Cash flow forecast  
Year ended 31 March 2022

	Mar-21 Actual	Apr-21 Actual	May-21 Actual	Jun-21 Actual	Jul-21 Actual	Aug-21 Forecast	Sep-21 Forecast	Oct-21 Forecast	Nov-21 Forecast	Dec-21 Forecast	Jan-22 Forecast	Feb-22 Forecast	Mar-22 Forecast	Total
Opening Balance	4,410,246	4,070,851	3,839,332	4,308,754	4,503,359	4,194,722	3,921,628	4,724,632	5,266,020	5,311,148	5,402,799	5,141,159	5,036,709	
<b>Revenue Receipts</b>														
Government Grant in Aid	-	-	-	176,000	-	-	198,000	-	-	199,000	-	198,000	-	771,000
Licence fees and other income	198,744	107,835	930,411	311,517	144,314	72,308	965,410	898,546	406,230	250,346	89,087	67,854	26,492	4,469,095
Other cash receipts	-	-	-	-	-	-	2,268	-	-	-	7,142	-	1,833	7,578
<b>Total receipts</b>	<b>196,911</b>	<b>107,835</b>	<b>930,411</b>	<b>487,517</b>	<b>144,314</b>	<b>72,308</b>	<b>1,165,678</b>	<b>898,546</b>	<b>406,230</b>	<b>449,346</b>	<b>96,229</b>	<b>265,854</b>	<b>24,660</b>	<b>5,247,673</b>
<b>Payments</b>														
Trade creditors	275,513	91,915	213,809	52,839	168,354	86,886	83,733	80,488	86,488	82,742	81,938	94,188	390,942	1,789,838
Other Cash payments	2,406	3,844	1,678	2,225	1,105	1,040	5,472	3,202	1,146	1,484	329	515	2,406	19,164
Salaries	131,974	128,949	124,655	122,307	128,068	156,046	165,738	165,738	165,738	165,738	167,031	167,031	167,031	1,956,045
PAYE & Niers & Pension	126,413	122,334	120,847	115,542	155,424	101,430	107,730	107,730	107,730	107,730	108,570	108,570	108,570	1,498,622
<b>Total Payments</b>	<b>536,306</b>	<b>339,354</b>	<b>460,989</b>	<b>292,912</b>	<b>452,951</b>	<b>345,402</b>	<b>362,674</b>	<b>357,158</b>	<b>361,103</b>	<b>357,695</b>	<b>357,869</b>	<b>370,305</b>	<b>668,950</b>	<b>5,263,668</b>
<b>Net Revenue Receipts/(payments)</b>	<b>(339,395)</b>	<b>(231,519)</b>	<b>469,421</b>	<b>194,605</b>	<b>(308,637)</b>	<b>(273,094)</b>	<b>803,004</b>	<b>541,388</b>	<b>45,127</b>	<b>91,651</b>	<b>(261,640)</b>	<b>(104,451)</b>	<b>(644,290)</b>	
<b>Total Revenue Cash Flow</b>	<b>4,070,851</b>	<b>3,839,332</b>	<b>4,308,754</b>	<b>4,503,359</b>	<b>4,194,722</b>	<b>3,921,628</b>	<b>4,724,632</b>	<b>5,266,020</b>	<b>5,311,148</b>	<b>5,402,799</b>	<b>5,141,159</b>	<b>5,036,709</b>	<b>4,392,418</b>	



# HTA (Human Tissue Authority) Policy

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## Reserves Policy

### Purpose

1. The purpose of this policy is to ensure that both the Executive and Board of the Human Tissue Authority are aware of the minimum level at which reserves need to be maintained and the reasons for doing so.

### Principle

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

## Reserves Policy

3. The HTA has a reserves policy as this demonstrates:
  - a) Transparency and accountability to licence fee payers and the Department of Health.
  - b) Good financial management.
  - c) Justification of the amount it has decided to keep as minimum reserves.
4. The following factors have been considered in setting this reserves policy:
  - a) Risks associated with its two main income streams, licence fees and Grant-in-aid, differing during the year from the levels budgeted.
  - b) Likely variations in regulatory and other activity both in the short term and in the future.
  - a) The HTA's known and likely commitments.
5. The policy requires reserves to be maintained at a level that ensures the HTA's core operational activities continue a day-to-day basis and, in a period of unforeseen difficulty, for a suitable period (refer to para 10 and 11).

## Cashflow

6. To enable sufficient cover for day-to-day operations, a cash flow forecast is prepared at the start of the financial year which takes into account the timing of when receipts are expected, and payments are to be made. Cash reserves are needed to ensure sufficient working capital is available throughout the year.
7. Normally the HTA experiences negative cash flow, (more payments than receipts), in the months July to August and again from November to April. Based on the forecast cash flow for 2021/22, there is an increase in the level of reserves, primarily due to the reduction in activity as a result of the COVID-19 restrictions and maintaining our income. We are recovering from regulated establishments and static expenditure base in 2021/22. Our reserves should be maintained such that there is always a positive cash balance.
8. The HTA is also mindful of the financial risks it faces, in particular that we may be required to undertake additional activities not planned or make additional spend not costed within budget. While every effort would be made to cover costs within the budget allocated for the year, it may be necessary to use reserves to meet the cash flow needs arising from additional necessary spend.
9. Funds of £0.9m are required to provide for adequate cash flow.

## Unforeseen difficulty

10. The level of reserves required for unforeseen difficulty is based on two elements: salaries (including employer on-costs) and the cost of accommodation. These are deemed to be fixed costs that would have to be paid in times of unforeseen difficulty with all other elements of HTA's running costs being regarded as semi-variable or variable costs and thus excluded from this calculation. These two areas currently represent **79%** of the HTA's total annual budget.
11. The certainty and robustness of HTA's key income streams and the predictability of fixed costs, as well as the relationship with our sponsor, DHSC (Department of Health and Social Care), indicate that 2 months' salary and accommodation costs is a prudent, but sufficient, minimum level of reserves to hold.
12. Based on the HTA's current revenue budget, the combined monthly cost of salaries and accommodation is around **£268k**. A reserve of two months would therefore be **£536k (rounded to £540k)**.

## Minimum reserves

13. The HTA's minimum level of reserves for 2020/21 will be maintained at a level that provides £540k for unforeseen difficulty and meets the cash flow volatility

requirement of £0.9m. The minimum cash reserves required for 2020/21 is therefore calculated as £1.4m. These reserves will be always in a readily realisable form.

14. Each quarter the level of reserves will be reviewed by the Director of Resources as part of the HTA's ongoing monitoring of its cash flow.
15. Each autumn as part of the HTA's business planning and budget setting process, the required level of reserves for the following financial year will be reassessed.
16. In any assessment or reassessment of its reserves policy the following will be borne in mind:
  - a) The level, reliability, and source of future income streams.
  - b) Forecasts of future planned expenditure.
  - c) Any change in future circumstances - needs, opportunities, contingencies, and risks – which are unlikely to be met out of operational income.
  - d) An identification of the likelihood of such changes in these circumstances and the risk that the HTA would not be able to meet them.
17. The HTA will include in its annual report and accounts a short statement about the level of reserves held and the reasons for holding these.
18. HTA's reserves policy will be reviewed annually by the Audit and Risk Assurance Committee.

## **Revision history**

**Reference:** HTA-POL-049

**Author(s):** Head of Finance and Governance

**Reviewed by:** HTA SMT (Senior Management Team)

**Approved by:** Audit and Risk Assurance Committee

**Owner:** Director of Resources

**Distribution:** HTA SMT (Senior Management Team) and the Board

**Protective Marking:** OFFICIAL

- (18/09/20 / Version 15.6: Reviewed and no changes were made)
- (26/08/21 / Version:16.0: Reviewed with changes to amount for unforeseen difficulty)

## **Audit and Risk Assurance (ARAC) meeting**

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**Date:** 14 October 2021  
**Paper reference:** 21/21  
**Agenda item:** 13  
**Author:** Morounke Akingbola

### **OFFICIAL**

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## **HTA Gifts and Hospitality Register**

### **Purpose of paper**

1. The purpose of this paper is to present to the Committee the Gifts and Hospitality Register as a standing item.

### **Decision making to date**

2. The register was reviewed by SMT (Senior Management Team) on 23rd September.

### **Action required**

3. The Committee are requested to note the one addition for the Government Arts Collection.

### **Background**

4. The HTA relocated to 151 Buckingham Palace Road (151 BPR) in December 2010. At this time, a number of artworks were donated to the HTA for the duration of its occupation.

5. When the HTA relocated to 2 Redman Place, an audit was conducted of the art works, and it transpired that one piece of artwork remained that was not on the HTA's register and did not belong to our then tenants NHS Resolutions.
6. It was agreed that the HTA should donate this artwork to the Government Arts Collection and a 'Deed of Gift' was signed on behalf of the HTA by Richard Sydee, Director of Resources, and the Government Arts Collection representative.
7. The Committee are requested to comment/note this donation.

## **Audit and Risk Assurance (ARAC) meeting**

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**Date:** 14 October 2021  
**Paper reference:** 21a/21  
**Agenda item:** 13  
**Author:** Morounke Akingbola

### **OFFICIAL**

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## **Declaration of Interests, Gifts and Hospitality Policy**

### **Purpose of paper**

1. To present the Committee with the Declaration of Interests, Gifts and Hospitality Policy for approval.

### **Decision making to date**

2. The policy was last reviewed by SMT (Senior Management Team) in October 2019 and presented to the Committee in January 2020. As per the review period, this policy is reviewed bi-annually.
3. SMT reviewed and approved the policy on 23<sup>rd</sup> September 2020.

### **Policy amendments**

4. There have been some small updates to the policy. The Committee are requested to note the following paragraphs that have been either amended or added as follows:
  - a. Para 10 - refers to the Ethical Code of the Chartered Institute of Purchasing and Supply.
  - b. Para 11 – Board Members are requested to provide updates to their declarations.

- c. Reference to other policies has been added at section 33.

### **Action required**

- 5. ARAC Members are required to approve the attached policy.



AUD 21b/21

Register of Gifts / Hospitality Received and Provided

Version: HTAG0001  
Oct-21

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
Provision	Artwork from 151 Buckingham Palace Road	Hanging in the HTA offices	01/07/2021	Unknown	151 BPR - HTA Office	Given	Human Tissue Authority	Richard Sydee	Director	Government Art Collection	Sarah McFadden

## HTA Policy

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### Declaration of Interests, Gifts and Hospitality Policy

#### Purpose

1. The aim of this policy is to enable the HTA to demonstrate both to the public at large and others in the sectors we regulate that its processes and decisions are objective and consistent, and to protect staff from unfair accusations of concealed interests.
2. All employees of the HTA should be aware of the Bribery Act 2010 which came into effect on 1 July 2011. This act creates specific offences of bribing, and being bribed, which apply to any function of a public nature; any activity performed in the course of a person's employment; and any activity performed by or on behalf of a body of persons.
3. All employees must ensure that they do not solicit or accept any financial or other advantage which results in the improper performance of their duties as an HTA employee.
4. This policy provides guidelines for the management of the registering of staff interests, and the accepting or refusing of gifts, considering the terms of the guidance to public bodies.

#### Scope

5. This policy applies to full time and part time employees on a substantive or fixed-term contract, Board Members and to associated persons such as secondees, agency staff contractors and others employed under a contract of service.
6. The Gifts and Hospitality Register will not be routinely published by the HTA, however, information contained in the register may be disclosed pursuant to any request for disclosure made under the Freedom of Information Act 2000.

#### Principles

7. It is acknowledged that in their role as employees of the HTA that individuals may be exposed to several potential conflicts of interests.

- Direct pecuniary interest – the most clear-cut situation where common law requires that executives with a direct pecuniary interest should not participate in the discussion or determination of matters.
  - Indirect pecuniary interest – again, common law requires that members of staff show consider whether participation in the preparation of items for discussion or discussion of a matter would suggest a real danger of bias. This should be interpreted in the sense that a member of staff might unfairly influence the case of a party to the matter under consideration. In considering whether a real danger of bias exists in relation to a particular decision, members of staff should assess whether they, a close family member, a person living in the same household as the HTA staff member, or a firm, business, or organisation with which the member of staff is connected are likely to be affected more than the generality of those affected by the decision in question. (A ‘close family member’ is regarded here as personal partners, parents, children, brothers, sisters, and personal partners of any of these.)
  - Professional/personal interests – These are more subjective, but it is just as important that they are declared. This would include involvement with a charitable trust or professional organisation within sectors or related clinical or scientific fields. Professional and personal interests are taken to include those not only of the individual staff member, but also interests of close family as defined above. It would also be necessary to make a declaration when asked to participate in preparing documents about specific issues for HTA Authority Members to discuss, if a member of staff has a close personal friend or previous association.
8. If in doubt, individuals are advised to declare the potential interest or at least consult the Director of Resources or relevant Director as soon as they are asked to participate in the preparation of an item for HTA or sub-Committee consideration. Anyone who is unclear about whether a particular interest constitutes a conflict of interest should discuss this with their line manager or Head of Finance in the first instance. The guiding principle is when in doubt it is better to ask for a record to be made, than not.

### **Declaration of Interests**

9. Staff should declare if they, their partners, family members or a close friend have financial, professional, or personal interests in: -
- Organisations licenced by the HTA, or other organisations involved the use, procurement of human tissue
  - Companies or individuals providing services for or bidding for contracts with the HTA.

10. All staff who are in contact with suppliers and contractors (including external consultants), and in particular those who are authorised to sign Purchase Orders, or place contracts for goods, materials, or services, are expected to adhere to professional standards as set out in the Ethical Code of Chartered Institute of Purchasing and Supply (CIPS).<sup>1</sup>
11. The Head of Finance periodically asks members of staff to update their details of personal and professional interests and will e-mail a form for completion and return (see appendix A). Any additional interests arising during the year should be e-mailed to the Head of Finance for inclusion in the Register of Interests. Board Members will be requested to provide updates also during the annual reporting process (December through March).

### Policy Statement

12. You must declare all offers of gifts and hospitality, made to or by you, regardless of value, in your role at the HTA. **All such offers must be declared whether accepted or declined.** Offers of gifts and hospitality may include items ranging from diaries, wall charts, and boxes of chocolates, to free international travel and accommodation.
13. Declarations must be recorded on HTA's Gifts and Hospitality Register (the register). The register is maintained by the Director of Resources and is potentially publicly available through Freedom of Information requests.
14. It is your responsibility to ensure that you are not placed in a position that risks, or appears to risk, compromising your role or the HTA's public and statutory duties. You should not secure valuable gifts and hospitality by virtue of your role at the HTA. You should not accept or provide any gift or hospitality while acting in an official capacity, if acceptance/provision will give the impression that you have been influenced/are deemed to be influencing the activity or work of the HTA.
15. This Policy also applies to spouses, partners, or other associates if it can be argued or perceived that the gift or hospitality is in fact for your benefit.
16. In exercising judgement as to whether to accept a gift or hospitality, the question should be asked what the public perception would be if the information were published given your role and circumstances.

### Receiving gifts

17. Staff are permitted to keep small, low value gifts e.g., promotional pens/mugs/calendars etc. All other gifts should be declined unless it is felt that to do so would cause embarrassment to the HTA. For example, to refuse a gift from an

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<sup>1</sup> The code can be found at: <https://www.cips.org/who-we-are/governance/cips-code-of-conduct/>

international delegation may cause embarrassment to both the HTA and the delegation.

18. All other gifts should be passed to the Director of Resources who, in conjunction with the Chief Executive, will decide on the most appropriate action, which may include:
  - Returning the goods to the supplier.
  - Sharing the gift with all staff.
  - Retaining the good within the HTA.
  - Donating the gift to charity; or
  - Allowing the member of staff to keep the gift.

### **Accepting offers of hospitality – genuine business reasons**

19. Hospitality offered should only be accepted where there is a direct link to working arrangements and a genuine business reason can be demonstrated, for example:
  - attendance or speaking at a conference, which provides complimentary subsistence.
  - attending a free training course; or
  - attending a reception for networking purposes.
20. It is recognised that, in the course of carrying out your duties, you will need on occasion to ensure good relationships with existing and future contractors and stakeholders and that this may involve for example, the receipt of modest working lunches and dinners. These are acceptable where there is a genuine business reason.
21. Hospitality invitations to events, which are purely social events, should be considered very carefully before accepting; in such circumstances, it may be much more difficult to substantiate a genuine business reason. All invitations should be recorded in the register whether received or declined.

### **Gifts and hospitality offered by the HTA**

22. HTA staff must be mindful that the value of all gifts and hospitality offered by the HTA are sourced from public funding, and the expectation is that such funding will be used for legitimate purposes and in keeping with value for money considerations.
23. In exceptional circumstances, it may be appropriate for the HTA to provide a gift of up to £50.00 in value, for example: providing a nominal gift to someone who spoke at an HTA conference free of charge.
24. It is acceptable for the HTA to provide modest hospitality in the way of working lunches and/or dinners to existing and potential contractors and stakeholders subject to a genuine business reason.

### **Declaration**

25. You should make your declaration as soon as possible after the offer or receipt of gifts or hospitality. All declarations are to go to the Head of Finance and Governance in the required format as shown below. The Head of Finance and Governance will record the declarations in the register. The register is an annual document and will be broken down and filterable by financial year. It is recommended that you make your declaration by email and retain a copy for your personal records.
26. Your declaration will need to include the following information:
- the date of any offers of gifts or hospitality, and the date of events where relevant.
  - the name, job title and the organisation of the recipient/provider.
  - the nature and purpose of the gift or hospitality received or declined.
  - the name of any other organisation involved.
  - the estimated value of the gift or hospitality.

**For example:**

Date received	12 Dec. 2016
Recipient (Name & Directorate)	Jane Brown (Resources)
Received from (Name, position & organisation Ltd)	Josh Sergeant (AAA)
Description of Gift/Hospitality received	Lunch
Value £ (Estimate if unknown)	Approx. £15.00
Reason given for providing gift/hospitality	Working lunch provided during contract discussions

27. Personal data of HTA employees processed by the implementation of this document will be done so in accordance with [HTA-POL-108 HTA HR Privacy Policy](#). Personal data of non-HTA employees processed by the implementation of this document will be done so in accordance with the HTA's [Privacy Notice](#).
28. You should consult the Director of Resources or Head of Finance and Governance for any guidance required on this Policy. **If you have any doubt about whether an item should or should not be accepted, you are advised to decline and declare it.**

**Monitoring**

29. The register will be reviewed quarterly by the Resources Directorate and provided to the Audit and Risk Assurance Committee at each meeting.
30. Staff will be reminded periodically of their requirement to declare gifts and hospitality provided/accepted/declined in accordance with this Policy.

**Training**

31. Staff will be required to undertake annual training via the Astute Learning platform.

### **Policy breach**

32. Staff who fail to declare the acceptance/provision/decline of hospitality and gifts in accordance with this policy may be subject to disciplinary action under the HTA's Disciplinary Policy.

### **Review**

33. This document will be reviewed every two years.

### **Other policies of relevance and references**

- Whistleblowing Policy
- Anti-fraud, Bribery and Corruption Policy
- Chartered Institute of Purchasing and Supply Ethical Code of the Chartered Institute of Purchasing & Supply (March 2013)

**HUMAN TISSUE AUTHORITY****HTA STAFF – REGISTER OF INTERESTS**

As a public body, the HTA is required to demonstrate that it has well defined and transparent arrangements for handling conflicts of interest, whether real or perceived. The HTA must be able to demonstrate both to the public at large and other stakeholders that its processes and decisions are objective and consistent.

An important mechanism for ensuring and demonstrating this objectivity is the maintenance of a register of interests. The Standing Orders require the Chief Executive to establish a register for Members of the Authority and staff. Members' register of interests is publicly available on the HTA website. A similar register of interests has been established for all staff. This register whilst not published on our website is available for inspection.

Members and staff should declare if they, their partners, relatives, or friend (as far as is known or might be considered significant) have financial, professional, or personal interests in: -

- establishments licensed by the HTA, or other organisations affected by the work of the HTA.
- Companies or individuals providing services for or bidding for contracts with the HTA.

If staff are in any doubt whether to declare an interest, this should be discussed with their manager or the Head of HR. It is better to declare something when in doubt.

Declaring an interest does not imply any inappropriate behaviour by staff, nor adversely affect your employment. There may be occasions when you are asked not to work on a specific issue if there is a conflict of interest as it is part of ensuring public confidence in the fairness and transparency of the HTA's decision making.

Please complete the form overleaf detailing any relevant interests including a "nil return."

We will be repeating this request for declarations in November and April (financial year-end). In the meantime, if your circumstances change, and a new interest arises that should be declared, please e-mail the Head of Finance and Governance at: [morounke.akingbola@hta.gov.uk](mailto:morounke.akingbola@hta.gov.uk).



Name \_\_\_\_\_

Address \_\_\_\_\_

Please complete Box A or Box B

**BOX A**

☐ I / my partner / relatives or friend (as far as is known or might be considered significant) have the following financial, professional, or personal interest in: -

\* Delete as appropriate

If not self, please state name of person with interest and relationship

\_\_\_\_\_

**Establishments licensed by the HTA, or other organisations affected by the work of the HTA (please give details)**

**Companies or individuals providing services for or bidding for contracts with the HTA (please give details)**

**BOX B**

☐ I have no interests to declare

Signed \_\_\_\_\_ Date \_\_\_\_\_

## **Revision history**

**Reference:** HTA-POL-051

**Author(s):** Head of Finance and Governance

**Reviewed by:** SMT

**Approved by:** Audit, Risk and Assurance Committee (ARAC)

**Owner:** Director of Resources

**Distribution:** Staff and HTA Board

**Protective Marking:** OFFICIAL

- Oct-19 / Version 1.3: No amendments)
- Nov-20 / Version 1.4: Minor amendments)
- August-21/ Version 1.4: Minor additions included reference to other policies)