Audit and Risk Assurance Committee Agenda

Date   15 October 2020
Time   10:00 – 12.00
Venue   Zoom meeting

Private Members Session:
ARAC Members private session (9:40 – 10:00)

Meeting:
Main ARAC meeting (10:00 – 12.00)

Agenda

1.	Welcome and apologies	
2.	Declarations of interest	Oral
3.	Minutes of 16 June 2020	(AUD 09/20)
4.	Matters arising from 16 June 2020 and forward plan	(AUD 10/20)
5.	ARAC Chair's Update	Oral
	Internal Audit (Confidential)	
6.	Internal Audit update	(AUD 11/20)
	Cyber Security review final report	Annex A
	Audit Tracking	
7.	Audit Tracker Update	(AUD 12/20)
	Risk Update	
8.	Risk Update	(AUD 13/20)
	• HTA Strategic Risk Register	Annex A
	• Risk Management Activity and plans for HTA's return to business as usual (Operational Risk Register)	Annex B
	• UK Transition	Oral
	• HTA Office Re-location update	Oral

	• Update on Risk appetite work	Oral
	Development Programme – Organisation Preparedness	
9.	Development Programme Report	(AUD 14/20)
10.	Cyber Security Strategy Update	(AUD 15/20)
	HA Risk Project	
11.	HA Risk Project Update and Progress	(AUD 16/20)
	LEEP Project update	
12.	LEEP Project status update	(AUD 17/20)
	Policy and Procedures	
13.	HTA Reserves Policy Update	(AUD 18/20)
	HTA Reserves Policy	Annex A
14.	HTA Gifts and Hospitality Register Update	(AUD 19/20)
	HTA Gifts and Hospitality Register	Annex A
	Regular reporting and updates	
15.	Reports on grievances, disputes, fraud and other information	Oral
16.	Topics for future risk discussions	Discussion
	Any other business	
17.	AOB	Oral

Meeting close- 12.00pm

Minutes of Audit and Risk Assurance Committee

Date	16 June 2020
Venue	Zoom
Protective Marking	OFFICIAL

Present	
Members	**In attendance**
Amanda Gibbon (AG, Chair) Glenn Houston (GH) Dr. Stuart Dollow (SD Dr. Charmaine Griffiths (CG) Prof. Gary Crowe (GC)	Allan Marriott-Smith (AMS, Chief Executive) Richard Sydee (RS, Director of Resources) Morounke Akingbola (MA, Head of Finance and Governance) Louise Dineley (LD, Director or Data, Development and Technology) David Thomson (DT, Head of Business Technology Item 10) Dr. Amy Thomas (AT, Head of Development) Nima Sharma (NS, Board Secretary, minutes)
Apologies Nicky Harrison, (NH, HTA) Jill Hearne (JH, NAO)	**External Attendees** Tony Stanley (AS, Government Internal Audit Agency) Karen Holland (KH, Government Internal Audit Agency) Audit Agency) Mike Surman (MS, National Audit Office) Jacky Cooper (JC, DHSC)

Item 1	Welcome and apologies
	1. Amanda Gibbon (the Chair) welcomed Members, HTA staff, and colleagues from the Department of Health and Social Care (DHSC), Government Internal Audit Agency (GIAA) and the National Audit Office (NAO). 2. The Chair noted apologies from Nicky Harrison and Jill Hearne.
Item 2	Declarations of Interest (Oral)
	3. The Chair asked Members to declare any personal or pecuniary interests in regard to the meeting's agenda; none were declared.
Item 3	Minutes of 30 January 2020 (AUD 01/20)
	4. The Chair asked the Committee if there were any further comments on the minutes from the 30 January meeting; there were none. The minutes were accepted as an accurate reflection of the meeting.
Item 4	Matters arising from minutes of 30 January 2020 and forward plan (AUD 02/20)
	5. The Chair noted that an update would be provided for actions arising from the meeting on 30 January 2020. Specifically, action three, the leavers and starters process, it was confirmed that a process has been designed and is being piloted. It was confirmed that evidence relating to the completion of this action would be shared with TS at Government Internal Audit.

	6. Members noted that action seven, relating to home working contracts, was paused at present to allow the Executive to reflect on how the offer may be adapted in light of HTA-wide adoption of remote working as a result of the COVID-19 pandemic. 7. The Chair advised that assurance mapping and the ARAC handbook could be removed from the matters arising log. The Chair also noted that there is still some work to do to ensure the Records Management Policy can be implemented. 8. The Committee noted the content of this update. **Action 1:** To remove completed actions from the matters arising log.
Item 5	**ARAC Chair's Update (Oral)**
	9. The Chair (AG) confirmed that she had: - Attended sessions with chair of staff forum; and - Held phone calls with Tony Stanley and Mike Surman in preparation for the meeting.

Item 6	**Internal Audit Update (AUD 03/20)**
	10. TS and KH attended from GIAA to provide an update on Internal Audit activity. KH introduced herself and the work of the GIAA. 11. AG invited TS to present the Anti-fraud Control and Payroll and Expenses audit reports to the Committee. He confirmed that the Anti-fraud Control audit was positive overall and resulted in an opinion of moderate assurance. He noted in particular that there are a good counter-fraud strategy, supporting policies and risk assessments. He noted that the high level recommendation, the provision of additional fraud training, had been completed with training delivered to all staff. Of the two medium level recommendations one had been completed and the other will be addressed later in the year with the delivery of a new HTA Handbook. 12. TS informed the Committee that there were a number of recommendations from the Payroll and Expenses audit, specifically a need to strengthen processes around payroll

changes, including additional signs offs and sample checking on payroll changes. MA confirmed that the existing SOP had been updated to reflect the recommendations set out in the audit and that these would need Internal Audit sign off.

13. Members agreed that since recommendation 8 was not agreed, the audit tracker should reflect what alternatives would be acceptable to Internal Audit to close this recommendation. These should be clearly set out in the audit tracker. Members emphasised that where there is a difference in opinion, it would be helpful if the Executive could clarify exactly what their response would be to each of the recommendations.

14. TS presented the Internal Audit plan and confirmed that SMT and Members had made comments on the timing and scope of some of the proposed audits in light of the current operating conditions.

15. Members sought assurance that the audit of inspection processes would examine consistency between sectors as well as within them and noted the additional risk that had arisen given that inspection activity had been suspended as a result of the pandemic. SMT confirmed that an assurance regime was being developed which did not involve a physical inspection, particularly for the Human Application sector and confirmed that the audit would look at ensuring cross-sector consistency.

16. Members and SMT were content to agree the audit plan as presented during the meeting.

17. TS presented the Annual Assurance Report which gave an overall opinion of moderate assurance for the year and he welcomed any questions around the assurance given as well as overall comments. No comments were made.

18. The Committee noted the content of this update.

Action 2: To review audit tracker to ensure where recommendations are not agreed there are suitable alternative suggestions stated.

7	Approval of Annual Report and Accounts (AUD 04/20)

19. RS presented this paper to the Committee and extended his thanks to Morounke Akingbola and Nicola Fookes for their work. He also extended his thanks to National Audit Office for their contribution during unusual operating conditions.

	20. RS informed the Committee that a few issues had been noted in the Accounts this year. He confirmed that there was a siginificant increase in staff costs due to higher pensions contributions.
	21. As a consequence of higher outstanding debt at the end of the financial year (resulting from COVID-19), the bad debt provision was increased in line with the HTA's accounting policy. Provision had also been made for additional travel costs incurred by staff as a result of the move to Stratford. Largely as a result of the additional provisions required, the year end outturn has resulted in a small overspend of c£40k.
	22. The NAO confirmed that an unqualified opinion is likely to be given when the accounts are signed. However, MS informed the committee that it has been challenging to complete routine physical checks on fixed assets because of the difficulty of accessing the building at 151 Buckingham Palace Road. MS highlighted that the letter of representation may need to include an assurance over the existence of certain assets, in particular the HTA's server.
	23. Members agreed that the report on page 105 in the papers should make it clear that additional funding for the transformation programme had been sought through releasing funds from the HTA's reserves rather than through seeking new external funding.
	24. Members confirmed they were content with the letter of representation and that it should include assurance about fixed assets that could not be verified during the audit if necessary (post meeting note- the verification of fixed assets was stated resolved in the NAO completion report).
	25. The Committee approved the annual report (annual governance statement) and accounts for signature by the Accounting Officer. The content of this paper was noted.
Item 8	**Audit Tracker Update (05/20)**
	26. MA presented this update and confirmed that were 47 recommendations on the audit tracker. MA presented each of the items open in the tracker to the Committee.
	27. TS confirmed that in terms of the key regulatory processes audit he had noted that legal awareness training had taken place. MA

confirmed that she would provide a copy of the calendar invitation for this training as evidence.

28. AG confirmed that it would be helpful to identify a target date for the Records Management work to come back to the Committee and that in the absence of this, a progress update should be provided in October with a review of the outstanding actions. SMT confirmed that discussions were taking place to ensure the phasing and sequencing of this work forms part of the HTA's emerging development plans.

29. An update was provided on a number of audit actions. These were as follows:

- Cyber Security - TS to give clear instructions about what is needed in order for this action be closed.
- Starters and leavers process - It was agreed that this would stay on the tracker and that TS would review the evidence to close this. It was agreed that the Head of HR would attend the October ARAC meeting to provide an update on this as well as the utilisation of capabilities audit.
- Business continuity and critical incident - It was agreed the actions would need further review once the HTA has relocated and that the move to new premises would necessarily trigger a requirement to draft a new critical incident plan. It was agreed that a paper on lessons learnt from the COVID-19 response would be brought to the October meeting and that Business Continuity would form a standing agenda item from the October meeting onwards.
- Payroll and expenses audit - It was agreed that the outstanding recommendations from this audit would be closed by October.

30. The Committee noted the content of this paper.

Action 3: MA to continue to work with TS to close any remaining actions.

Item 9	**Risk Update (06/20)**
	31. RS presented this paper to the Committee.
	32. He referred the Committee to the risk register and outlined that there had been increasing pressure in each of the 6 strategic risks. He confirmed that the Board had been provided with updates about this and that the HTA had adapted well to the pressures from the COVID-19 pandemic. He asked Members to note that there had been a considerable amount of stress on the Post-Mortem sector over the last quarter.

	33. RS provided the Committee with specific details for risk two. There were concerns that the HTA was not in a position to inspect at present, particularly, for newly licensed HA establishments and emergency mortuaries. Members questioned the Executive on how it was planning to maintain regulatory oversight in the face of an absence of inspection. A more detailed update would be provided to the full Authority at its forthcoming meeting.
	34. The Committee was referred to paragraph 14 of the paper which outlined a proposal for developing an overarching risk appetite statement. Members were informed that their input into shaping this process would be welcomed. It was proposed that further discussion would take place with Board members in a working group that would be convened in September.
	35. An update on the HTA's position in preparation for Brexit was provided.
	36. An update on the office relocation project was provided. It was acknowledged that the HTA would be re-defining how it would be expected to work in the midst of the pandemic and what changes would be required to the HTA's working practices. The Committee was informed that the Office Relocation Working Group would be reviewing social distancing practices.
	Action 4: To convene a working group to take forward work to reshape the HTA's management of risk.
Item 10	**Data, Technology and Development Update (including Cyber Security) (AUD 07/20)**
	37. LD presented this update to the Committee, sharing some reflections since the last meeting as well as a report on projects completed in quarter four. These included the launch of Office 365 and cloud migration which were both successfully completed.
	38. The Committee was informed that six targets for development had been prioritized which would be scoped out further. LD confirmed that an update would be given on projects such as the strengthening of horizon scanning and further IT developments, including the IT strategy, EDRMS and Office 365 development at the July Board meeting.

	39. Members asked whether the Executive had the right support to be able to plan for quarter two development projects. SMT confirmed that they would be exploring how to prioritise and make best use of resources and that funding had been ear-marked for development projects.
	40. DT provided an update on the Cyber Security Strategy and highlighted that the strategy focusses on the minimum safety standards and core principles to manage the risks the HTA is exposed to as an organisation.
	41. He informed the Committee that the HTA has a good understanding about cyber security and the potential risks. Members agreed that is is important to have increased awareness, reinforcing that cyber security is a responsibility of every staff member.
	42. Members questioned the Executive about the resources required to maintain cyber security. DT confirmed that an automated system will identify any cyber security risks so that the HTA can manage these. Members agreed that it would be helpful to build on the level of threat and the HTA's response to this.
	43. The Committee noted the consent of this paper.
	Action 5: To present a dashboard style report relating to cyber security risks.
Item 11	**SIRO Report (AUD 08/20)**
	44. At the request of the Chair, this item was discussed prior to item 7, Approval of Annual Report and Accounts during the meeting in order to allow the committee to take assurance from the SIRO report before approving the Governance Statement. RS presented this report to the Committee which has been reframed this year to assess compliance against the NCSC Minimum Cyber Security Standards.
	45. Members noted the paper and agreed that the new standards made a helpful framework against which to assess the organisation's cyber security arrangements. Members stressed

	that it is important for staff to identify vulnerabilities in their own systems and that the HTA needs to strengthen its visibility of this requirement.
Item 12	**White space (Oral)**
	46. There was nothing further raised under this item.
Item 13	**Reports on grievances, disputes, fraud and other Information (Oral)**
	47. Members noted that an employment tribunal was pending relating to a former employee. More information would be given outside of the meeting.
Item 14	**Topics for Future Discussion (Oral)**
	48. Members agreed that further deep dives should be carried out by ARAC at future meetings. It was provisionally agreed that a deep dive into the Licensed Establishment Engagement Programme would be undertaken at the October meeting.
Item 15	**Any Other Business (Oral)**
	49. Members questioned whether the use of Zoom was an appropriate platform to hold ARAC and Board meetings due to reported security concerns. The Executive confirmed that the use of Zoom is in line with central guidance and that it will continue to be used to support meetings at present.

HTA Audit and Risk Assurance Committee

Matters arising and forward plan

Thursday 15 October 2020

Meeting	Action	Responsibility	Due date	Progress to date	Status
12 June 2019	Action 2: To review and sign off the Records Management Policy at the October 2019 meeting.	Director of Resources	01 October 2019	An update to be provided during the October ARAC meeting. **Ongoing. Update to be provided on plans/timescales for this piece of work.**	Live
22 October 2019	Action 6: HA risk update and progress with remaining actions to be provided at the June ARAC meeting.	Head of Regulation (HA)	15 October 2020	This action will be presented at the June 2020 meeting. **Ongoing to be presented at October 2020 meeting.**	Live
30 January 2020	Action 1: Delegation schedule in the Decision Making Framework to be reviewed by ARAC at its meeting in June.	ARAC	15 October 2020	This will be reviewed at the October meeting. **Ongoing.**	live
30 January 2020	Action 3: The leaver's and starters process to be reviewed at the June meeting.	Head of HR	15 June 2020	An update to be provided during the June meeting. **Head of HR to attend the October ARAC meeting to provide an update.**	live
30 January 2020	Action 8: The updated Risk Management Policy to be presented at the May Board meeting.	Head of Finance	16 July 2020	To be presented at the Board Meeting in November. **Ongoing. This will be presented to Board in November**	live
15 June 2020	Action 2: To review audit tracker to ensure where recommendations are not agreed there are suitable alternative suggestions stated.	Head of Finance	15 October 2020	An update will be provided at the October meeting	Live
15 June 2020	Action 3: MA to continue to work with TS to close any remaining actions.	Head of Finance	15 October 2020	An update will be provided at the October meeting	Live
15 June 2020	Action 4: To convene a working group to take forward work to reshape the HTA's management of risk.	Director of Resources	15 October 2020	Work is underway. An update to be given at October meeting. Draft statement to be shared with Chair(s) of ARAC prior to the Board	Live
15 June 2020	Action 5: To present a dashboard style report relating to cyber security risks.	Head of Business Technology	15 October 2020	**To be presented at the October ARAC meeting.**	Live

Risk exploration topics

Topic	Meeting	Progress
Risks posed by sectors and the HTA's approach to protect public confidence • The HTA Inspection Rationale	February 2017	On the agenda for the February 2017 meeting. **Complete.**
Risks posed by sectors and the HTA's approach to protect public confidence Breadth of activity, regulatory approach and risk assessments for various aspects of the Human Application Sector – Follow-up from Authority seminar in February 2017.	May 2017	This item has been scheduled to occur as a follow up to the authority member seminar scheduled for the morning of the February Authority Meeting. **Complete.**
HTA interaction with DIs/DI Training and Recruitment	November 2017	Due to competing work priorities within the Regulation Directorate, The Chair of ARAC has agreed replace this topic with an item looking at the recommendations arising the from the Risks in the Human Application Sector project. We will seek another date for the DI work deep dive, but the meeting after next is likely to look at recruitment and retention risks.
Risks in the Human Application Sector project.	November 2017	Complete.
Management and succession arrangements to assure the continuity of licensing and regulation activity	February 2018	Complete.
Risks associated with Cyber Security	June 2018	Complete. To be added as Standing Item.
Risks associated with the HTA's Licensed Establishment Relationship programme	TBC	As agreed at the 1 February 2018 ARAC Meeting. At 19 June 12018 ARAC Meeting, the Committee agreed to postpone its investigation of the HTA's Licensed Establishment Relationship Programme, which was scheduled for 23 October 2018 ARAC meeting. The Committee elected instead, to explore the risks and assurance associated with the HTA's staff induction process.
The risks and assurance associated with the HTA's staff induction process.	October 2018	At 19 June 12018 ARAC Meeting, the Committee elected to explore the risks and assurance associated with the HTA's staff induction process.
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 TBC.
Media handling- Critical incident handling	TBC	Subject to Internal audit
Risks posed by sectors and the HTA's approach to protect public confidence.	TBC	HA and PM done. Poor risk profile with some of the other sectors.
Post Mortem sector (due at Authority Meeting 04 May 2017)	TBC	This was done at the Authority meeting- will need to consider doing this at ARAC.
Fraud in Public Sector and lack of Board oversight	June 2020	
HTA Office re-location	30 January 2020	
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	Richard to confirm

Future training

Topic	Meeting	Provider	Progress
Joint ARAC Member/Management Team training seminar – undertaking risk assurance mapping and interdependency across the wider health group	February 2017	Internal Auditor/Director of Resources	To focus on wider suggested best practice in accordance with the Risk Management Policy and Strategy and consideration of wider interdependence across the health group. **Complete.**
Value for money auditing and the optimal deployment of resources		NAO	NAO have been invited to host a training session on 18 May 2017. **Complete.**
A NAO perspective on the risks emerging within the health sector	February 2018	NAO Catherine Hepburn	**Complete**.
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.
Observation and feedback from another ARAC Chair	October 2018	Anne Beasley, formerly Director General of Finance and Corporate Services at the UK Ministry of Justice	Rescheduled to occur after the ARAC meeting in June 2018 but postponed until 23 October due to the availability of the observing Chair.
NAO presentation the issues and challenges experienced by other ARACs.	February 2019	George Smiles,(NAO)	At the ARAC meeting on 01 February 2018, Members invited George Smiles to provide them with a presentation at the October ARAC meeting on the issues and challenges experienced by other ARACs. **Postponed**
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.
No training	October 2019	Not applicable	No training
IFRS training	January 2020	NAO	Complete.
Fraud Awareness	June 2020	TBC	

Forward plan	**Forward Plan**

Standing items	Assurance reports from Internal Audit Audit recommendations tracker report Risk update includes strategic risk register review and **update on UK exit from the EU.** Polices/procedures updates Cyber security (as requested by the ARAC on 19 June 2018)	
Meeting		
January 2020	Review and approval of the Internal Audit proposed Audit plan for the financial year 2019/20 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) Review gifts and hospitality register Update on the review of the risk management policy and strategy	
June 2020	Approval of the Annual Report and Accounts 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) Review and approval of the Internal Audit proposed Audit plan for the financial year Internal Audit Annual statement. (Draft Note: RS to discuss the approach to this with PF, invite Information Risk management - SIRO report Annual review of the Operational Risk Register	
October 2020	Review of HTA Reserves Policy Review of ARAC Handbook- Annual refresh Review of Gifts & Hospitality Register Risk in the Human Application Sector- general update to be provided Operation risk register to be reviewed. Business Continuity standing agenda item	
January 2021	Review and approval of the Internal Audit proposed Audit plan for the financial year 2020/21 Review of the Audit & Risk Assurance Committee's performance including Members' skills and training.	

Internal Audit Update- Confidential

HTA
Human Tissue Authority

Audit and Risk Assurance Committee paper

Date	15 October 2020	**Paper reference** (AUD 12/20)	
Agenda item	7	**Author**	Morounke Akingbola Head of Finance and Governance
Protective Marking	OFFICIAL		

Audit Tracker Update

Purpose of paper

1. The purpose of this paper is to update the Audit and Risk Assurance Committee on the progress made in response to external and internal audit recommendations.

Decision-making to date

2. Two audits have been undertaken and completed since the June 2020 meeting and the final reports remain outstanding.

3. This paper was reviewed and approved by the Director of Resources on 9 October 2020.

Action required

4. Members of ARAC are required to:

    a) Consider the HTA's overall progress on the delivery of actions arising from internal and external audit recommendations.
    .

Summary of outstanding recommendations

Recommendation Source	Total	Completed as planned	Completed later than expected	In progress as planned/on going	In progress with some delay	Removed as directed by Committee	Deferred/No further action being taken	Not started or N/a
IA – Records Management (incl GDPR)	11	2	1	0	0	0	8	0
IA – Utilisation of Capabilities	6	0	1	0	5	0	0	0
IA – Critical Incident Management	6	0	0	0	0	0	3	3
IA – Business Continuity Management	6	0	0	0	0	5	0	1
IA – Payroll and Expenses	4	1	0	0	3	0	0	0
IA – Anti-Fraud Controls	2	0	1	0	0	0	0	1
COUNT	35	3	3	0	8	5	11	5

IA – Internal Audit – GIAA

EA – External Audit - NAO

Complete as per HTA, however evidence of completion required to GIAA
Some work is complete, however further work required which is to be built into outline plan
Work that has been deferred or is on-going

Detail - outstanding recommendations

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
2018/19			
GDPR Compliance	Accountability and governance - appropriate technical and organisational measures are not in place and management is unable to demonstrate the steps it has taken to protect individual rights. The lack of these measures mean that it may not be possible to offer effective mitigation in the event of enforcement action. (Governance)		
HTA to develop a comprehensive RRD policy and update retention periods on the Privacy notice and PDI accordingly	Agreed. ~~Target date – July 2019~~	**June 2019** Work is ongoing to finalise the records retention document, it is anticipated this will be complete by July 2019. **October 2019** Resource required to co-ordinate work that will need to be done across the organisation, prior to release of RRD. **January 2020** This is now incorporated into the records management policy (to be discussed with ARAC).	Richard Sydee Director of Resources **COMPLETE**
RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Records Management – Risk 1	HTA's records management strategy and policy are not sufficient to ensure compliance with statutory obligations		
The Records Management policy currently in draft should be finalised and signed off by senior management as a matter of urgency. This policy will complement existing policies, with a clear focus on records management requirements, roles and responsibilities and should cover such topics as retention and disposal. This policy should be signed off by the Senior Management Team and	Following work undertaken by Information Governance consultants the Records Management policy has now been finalised. This will be reviewed and signed off by the SMT ahead of June ARAC meeting *Target date – May 2019*	**June 2019** Draft has been attached to Annual SIRO assessment. **October 2019** Policy in place, retention schedule to be released when resource available to co-ordinate the work required prior to release	Richard Sydee Director of Resources **COMPLETE as far as policy developed.**

the Audit and Risk Assurance Committee. Once agreed, this should be circulated to all HTA staff.		**January 2020** The Executive to discuss all the records management recommendations/actions with ARAC.	
Records Management	HTA's records management strategy and policy are not sufficient to ensure compliance with statutory obligations		
The FOI guidance should be reviewed and updated as soon as possible	Completed as part of GDPR work	N/a **October 2019** Evidence of completion to be provided to GIAA	**COMPLETE as far as guidance developed.**
RECOMMENDATION	**AGREED ACTIONS**	**PROGRESS**	**OWNER / COMPLETION**
Records Management - Risk 2	The systems in use to facilitate information retention, storage and retrieval do not promote compliance with legislative requirements of HTAs records management strategy and policy		
The revised records management guidance should include specific references to the use and updating of the Information Asset Register, linking to the roles and responsibilities in the Information Governance Policy, to ensure this is being used and updated on a consistent basis, so that reliance can be placed on the information on there.	We accept this recommendation and believe it has been covered in the finalisation of the records Management policy as outlined in our response to recommendation 1 **Target date – May 2019**	**June 2019** As per response to recommendation 1. **October 2019** Evidence to be provided to GIAA	Richard Sydee Director of Resources **COMPLETE as far as policy developed.**
Records Management	HTA's records management strategy and policy are not sufficient to ensure compliance with statutory obligations		
The Senior Responsible Officer (SIRO) should ensure periodic checks are carried out on the Information Asset Register, to ensure IAOs are fulfilling their responsibilities and the register is up to date	We will implement quarterly checks as part of SIRO oversight, to be included as part of annual assurance statement to ARAC. Following this audit we have reviewed our Information Asset Register and ensured that the register contains all relevant and	**June 2019** Review has been undertaken at year end and IAR is now up to date. **October 2019** Evidence of completion to be provided to GIAA	Richard Sydee Director of Resources **COMPLETE**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
up to date information as well as links to relevant policies. **Target date – May 2019**			

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Records Management - Risk 3	Risks and Issues are not appropriately identified and mitigated		
The revised records management guidance should include specific references to the use and updating of the Information Asset Register, linking to the roles and responsibilities in the Information Governance Policy, to ensure this is being used and updated on a consistent basis, so that reliance can be placed on the information on there.	We believe it should be the risk policy that provides the risk assessment methodology for the records management risk and will update this document appropriately **Target date – May 2019**	**June 2019** Additional objective has been drafted and will be added to the objectives of IAOs and all relevant staff for the 2019/20 reporting year. **October 2019** Evidence of completion to be provided to GIAA	Richard Sydee Director of Resources **COMPLETE**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Records Management - Risk 4	The accountability and oversight arrangements used to monitor delivery of records management policy and progress are not effective		
HTA should carry out structured training and awareness for all staff with records management responsibilities	Agreed – will be included in induction training and as part of annual refresher training for all staff in relation to cyber security and information governance. **Target date – June 2019**	**June 2019** This is part of the agenda for the All staff away day in July **October 2019** Evidence of completion to be provided to GIAA	Diane Galbraith Head of HR **COMPLETE**
A DRO should be appointed/nominated, and the roles and responsibilities of this position incorporated into the job description.	Given the size of the organisation it is not possible to simply add a further responsibility to an existing staff member without fully understanding the resource implications. Director of Regulatory	**June 2019** Definition for DRO and local records managers have been drafted. We would like to discuss the practicalities of implementing this with ARAC	Hazel Lofty Director of Regulatory Development

	Development and Head of Business Technology to discuss requirement and advise SMT of appropriate response **Target date – June 2019**	**October 2019** Evidence of completion to be provided to GIAA	**COMPLETE**
[Records Management – Risk 4](#)	The accountability and oversight arrangements used to monitor delivery of records management policy and progress are not effective		
Any individuals with specific Records Management responsibilities should have these responsibilities clearly included in their job descriptions	Agree – although would challenge urgency as links to recommendation 6. Will be completed as part of Recommendation 6, relevant IAO's will be identified and a standing IAO objective added to the PDP of those with IAO responsibilities **Target date – June 2019**	**June 2019** Job descriptions to be updated in line with drafted PDP objective. **October 2019** Evidence of completion to be provided to GIAA	Richard Sydee **COMPLETE**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Utilisation of Capabilities (Risk 1)	Lack of clarity surrounding organisational strategy regarding capability and knowledge management		
(1) The strategic and operational Risk Registers need to be developed to fully articulate the controls/mitigations in place to address the risks, as well as including contingency measures where appropriate.	Will review the Risk Registers to address this were possible. ~~Target date – End September 2019~~ ~~**Revised target date – End December 2019**~~ **Revised target date – Q1 2020/21**	**October 2019** Review of this risk began with a deep-dive and proposed restructure of the risk at the September HTAMG. This has not yet been written up but will be completed by the end of the calendar year. **January 2020** This work became an organisation-wide project to review operational risks and mitigations as part of the annual business planning round. The work is ongoing to be completed by end June. **June 2020** A project to review indicators across all functions has been implemented. It was interrupted by the COVID-19 emergency; however, a revised operational risk register is now in pilot and led by Head of Planning and Performance. **October 2020** In the face of delays to the full review of the risk registers – the SRR and ORR have been fundamentally rewritten to account for the recommendations of this audit. Evidence provided to the October ARAC meeting.	Sandra Croser Head of HR & SMT **IN PROGRESS W/DELAY**
(2) The strategic risk register could be strengthened by utilising assurance mapping (across the 3 lines of defence) to gain greater assurances over some of the risk and control areas.	Will review the Risk Register and strengthen the controls for risk and control where possible. ~~Target date – End September 2019~~ ~~Revised target date – End December 2019~~	**October 2019** As recommendation 1 **January 2020** At its meeting on 9 January, SMT took the decision not to undertake further assurance mapping in this business year. SMT is content that adequate controls	Sandra Croser Head of HR & SMT **IN PROGRESS W/DELAY**

	Revised target date September 2020	are in place, and that further mapping is not sufficiently value-adding given other current priorities. **June 2020** A project to review risk register across all functions has been implemented. It was interrupted by the COVID-19 emergency; however, a revised strategic risk register is now in pilot and led by Head of Finance. **October 2020** In the face of delays to the full review of the risk registers – the SRR have been fundamentally rewritten. Controls are in place for all key risk causes and are assurance mapped. Evidence provided to the October ARAC meeting.	
(3) We recommend that the handover process is formalised (a checklist for example) to ensure all corporate knowledge is retained and the development of standard operating procedures for all key roles.	A handover checklist will be developed to capture role specific key deliverables, key stakeholders and contacts based on the Capability Framework when developed. ~~Target date – End November 2019~~ ~~Revised target date – End March 2020~~ **Revised target date end September 2020**	**October 2019** Work has not yet commenced, and we suggest a revised target date of end of March 2020. **January 2020** There is currently a small pilot currently underway. A template covering key contacts and the main interfaces between functions and teams should be available by end of March 2020. **June 2020** This work was interrupted by the COVID-19 emergency. Should now be available by end of Q2. **October 2020** Handover checklist has been produced and is in operation.	Sandra Croser Head of HR & SMT **IN PROGRRSS W/DELAY**
Utilisation of Capabilities (Risk 2)	Resourcing plans do not effectively identify, present or articulate current skills and new skills requirements		
(4) A skills audit should be undertaken and documented in a matrix to capture current skills in the organisation against the capability needs of the organisation. This	Corporate and individual training needs are currently identified from the PDP output which then drives the individual and corporate	**October 2019** Work has not yet commenced, and we suggest a revised target date of end of March 2020 to tie in with the next PDP round.	Sandra Croser Head of HR & SMT

| should be reviewed and kept up to date in line with the PDP process and learning and development to identify individuals with potential for upskilling and development. | training agenda. To strengthen this process, a comprehensive training needs assessment was conducted across the organisation and specifically looking at the RM roles in April. This included the self-assessment of current skills and experiences.
This document will also be used in building the development agenda for 2019/2020
From this a documented skills matrix will be shared and updated on Impact with a purpose of peer to peer learning and upskilling.
In addition, a biweekly Lunch and Learn has been initiated to enable the sharing of skills and experience along with general information sessions.
~~Target date – End November~~
~~Revised target date – End March 2020~~

Revised Target date end of Q3 | **January 2020**
A training needs audit was carried out following the PDP process in the summer. A training programme was designed to meet the needs identified, this is ongoing.
A data team of internal experts has been created to share knowledge and experience by developing short How to Videos which will be shared across the HTA.
A Q&A session was arranged to better understand the needs for more training in the HT Act. A small team is building a programme to deliver sustainable training and awareness sessions which will also be delivered by external HT Act expert (Field Fisher).
The Lunch and Learn programme is well supported and has covered a wide range of topics from 'How to get more from Excel' to better 'Understanding Diversity and LGBTQ+'.All staff have been asked for approval to use and share their output from the Skills audit, only one has so far refused this.
An 'Ask Me' template will be developed for staff to better utilise the internal skills to build their own.
June 2020
A new skills audit will be conducted following the redesign work for return following the COVID-19 emergency**.**
October 2020
Capability that we need has changed as new opportunities have arisen as presented by COVID and the additional funding available in 2020/21. The current nature of the capability risk in now fundamentally different to when the audit was completed. | **IN PROGRESS W/DELAY** |

		Director and Head of HR are assessing capability needs as part of future operating model strand of development programme. **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**	
Utilisation of Capabilities (Risk 3)	Resourcing plans do not effectively identify, present or articulate current skills and new skills requirements		
(5) A forum such as a workforce subcommittee should be established with terms of reference to look holistically at people and staffing issues across the organisation focussing on short and long term impacts and deliverables.	The SMT and Head of HR will develop a short and longer term People plan based on current and future needs as part of our strategy to move to more remote working. A regular assessment of key role / key people development needs will be made with a view to both development and succession planning. We are not in the position to create a succession plan for all roles as a number are standalone or the department is too small to support a full succession plan. The headcount limitation is unlikely to change in the foreseeable future. Target date – End November 2019 **Revised target date – End March 2020**	**October 2019** Work has not yet commenced, and we suggest a revised target date of end of March 2020 to tie in with the start of the new business year. **January 2020** Head of HR and SMT regularly review the current skill set and the expected skills set before backfilling any vacancies (most recently 9 January SMT meeting). This process assesses the most appropriate use of headcount given the goals and priorities as they evolve. Assessment of the relative priority of key roles and succession planning is taking place as part of business planning for 2020/21. **June 2020** This is an ongoing 'business as usual' activity. **October 2020** Established a formal role within SMT terms of reference to look holistically at people and capability	Sandra Croser Head of HR & SMT **COMPLETE**

		issues across the organisation focussing on short and long term impacts and deliverables.	
(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.	A capability framework will be developed which will also identify the key people and key roles across the organisation. Knowledge and experienced required for each role will be documented along with training expectations for that role. Where possible a nominated deputy will be identified. However, given the size of the organisation and the recent stress audit, workload and overstretch will need to be carefully considered. ~~Target date – End November 2019~~ ~~Revised Target date – July 2020~~ **Revised Target date end Q3 2020**	**October 2019** 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**.** **January 2020** 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. **June 2020** Due to the redesign work being led by Director for Data, Technology and Development, for the return following COVID-19 this work cannot be completed until organisational design work has been completed and a skill assessment has been made for the support of the HTA going forward. **October 2020** As of June update	Sandra Croser Head of HR **IN PROGRESS W/DELAY**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Critical incident management – Risk 1	The existing risk mitigations and controls in place are inadequate in reducing the risk of critical incidents taking place, or managing the impact of incidents once they occur.		
1.1 We recommend that HTA review the strategic risk register and consider the type of controls listed as the control framework should have a balance of preventative, directive and detective controls.	Agreed – we will review the SRR where relevant and consider which preventative, directive and detective controls are or can be put in place. ~~Target date – March 2020~~ ~~Revised target date – end Q2 2020~~ Revised target date – end Q3 2020	**June 2020** We have undertaken a review of our SRR with Accenture and will be moving forward with a change project over this Business year – this will now be incorporated into that change work. **October 2020** Workshops were attended during March and April. A high level plan has been drafted which includes a review of the SRR and the type of control actions.	Richard Sydee Director of Resources **DEFERRED to Q3 2020**
RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Critical incident management – Risk 1	The existing risk mitigations and controls in place are inadequate in reducing the risk of critical incidents taking place, or managing the impact of incidents once they occur.		
1.2 HTA to include all SOPs which are linked to the management of a critical incident as links or separate annexes in the critical incident response plan.	Not fully agreed– although we accept this would be good practice there is limited resource available for this type of activity at present and the identification of a Critical Incident within the HTA would likely be indicative if the relevant SOPs. We will include this work within the scope of the review process currently being undertaken of SOPs by the Quality forum **Target date December 2020**	**June 2020** Not due **October 2020** Not due	Richard Sydee Director of Resources **NOT STARTED**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Critical incident management	The existing risk mitigations and controls in place are inadequate in reducing the risk of critical incidents taking place, or managing the impact of incidents once they occur.		
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.	Not fully agreed– we are concerned that recommendations 1.3 and 1.4 represent collectively a significant piece of work that, although useful, would not add significantly to the level of assurance. We will feed these recommendations into any work we may undertake to as part of our annual review of the operational risk register **Target date – December 2020**	**June 2020** Not due. **October 2020** Not due	Quality and Governance Manager – when appointed **NOT STARTED**
1.4The 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	See above **Target date December 2020**	**June 2020** Not due. **October 2020** Not due	Quality and Governance Manager – when appointed **NOT STARTED**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Critical incident management – R2	HTA's critical incident response plan is not reviewed or tested on a regular basis and "lessons learned" from any incidents are not incorporated into the plan or reported to senior management.		
1.5 We recommend that management consider developing a testing programme which outlines what they plan to test annually, with a clear caveat that this may be superseded by live critical/major incidents.	Agreed – although we will limit this to documenting the requirement for an annual test, which would be designed to test areas not previously explored by testing or live events in the previous three years. ~~Target date – March 2020~~ **Revised date – end Q4 2020**	**June 2020** This has been overtaken by recent events. The requirements of responding to COVID19 in terms of Business Continuity and Critical workload increase has been tested thoroughly in our response to the pandemic. **October 2020** As per the June update ongoing management of the COVID19 response has meant a focus on lessons learned in preparation for a potential second wave. This work will be undertaken once a steadier position is achieved.	Richard Sydee Director of Resources **DEFERRED**
RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Critical incident management – R3	HTA staff are not be aware of, and therefore do comply with, the organisation's critical incident response plan. This could lead to delays in the recovery of key services or inappropriate action being taken by staff in the event of a disaster		
See risk 4			
RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Critical incident management – R4	There is a lack of capacity or capability to effectively deal with any critical incidents which occur, including undertaking appropriate communications during any major incidents.		

(AUD 12/20)

| 1.6 We recommend that appropriate training is identified and implemented for role owners and delegated role owners with critical incident responsibilities. | Agreed – we will identify relevant Business Continuity Management System (linked to ISO 22310) foundation and Implementer courses for our CIRP administrator and programme manager

Target date – June 2020
Revised date – end Q4 2020 | **June 2020**
This work has been delayed. Our response to COVID19 has required some reprioritisation. Given our successful reliance on our plans during the pandemic we are confident that they remain sufficiently robust.
October 2020
As per the June update ongoing management of the COVID19 response has meant a focus on continued BC activities, role holder training seems inappropriate at present but will be rolled out once a new policy has been finalised. | Richard Sydee Director of Resources & Sandra Croser Head of HR

DEFERRED |

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RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Business Continuity Management – R1	BCPs are not adequate and have not been updated to reflect improvements and changes proposed and agreed at the ARAC. This could lead to delays in the timely recovery and provision of critical business process and functions.		
1.1 We recommend that a separate BCP is produced, or as a minimum, a separate annex is added to the CIRP which specifically covers discrete business continuity arrangements.	Agreed – we will draft a separate BC plan based on the existing BC elements of the Critical Incident Response plan. This will be drafted for our current location with a commitment to review and update post our relocation to new offices Target date – March 2020 Revised date – end Q3 2020	**June 2020** We have relied heavily on our existing single plan successfully over the past three months. We will look to revisit this as part of a review policies that will need to change when we re-locate, but for now propose to not undertake the earlier phase of this work. **October 2020** Not due	Richard Sydee Director of Resources **DEFERRED**
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.	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. Target date – March 2020 Revised date – end Q3 2020	**June 2020** 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. **October 2020** Not due	Richard Sydee Director of Resources **DEFERRED**
Business Continuity Management – R1	BCPs are not adequate and have not been updated to reflect improvements and changes proposed and agreed at the ARAC. This could lead to delays in the timely recovery and provision of critical business process and functions.		
1.3 HTA should formally agree and document the contingency arrangements in the event that the current building is not available to staff for any length of time.	Agreed – this will from part of our new BC plan. Target date March 2020	**June 2020** Our existing plan has coped well with the closure of 151BPR. We will consider this in line with the above responses.	Richard Sydee Director of Resources

		Revised date – end Q3 2020	**October 2020** Not due	**DEFERRED**
RECOMMENDATION		**AGREED ACTIONS**	**PROGRESS**	**OWNER / COMPLETION**
Business Continuity Management – R2		BCPs are not tested on a regular basis and "lessons learned" from live drills are not incorporated into the BCPs or reported to senior management.		
1.4 We recommend that management document the BCP testing programme which outlines what they plan to test annually, with a clear caveat that this may be superseded by live business continuity events.		Agreed – although we will limit this to documenting the requirement for an annual test, which would be designed to test areas not previously explored by testing or live events in the previous three years. ~~Target date – March 2020~~ Revised date – end Q3 2020	**June 2020** In line with the above responses we have not considered this given the need to respond to COVID19. **October 2020** Not due	Richard Sydee Director of Resources **DEFERRED**
Business Continuity Management – R2		BCPs are not tested on a regular basis and "lessons learned" from live drills are not incorporated into the BCPs or reported to senior management.		
1.5 We recommend that HTA formalise the process to record lessons learned and follow-up of actions by management.		Agreed – will be detailed in the new BC plan ~~Target date – March 2020~~ Revised date – end Q3 2020	**June 2020** As outlined above this work will be delayed and considered as a part of the policy revision ahead of our relocation. **October 2020** Not due	Richard Sydee Director of Resources **DEFERRED**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Business Continuity Management – R2	HTA staff may not be aware of, and therefore may not comply with, the organisation's BCPs. This could lead to delays in the recovery of key services or inappropriate or ineffective action being taken by staff in the event of a disaster/emergency.		
1.7 HTA to ensure any induction as part of the office relocation includes training and awareness on BCP for all staff.	Agreed **Target date – November 2020 (or date of relocation)**	**June 2020** Not due. **October 2020** Not due	Richard Sydee Director of Resources **NOT STARTED**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Payroll and Expenses	Inadequate policies and procedures		
2. Policy and procedures regarding appointment of secondments: temporary promotions and additional duties should be enhanced as follows:			Sandra Croser Head of HR
• The Cascade Go HR system will be utilised to diarise review dates of secondments and additional duty allowances for HR, Line Management, Director/Budget Holder and the employee.	Agreed **Target date – June 2020**	**June 2020** On-going **October 2020** We are using Iris (Cascade Go) to diarise review dates. Evidence to be provided before next meeting.	**COMPLETE**
• In the event a future end date or review date cannot be determined, HR to review with the Director/Budget Holder proportionate intervals (no more than annually).	Agreed **Target date – June 2020**	**June 2020** On-going **October 2020** Update to be provided at meeting	**STATUS UNKOWN**
4. The existing code of conduct to be reviewed and where appropriate updated and communicated to all staff.	Agreed. Code to be reviewed and link to revised values will be conducted. **Target date – September 2020**	**June 2020** Not due **October 2020** Update to be provided at meeting	**STATUS UNKNOWN**
Payroll and Expenses	Incorrect payments to starters and leavers		
5. HTA should revise the processes around instructing changes to the payroll as follows: • Any changes are signed off (and officially recorded) by the individual and line manager prior to HR and CEO sign-off, to ensure there is	Agree – changes to pay/hours should be signed off by the Director and HR on a separate form **Target date – Ongoing**	**June 2020** New forms have been designed and agreed between HR and Finance **October 2020** New forms have been designed but roll out delayed due to change in priorities	Sandra Croser Head of HR **IN PROGRESS W/DELAY**

appropriate checks and segregation of duties;			
• A standard template should be introduced for employees and managers to record Payroll change information with suitable prompts for all eventualities and boxes to record dates and signatures of those reporting changes and approving (where necessary).	Agree that the Contract Variation form will be designed to facilitate changes to pay/hours only. ~~Target date – June 2020~~ **Revised target date – Dec 2020**	**June 2020** New forms being piloted with agreement between Finance and HR **October 2020** As above	
Payroll and Expenses	Incorrect payments to starters and leavers		
6. HR Manager to issue the contract to the new starter where the contract is not signed and encourage prompt signing.	Agreed **Target date – N/a**	**June update:** None **October 2020** HR to provide evidence Contract has been signed.	Sandra Croser Head of HR **COMPLETE**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Anti-Fraud Controls	Specific fraud risk management policies are not in place, regularly reviewed and communicated to support staff awareness and reporting		
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.	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. ~~Target date – June 2020~~ Target date – end Q3 2020	**June update** A HTA Handbook will be designed and delivered by later in the year due to the impact of COVD-19.	Sandra Croser Head of HR **NOT STARTED**
Anti-Fraud Controls	A lack of effective fraud risk oversight and control at local and senior management level, with risks not fully captured and actions not taken to mitigate risks.		
1.3. HTA should carry out additional fraud awareness activity for all staff and ensure that fraud guidance and procedures is prevalent on electronic platforms, as well as discussed at team meetings.	Agreed – we will ensure this is added to our new intranet when it is complete and update staff annually. ~~Target date – June 2020~~ Revised target date – Dec 2020	**June update:** Staff have accessed training and when available, content is added to the intranet informing staff of current fraud to be aware of particularly during the COVID-19 pandemic. **October 2020** We have not added new content to the intranet around fraud awareness. We will reach out to other ALBs to see what is available	Morounke Akingbola Head of Finance **COMPLETE (April, however more is needed)**

Audit and Risk Assurance Committee paper

Date	15 October 2020	**Paper reference**	AUD (13/20)
Agenda item	8	**Author**	Richard Sydee
			Director of Resources

Protective Marking	OFFICIAL

Risk Update

Purpose of paper

1. To provide ARAC with an update on HTA's strategic risks and proposed mitigations at September 2020.

Decision-making to date

2. This paper was approved by the Director of Resources on 9 October 2020.

Action required

3. ARAC Members are required 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 register is updated. The strategic risk register that was updated at the beginning of January is at Annex A.

5. Risk 1 – Failure to regulate appropriately (Yellow). 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 yellow scoring. Work continues to finalise an alternative virtual model for site visits and we anticipate this being trialled in quarter three. SMT will review recommendations for safe site inspections later this month before making a decision on the possible resumption of site visits.

1. Risk 2 – Failure to manage an incident (Yellow). Although this was judged initially to be slightly heightened in March the response to COVID-19 restrictions and our continued ability to operate has been assessed as evidence that this risk as not increased in the current circumstances.

2. Risk 3 – Failure to regulatory expectations (remained Yellow). This risk has seen no change to its rating since ARAC last met in June 2020. The HTA continues to manage the impact of COVID-19 restrictions on its operations and employees effectively.

3. Risk 4 - Failure to utilise capabilities effectively (Amber). Absence levels relating to COVID-19 have thankfully been limited, although we continue to monitor the unequal balance of workload across the organisation, redeploying resources and utilising some under capacity on change and development programmes. At this time the HTA has five vacancies and is considering the best approach to meet short term skill shortages before commencing with permanent recruitment.

4. Risk 5 – Insufficient, or ineffective, management of financial resources (Yellow). Invoicing for all sectors was undertaken in September, we received a positive response to pre issue communications and the response so far has been in line with previous years. We are in the process of reviewing our finance at the mid-year point and we consider reallocation of funds to priority programmes over the second half of the business year.

5. Risk 6 - failure to achieve the benefits of the organisational transformation programme (Yellow). Progress is being made on our portfolio of work, with the replacement website and work on our future DRMS solution moving forward. We expect to see final plans for the second half of the year shortly.

HTA Strategic Risk Register
September

The easing of restrictions associated with the COVID19 pandemic in early July , followed by the application of various additional regional lockdown measures, has brought an increasing realisation of the need to develop and manage expectations about future plans in the context of adapting to a new normal of living with Covid, rather than a return to normal. The senior team is therefore continuing to balance a number of competing pressures: when and how to safely return to undertaking site visit inspections (and the form these should take), balancing resources between regulatory delivery and development, the work associated with UK Transition, given greater certainty now that there will be no extension of the transition period, and the office move. Operating in this highly uncertain and fast-changing context increases the risk of sub-optimal allocation of resources and so we are also increasingly focusing on greater depth and clarity of business and resource planning to ensure that resources are applied to areas of greatest risk. As of September, we feel that we have the right actions and plans in place to mitigate/reduce current risks. There is an element of acceptance of some risks for a period after which a review of plans will be conducted.

Overview: Risks reflect the strategy for 2019 - 2022. Our highest scored risks are: *failure to regulate appropriately* - the score for which increased as a result of the continuing absence of site visit inspection as part of our regulatory toolkit during this initial phase of the pandemic and the current position on introducing an alternative; *failure to manage expectations of regulation*, which reflects the fast-pace of change within the sectors we regulate, the low likelihood of legislative change in the foreseeable future and the ongoing temporary removal of routine site visit inspections as a regulatory tool; *failure to utilise our capabilities effectively*, which reflects the fact that business plans are being redeveloped at pace to adjust to the current limitations on activities as a response to changing Covid-related government restrictions whilst also seeking to take advantage of this opportunity to quickly take forward long-planned strategic change through the development programme. The organisation has adapted well to this new working environment and is developing new regulatory tools to supplement our existing non-site visit activity, that will allow continued oversight of our sectors. SMT believes the overall risk level has remained level.

Other notable risks: Understanding the impact and resource required to deal with UK Transition and the medium to long-term impact of the UK's departure from the EU is proving challenging. Horizon scanning for emerging issues and liaison with DHSC remain a key focus.
Progress on other development activity has continued to gather pace using the additional funds available this year from the cessation of site visits and a recruitment freeze that are being invested for optimum benefit this business year. In particular, this includes work to support our office move and to build a foundation for future strategic development. Work is now commencing on these development priorities.

Risk	June 2020	July 2020	Aug 2020	Sept 2020	Comments
1 - Failure to regulate appropriately (Risk to Delivery a-d & f and Development a-d)	→	→ 10	→ 10	→ 10	Whilst we have a good regulatory framework for normal times, with a strong assured position on our key regulatory processes from an Internal Audit review within the past 18 months. We coped well with the novel challenges and intensity of increased activity in the PM sector during the peak of the pandemic but continue to face new challenges arising from this new context, particularly the suspension of one key regulatory process, site visits, across all sectors since mid-March. Activity in the PM sector is now stable and in good control and we continue to use all other regulatory tools and processes. We have been developing remote risk profiling and inspection processes through the virtual regulatory assessment work, prioritising the HA sector where we have undertaken a targeted survey of all establishments that is now being followed-up with discrete interventions. As government restrictions are starting to be eased, albeit this varies by region, we are planning on how to safely undertake site visits, again prioritising the HA sector. Our inability to meet our legal obligation to undertake biennial site visits in this sector since mid-March 2020 is being managed as an issue, of which the Board and DHSC sponsors are aware. The continuing absence of site visit inspections by the HTA may result in an increase in this risk, or perception of this risk by external stakeholders, although this may vary by sector. We anticipate moving from developing and assessing the viability of a virtual model to pilot during Quarter 3 and build on in the remainder of the business year. A decision on safe site visits will be taken in October reviewing government advice at that time. These activities help mitigate this risk. SMT believe this risk is stable in September 2020.
2 - Failure to manage an incident (Delivery, Development and Deployment)	→	→ 6	→ 6	→ 6	We have plans in place to manage an incident and are reviewing and responding to the final reports from the internal audit review of our Business Continuity and Critical Incident Management arrangements, which provided moderate levels of assurance in both areas. Actions will be discussed with ARAC in due course. The HTA response to managing the impact of the pandemic using these existing plans has been a significant stress test of their adequacy. They have not so far proved wanting. At present the greatest concern is the emergence of another significant incident in parallel that results in compound management stretch. SMT believe this risk is stable in September 2020.
3 - Failure to manage expectations of regulation (Risk to Delivery e and Development c)	→	→ 12	→ 12	→ 12	We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DHSC 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. Looking forward, the Development programme has included a specific workstream to strengthen horizon scanning on emerging changes to policy or activities where the HTA may be required to act or offer an authoritative voice. This proactive approach should identify perimeter issues. The maintenance of the risk level in this area reflects the continuing activity to maintain our contingency arrangements in response to the Covid pandemic and the smoothness of our adjustment to this changed context. We have also made good progress with the development programme, including planning for the developments required as part of the UK Transition. Each of these themes has required developments and changes to ways of working and further updating of communications on our role, guidance to licensed establishments and the maintenance of public and stakeholder confidence. The generally positive results of the stakeholder evaluation commissioned in quarter 4 of 2019/20 was reported to the July Board meeting and has provided helpful insight into opportunities to strengthen and include in our development plans for this year. SMT believe this risk is stable in September 2020.
4 - Failure to utilise our capabilities effectively (Delivery a-e) (Development a-d) (Deployment a, c and d)	→	↑ 16	→ 16	→ 16	Recruitment was put on hold in quarter 1. SMT considered the five vacancies we had within headcount in July and agreed to focus recruitment on building our development programme objectives for the remainder of this year. We have started to recruit to a range of contract positions to meet these needs and have appointed a temporary Change Manager who took up post in mid-August, and have gone out to recruitment for a Data and Intelligence Lead. We have also approved recruitment to fill a temporary Regulation Officer vacancy to address workload pressures. Workload and pressure on staff continues to be monitored closely by the management team and improvements in management information introduced during Quarter 1 have been helpful in supporting this approach and embedding better use of data and management information throughout the business. ARAC has supported the temporary deprioritisation of the response to the records management internal audit. As a result, the HTA will be tolerating a degree of risk in the medium term. The scoping of development of our EDRMS forms part of development plans for 2020/21 building on the preparatory work completed in quarter 4. The sequencing of this work will need to take into account interdependencies across the development programme. As of September, the HTA continues to operate in an uncertain environment and is now assessing how best to adapt and move to a new operating normal. During the initial peak of the pandemic we agreed to plan over a shorter time horizon quarter by quarter. There is now an impetus to plan over a longer horizon. In the light of the competing pressures and the uncertainty, there was a risk of people resource being used ineffectively. SMT believe the planning and monitoring activity undertaken from July has stabilised this risk. SMT believe this risk is stable in September 2020.
5 - Insufficient, or ineffective management of, financial resources (Deployment b)	→	→ 8	→ 8	→ 8	We await final confirmation of the GIA settlement for the 2020/21 financial year from DHSC finance colleagues, although we have received indications that the 19/20 GIA settlement will roll forward this confirmation is still awaited. The ability to maintain the organisation and ensure continuity of payments and salaries processing could be impacted by the pandemic. Although the decision to defer invoicing for the HA sector until September does not represent an explicit risk, the wider implications for organisations in all sectors unable to undertake activity could reduce income for 2020/21. At present we believe this to be a increased likelihood which has increased the pressure on risk 4 and this heightened position will likely continue for the first half of the financial year. In addition to the potential issue in obtaining payment from establishments who may be suffering reduced income or cash flow issues themselves as a result of the pandemic, we are also conscious that there may be a risk that some establishments challenge payment of license fees if they develop a perception that the lack of site visits by the HTA means they are not obtaining value for money for their fees. SMT believe this risk can be managed through continuing proactive communication with our sectors to demonstrate the range of continuing regulatory activity still being undertaken. SMT believe this risk is stable in September 2020.
6 - Failure to achieve the benefits of the HTA Development Programme (Development objectives a-d)	→	→ 9	→ 9	→ 9	The removal of costs associated with site visit inspection along with the pause in recruitment has provided some headroom for development investment within the existing budget. The scoping of what could be achieved to fulfil the HTA's strategy has progressed well and at present the risk is stable. The office move project is underway and progressing well, and is being managed by the HTA's permanent project manager (PM). The impact of the move on other activities in the next business year are being accounted for and this remains one of our priority activities for next year. This new PM will also support detailed planning of the next phase of our transformation work. Although there has been more uncertainty about the timing of the office move the successful delivery of a number of projects to the end of the 2019/20 business year (HTA Intranet, Office 365 upgrade, adoption of remote working, future EDRMS requirements and data and intelligence review) has lead to a downgrading of the impact and likelihood score for this risk - now 3/3. There is still more to do, but the work to date represents a significant proportion of the "must do" element of this programme. SMT believe this risk is stable in September 2020.

Risks are assessed by using the grid below

Risk scoring matrix

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

Strategic Objectives

Delivery objectives
•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.
•Deliver effective regulation of living donation.
•Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit.
•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.
•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 objectives
• 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.
• Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
• 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.
• Begin work on implementing a future operating model, which builds our agility, resilience and sustainability as an organisation.

Deployment objectives
• Manage and develop our people in line with the HTA's People Strategy
• 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

Lines of defence are:
1 - Embedded in the business operation
2 - Corporate oversight functions
3 - Independent of the HTA

Lines of defence	
1.	Management control and internal controls (frontline)
2.	Risk Management functions (senior management)
3.	Internal Audit (board/audit committee)

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	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: **Allan Marriott-Smith**	*Causes* • *Failure to identify regulatory non-compliance* • *Regulation is not transparent, accountable, proportionate, consistent and targeted* • *Regulation is not sufficiently agile to respond to changes in sectors* • *Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IAs)).* • *Inadequate adherence to agreed policies and procedures in particular in relation to decision making* • *Poor quality or out of date policies and procedures* • *Failure to identify new and emerging issues within HTA remit* • *Failure to properly account for Better Regulation* • *Insufficient funding in regulated sectors* • *Failure to deal with regulatory consequences of the Transition Period and the period after 31 December 2020.* • *Failure to properly manage the business impact of the coronavirus pandemic.* *Effects* • *Loss of public confidence* • *Compromises to patient safety* • *Loss of respect from regulated sectors potentially leading to challenge to decisions and non-compliance* • *Reputational damage*	5	4	Ongoing	**Regulatory model** HTA Strategy 2018 to 2021 clearly articulates the HTA's regulatory model	5	2	In the current absence of site visit inspection, work will be undertaken to develop a risk assessment and a virtual regualtory assessment proposal. A revised strategy reflecting this change is in development.	X			Preventative	Authority developed and approved the current HTA Strategy and is aware of the risk associated with current impossibility of site visit inspections.	HTA Strategy published in May 2019 and pilot virtual regulatory assessment in the HA sector commenced in quarter three 2020/21.
						Regulatory decision making framework				X			Preventative	Reports to Authority of key decisions in Delivery Report	Satisfactory Report made in July 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.
						Annual scheduled review of Strategy				X	X		Preventative	Outputs from annual strategy review translate into revised annual Strategy	Annual strategic planning away day completed in January 2020.
						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.				X	X		Preventative	Business plan for 2020/21 has been produced and approved for publication by the sponsor Department.	Quarterly reporting to Authority and DHSC in May 2020 reflected progress against business plans.
						Well established processes support our core regulatory business.						X	Detective	Internal audit conducted on Key Regulatory Processes, receiving substantial assurance and noting good areas of best practice	Final report received April 2019 and showed substantial assurance. Two low priority recommendations have been followed-up with actions 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.
						Quality management systems HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model				X			Preventative/ Monitoring	Identified staff member temporarily responsible for QMS, automated review reminders, management oversight of progress on updates	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 includes evidence of degree to which the documents are current.
						People Adherence to the HTA People Strategy which has been substantially amended and approved by the Authority				X			Preventative	Management information and assessment presented to the Board quarterly.	Quarterly report made at July 2020 Authority meeting. Mid-year PDP reviews due to be completed by 2 October 2020.
						Training and development of professional competence				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, Regulation-led (RM-Training Programme) e.g. quarterly Regulation Training Mornings (most recent being 1/6/20) and 'Lunch and Learn' programme.
						Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas			As vacancies arise, SMT take the opportunity to review business requirements and target building capability and filling skills gaps.	X	X		Preventative/ Monitoring	SMT assessment of skills requirements and gaps as vacancies occur, Recruitment policy	Staffing levels and risks reported quarterly to the Authority Recent vacancies have been used to introduce new skills to the HTA e.g. recruitment of a data analyst in January 2020, recruitment of a project manager and inward secondments to support intranet development activity and management of FOIs.
						Transition period Close liaison with DHSC to ensure communications are in line with government policy and that appropriate arrangements are made to support DHSC and stakeholders during the transition period.			Fortnightly Transition Period oversight meetings from February 2020 with a standing item on the SMT agenda. Continued close liaison with DHSC policy and communications teams, through fortnightly catch-ups of DHSC with ALBs. High level resource planning done for 2020/21 business plan in preparation for anticipated changes at the end of Transition	X	X		Preventive / Detective / Monitoring	Weekly reporting by ANH to SMT under standing item on SMT agenda. Short fortnightly Heads meetings give an overview of any enquiries and feedback steers and guidance from DHSC. These are reported to SMT.	Minutes of weekly SMT meetings.
						Regulatory model			Development work being undertaken to become a more data-driven risk based regulator as part of the HTA Development Programme.	X			Preventative		
						Other			Strengthening horizon scanning arrangements	X			Preventative		

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
2	**Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:** • **relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)** • **caused by deficiency in the HTA's regulation or operation** • **where we need to regulate, such as with emergency mortuaries** • **that causes business continuity issues** **(Risk to all Delivery Development and Deployment objectives)** *Risk owner:* **Nicky Harrison**	<u>*Cause*</u> • *Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)* • *Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)* • *Failure to work effectively with partners/other organisations* • *Breach of data security* • *IT failure or attack incident affecting access to HTA office* • *External factors such as terrorist incident, large scale infrastructure failure or pandemic* <u>*Effect*</u> • *Loss of public confidence* • *Reputational damage* • *Legal action against the HTA* • *Intervention by sponsor*	5	3	Future, should event occur	Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff	3	2		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.
						All specific roles identified in the Critical Incident Response Plan are filled.				1 / X	2	3	Preventative	Evidence of regular review and updating of the CIRP and no specific CIRP roles left vacant.	CIRP reviewed and updated to version 19 in July 2019. Further minor changes proposed February 2020 updated roles following staff changes.
						Media handling policy and guidance in place and Critical Incident Response Plan includes requirement to involve Comms team. Comms Team have embedded media handling and development of lines to take into business as usual.			Comms Team maintain close working relationships with colleagues across the business and proactively raise awareness of the need for Comms role in shaping lines and dealing with media.	X			Preventative	Policy reviewed as scheduled. Reports on media issues and activity in Delivery 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			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy				X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Police referral process used regularly by SMT and captured in SMT minutes.
						Onward delegation scheme and decision making framework agreed by the Authority				X	X		Preventative	Standing Orders and Authority minutes	Standing Orders published May 2017, due to be updated at November Board meeting.
						Regulatory decision making framework			Regulatory Decision Making process and SOP regularly reviewed and disseminated to staff.	X			Preventative	Reports to Authority of key decisions in Delivery Report	RDMs summarised in quarterly reporting to the Board. Regulatory Decision Making SOP reviewed and updated February 2020.
						IT security controls and information risk management				X	X		All	SIRO annual review and report Internal audit reports	Cyber security review - standing agenda item at ARAC - last discussed June 2020.
						Critical incident response plan regularly reviewed and tested			Actions associated with the internal audit reported in February 2020.	X	X		Preventative	Critical Incident Response Plan and notes of test, reported to SMT Use of CIRP reported to SMT.	CIRP used to manage response to coronavirus pandemic in March 2020.
						Evaluate test exercise of incident and feedback to all staff.			Question over whether a test of the Plan is required in light of the recent stress test presented by the coronavirus pandemic.	X			Preventative		
						Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA.				X			Preventative / Detective / Monitoring	Inspections (and audits for ODT) include assessment of licensed establishments' knowledge and use of the relevant HTA incident reporting process.	Findings at inspection. Monitoring establishments' reporting of incidents through the HTARI, HA SAEARs and ODT SAEARs groups.
						Management of Transition Period to 31 December 2020 following the UK's departure from the EU							Preventative / Detective / Monitoring	Engagement with DHSC on planning for the end of the transition period. Director-level oversight as SRO (Director of Regulation), fortnightly oversight meetings with relevant Heads, regular reporting to SMT.	Regular reports to SMT - standing item on SMT agenda from February 2020.

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK I	RESIDUAL RISK L	ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
3	*Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach* *(Risk to Delivery objective e, and Development c)* Risk Owner: **Louise Dineley**	*Cause* **External factors** • *No scheduled review of Human Tissue Act and associated regulations, or Quality and Safety Regulations (other than for EU Exit)* • *Rapidly advancing life sciences* • *Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates* • *Introduction of deemed consent for Organ donation in England* • *Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario* **Matters which certain stakeholder groups believe require review** • *Scope of relevant material e.g. waste products* • *Licensing requirements e.g. transplantation research* • *Regulation relating to child bone marrow donors* • *Issues raised by emergence of social media e.g. non-related donors* • *Strengthening of civil sanctions for non-compliance* **Matters which stakeholders/public may expect to be inside regulatory scope** • *Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure* • *Police holdings* • *Products of conception and fetal remains* • *Data generated from human tissue* • *Funeral directors* • *Forensic research facilities* • *Cryonics* • *Body stores / Taphonomy* • *Imported material* • *Clinical waste* • **Other** • *Inadequate stakeholder management* *Effect* • *Diminished professional confidence in the adequacy of the legislation* • *Reduced public confidence in regulation of matters relating to human tissue* • *Reputational damage*	5	4	Ongoing	Log of issues known to the HTA with respect to the legislation to inform DH and manage messages	4	3			X		Monitoring	Ongoing log	Log in place and stable.
						Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope			*Outcome of internal audit on the adequacy of these arrangements is anticipated in October with advice on improvements*	X			Preventative/ Detective	Stakeholder Group meeting minutes Authority minutes (including Public Authority Meeting) TAG and HWG meetings	Last stakeholder group meeting in October 2019 Public Authority Meeting in May 2019; Histopathology Working Group *February 2020*; Transplant Advisory Group *October 2019*
						Active management of issues raised by the media – including the development of the HTA position on issues					X		Preventative/ Detective	Quarterly reports to Board on communication (including media) activities	Last report *July 2020*
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence					X		Monitoring	Quarterly Accountability meetings with DH	*Last assured position from DHSC on 31 July 2020*
						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 May 2020.
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge				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, 2020.*
						No further changes to HTA's Standards since significant changes launched April 2017 but significant activity to update Codes of Practice for Organ Donation and Transplantation (and consent) to support the introduction of deemed consent for organ donation, with the new law due to go live in May 2020.				X			Preventative	*Updated guidance published. Updated Codes of Practice to support deemed consent published.*	*Supplementary guidance on PM standard on traceability issued Feb 2019. Further guidance developed on PM Standards in consultation with HWG, eg on three points of identification, long-term storage of bodies and dealing with consent for testing for infection of deceased in cases of sharps injuries. Updated Code of Practice for Organ Donation and Transplantation laid in Parliament February 2020.*
						Extensive Professional Evaluation Survey being undertaken in Q4 2019/20. Report to Board in July 2020.				X			Preventative	*Evidence from Professional Evaluation*	*Evidence from Professional Evaluation presented to the Board in July.*
						Proactive horizon scanning and development of policy in emerging/complex areas. Further strengthening building on existing system.				X			Preventative	*Horizon scanning improvement is one of the six strands of the development programme*	*Update on this work presented at July Board meeting*
									Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners) to inform planning for the Transition Period and the period after 31 December 2020.	x			Preventative	*Development programme workstream 20/21. Programme reporting via a fortnightly steering group and weekly updates to SMT.*	

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
4	**Failure to utilise people, data and business technology capabilities effectively** **(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)** Risk Owner: **Louise Dineley**	• **_Cause_** _Lack of knowledge about individuals' expertise_ • _Poor job and organisational design resulting in skills being under used_ • _Poor line management practices_ • _Poor project management practices_ • _Poor leadership from SMT and Head_ • _Loss of productivity as a result of the effects of changes to ways of working_ • _Data holdings poorly managed and under-exploited_ • _Inadequate business technology or training in the technology available_ • _Lack of ring-fenced resource for 'no-deal' EU Exit_ **_Effect_** • _Poor deployment of staff leading to inefficient working_ • _Disaffected staff_ • _Increased turnover leading to loss of staff_ • _Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed_ • _Poor use of technology resulting in inefficient ways of working_ • _Inadequate balance between serving Delivery and Development objectives_	4	4		**People capability**	4	4							
						People Strategy for the period 2019 to 2021 is in effect				X	X		_Preventative/ Monitoring_	_Authority approval of the Strategy_	_Authority 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 2020._
						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/polici es_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 2020_
						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_	_Interventions have commenced including full leadership team workshop in September 2020_
						Handover process is formalised via a checklist to ensure corporate knowledge is retained				X			_Preventative/ Monitoring_	_Handover checklist is in place and in operation._	
									More formal assessment of future capability needs and how these should be met including through better knowledge of internal skills	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 review is in process supported by external advisers. Due to be in place by end October 2020_
						Data capability									
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)				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				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				X	X	X	Preventative/ Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Annual SIRO report presented to ARAC June 2020
						Business technology									
						Identify refresher training and targeted software specific training needs.				X			Preventative	Evidence of targeted training in last quarter. Further strengthening of core training requirements included in updated induction programme.	

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
5	Insufficient, or ineffective management of, financial resources (Risk to Deployment objective b Risk Owner: Richard Sydee	**Cause** • Fee payers unable to pay licence fees - • The number of licenced establishments changes, leading to reduced fee income • Management fail to set licence fees at a level that recover sufficient income to meet resource requirements • Failure to estimate resource required to meet our regulatory activity • Poor budget and/or cash-flow management • Unexpected increases in regulatory responsibilities • Unforeseeable price increases / reductions in GIA • Fraudulent activity detected too late **Effect** • Payments to suppliers and/or staff delayed • Compensatory reductions in staff and other expenditure budgets • Increased licence fees • Requests for further public funding • Draw on reserves • Failure to adhere to Cabinet Office Functional Standards **Leading to:** • Inability to deliver operations and carry out statutory remit • Reputational damage and non payment of fees	5	4	Ongoing	Budget management framework to control and review spend and take early action	2	4		X	X		All	Budgetary control policy reviewed annually and agreed by SMT	Last review January 2019 - revised version in August 2020. (Being reviewed by SMT)
						Financial projections, cash flow forecasting and monitoring				X			Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report to Authority July 2020
						Licence fee modelling							Preventative	Annual update to fees model	Update agreed by the Authority November 2019 meeting
						Rigorous debt recovery procedure				X			Preventative	Monthly finance reports to SMT and quarterly to Authority	This has changed in response to COVID19 impact on licence holders - April licence fees have been deferred until September. 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 2019
						Delegation letters set out responsibilities				X	X		Preventative	Delegation letters issued annually	Issued in May 2020
						Fees model provides cost/income information for planning				X			Preventative	Annual review of fees model, reported to SMT and Authority	Update agreed by the Authority November 2019.
						Annual external audit						X	Detective	NAO report annually	Last report in June 2020 - clean opinion
									Monitoring of income and expenditure (RS) Ongoing			X	Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report July 2020
									Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) Ongoing	X	X		Detective	Quarterly Finance Directors and Accountability meetings	FD from NHS Resolution, HRA, NICE and CQC maintain contact over common issues 2019/20 - last met July 2019 DHSC Finance wrote in September indicating confirmation of GIA funding sometime in October 2019 Confirmation of 2020/21 GIA recovered in December 2019 - no formal lnote of delegation st present.
									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 devleoped and presented to ARAC Oct-19. Annual training of staff completed n Q4	Cabinet Office responses/feedback, although fraud prevention now part of BAU for the organisation.

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	LOD 1	LOD 2	LOD 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
6	**Failure to achieve the benefits of the *HTA Development Programme*** **(Development objectives a-d)** **Risk owner** **Louise Dineley**	**Causes** • Uncertainty of funding • Programme and project benefits poorly defined and understood • Inadequate programme and project governance arrangements • Poorly specified programme and projects • Insufficient programme, project and change management skills • Inadequate leadership of change • Inability to access the necessary skills required at a affordable cost • Lack of staff buy-in to change • Management and Head stretch of delivering transformation alongside business as usual and other development activity • Insufficient agility in (re)deploying people to change projects • Poorly specified procurement and inadequate contract management • Realisation of single points of failure for DDAT and People Strategy **Effects** • Wasted public money • Failure to achieve the central strategic intent of the Authority • Distracts senior management from operations at a time when demands have increased • Reputational damage • Unaffordable cost over run • Staff demotivation • Data remains under-utilised • Technology inadequate to meet future needs (cost, functionality) • Limited ability to achieve improvements in efficiency and effectiveness • Pace of change is inadequate and impacts negatively on other work	5	4		SMT experience of organisational change, programme and project management.	3	3	*Change Manager appointed in August 2020 to support the development of capacity & capability across the organisation*	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 communciations 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 in Q3 & Q4 to strengthen phasing of actions, resource deployment and consolidation of actions to encourage smarter working.*	X			Preventative	*Progamme plan in place*	Update reported to July Board meeting
									Embed Benefits Realisation Management methodology within programme	X			Preventative		
									Introduce a Programme Management Office	X			Preventative		New PM appointed, procedures and PMO to be established by - date TBC
									Authority approval to proceed at key Gateway decision points		X		Monitoring		
									Act on the formal training needs analysis undertaken for the HTA more widely to identify and improve the level of internal capability to deliver the programme	X			Preventative	Formal training needs analysis data provided to HTA April 2019	Date TBC
									Training plan to encompass project and change management and HTA approach	X			Preventative		Date TBC
						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, significant progress made at end of 2019/20 budsiness year and work ongoing on 2020/21 plan.
									SROs identified for Programme and individual projects	X			Preventative		Date TBC
						Project management includes a monitoring of costs			Schedule a regular programme of staff engagement events	X			Preventative		Date TBC
						Scope of projects aims to deliver benefits including on a phased and incemental design			Establish an external stakeholder communications and engagement plan	X			Preventative		
									Recruitment of new Authority Member(s) with digital and organisational change experience		X		Monitoring		To be actioned at next recruitment round
						Agreed priorities in Business Plan and underpinning foundations for future strategy maintain required pace			Programme to become a focus for appropriate internal audit			X	Monitoring/ Detective		
									Appointment of external critical friend to counter potential optimism bias			X	Preventative		

Audit and Risk Assurance Committee paper

Date	15 October 20209	**Paper reference**	AUD (13/20) Annex B
Agenda item	8	**Author**	Morounke Akingbola
			Head of Finance and Governance

Protective Marking	OFFICIAL

Operational Risk Register

Purpose of paper

1. To present the Operational Risk Register.

Decision-making to date

2. None.

Action required

3. ARAC Members are required to comment on the operational risks within the HTA Operational Risk Register attached to this paper.

4. This paper was reviewed and approved by the Director of Resources on 9 October 2020.

Background

5. The operational risks are normally reviewed by the HTA Management Group (HTAMG) and this continued up to the beginning of the COVID-19 pandemic.

6. Due to the challenges around agile business planning, HTAMG found that they were mainly focused upon dealing with issues that arose rather than the existing risks. This continued into quarter one of the 2020/21 business year.

7.   Whilst the attached register has now been updated, it has been felt by the Heads of Department that the current risks may need tweaking prior to a more detailed review of how risks are articulated and managed.

8.   The Committee are asked to note that the summary page showing comments against each risk is up to date as of August and September 2020, however, the risk scores/RAG rating, may not be fully reflective of the narrative.

9.   In order that the operational risk register remains relevant, time will be allocated at the weekly HTAMG meetings to look at those risks that it is felt need some revision.

HTA Operational Risk Register 2020-2021

OPERATIONAL RISK REGISTER
SUMMARY OF EACH RISK

Impact		Rare	Unlikely	Possible	Likely	Almost Certain
5	Very high	5 Medium	10 Medum	15 High	20 Very High	20 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

HTA
Human Tissue Authority

Ref	Risk	Risk Owner	Q1	Jul-20	Aug-20	Sep-20	Comments
1	Failure to provide accurate advice or to make evidence-based regulatory decisions, leading to known or inadvertent breaches of statutory and regulatory requirements (Delivery a-c)	Heads of Regulation (JP lead)	8	8	8	8	Update Q1 - Activity levels affected by pandemic (lockdown) Update: July - August: Business as usual activities are being delivered, though living donation cases are rising significantly so the LOD team are busy and have less capacity for other work. Risks to the delivery of the Virtual Regulatory Assessments (VRA) and Safe Site Visits projects have been identified and proposals are being drafted. Two additional RMs have been identified to be trained to assess emergency mortuary licence applications. Update for September: Virtual Regulatory Assessments (VRA) and Safe Site Visits projects are Amber on the business plan. The unexpected loss of key members of the project team has introduced delays to the VRA project and the Safe Site Visits is Amber due to tight timescales. The plan to start VRAs in the HA sector is Red, this work will begin in October. Living donation cases are increasing, along with an increase in ODT SAEARs.
2	Inadequate management of stakeholder relationships (Delivery d-e)	Head of Communications (MS)	9	9	9	9	Update Q1: with COVID-19 hitting and lockdown measures coming into effect, there was potential reputational damage through inaction, delayed action, or incorrect action in response to the national situation. Suspending scheduled on-site inspections helped mitigate this, as well as a relatively uniform approach by other regulators. Update Q2: As the country moved out of lockdown, and BAU activities came back online alongside an ambitious range of change projects, there is a risk that we don't engage stakeholders early and adequately enough, or we don't follow through and deliver on our plans once they have been communicated. We are also entering a potential second wave as we move towards Q3 and a busy period leading up to the UK Transition out of the EU, both of which bring their own unique challenges and potentuial impacts on our relationships with our stakeholders.
3	Failure to deliver development and change activities (Development a-d)	Head of Development (AT)	0	0	12	12	Update for Q1: imperative for change activity driven by COVID 19 response with focus on business critical areas Update for Q2: demands for change driven through development programme which, along with COVID 19 response, has resulted in increased focus on change activity. Competing priorities mean that although there in increased focus on change risk score is unchanged. Overall risk analysis below will be reviewed in Q3 to factor in organisational changes and development programme.
4	Failure to manage staff turnover and workforce capability (Deployment a)	Head of HR (SC)	12	12	12	16	Update for Q1 - The pandemic response put considerable pressure on the organisation's ability to manage the workforce effectively. This is the result of uncertainty in the external environment and the dramatic changes to ways of working (moving to remote working entirely) and job content (removal of site visit inspections and new pressure e.g. in the PM sector). Delivery continued and turnover was significantly reduced. Update for Q2 - The position continued to stabilise during the quarter as remote working became normalised. There is considerable effort being put into new activity (safe site visits, virtual regulatory assessments, development programme and other change projects - office move, website development and EU transition. There is some evidence that the business plan for Q3 and Q4 will be difficult to deliver with the resources allocated as they are at present and there will be work undertaken on this in early Q3. Staff turnover continues to be low.

HTA Operational Risk Register 2020-2021

Ref	Risk	Risk Owner	Q1	Jul-20	Aug-20	Sep-20	Comments
5	Inadequate management of finances (Deployment b)	Head of Finance and Governance (MA)	8	12	12	12	April - June update: Small positive variance against budget. The impact of the COVID-19 pandemic has seen deferment of our billing which may have an impact on cashflow in quarters 2 and beyond. The residual risk has been amended to reflect this. July - August update: Currently still within budget. There still remains a risk to income collection and an impact on our cash as we approach the September run. This has been reflected in its probability and impact score. September - As of above. A detailed review of expenditure plans to be undertaken in October. A reversal of provisions made at the end of 2019/20 will impact on available funds.
6	Inadequate management and utilisation of data and business technology (Deployment c)	Head of Business Technology (DT)	0	0	12	12	Update Q2: As we continue to operate in a fully remote way and having moved to Office 365 at the start of the business year, the risk focus continues to be around our new ways of working and the inherent risk arising from a lack of knowledge in how to use the new platform, alongside the elevated threat from opportunistic malicious actors taking advantage of the uncertainty and anxiety caused by the external environment. System level monitoring is in place and active threat hunting is undertaken on a regulr basis.
7	Inadequate business planning (Governance)	Head of Planning & Performance	9	9	9	9	August update: business planning has been disrupted so far this year by COVID-19 uncertainty, and there are now some risks to delivery of the big projects. Project plans are being developed/amended and a new form of resource planning is to be trialled for Qs 3 and 4. Risk remains unchanged for the moment.

Reference		Comments:
1	Failure to provide accurate advice or to make evidence-based regulatory decisions, leading to known or inadvertent breaches of statutory and regulatory requirements Linked to Strategic Risk 1 & 2	Update Q1 - Activity levels affected by pandemic (lockdown) Update: July - August: Business as usual activities are being delivered, though living donation cases are rising significantly so the LOD team are busy and have less capacity for other work. Risks to the delivery of the Virtual Regulatory Assessments (VRA) and Safe Site Visits projects have been identified and proposals are being drafted. Two additional RMs have been identified to be trained to assess emergency mortuary licence applications. Update for September: Virtual Regulatory Assessments (VRA) and Safe Site Visits projects are Amber on the business plan. The unexpected loss of key members of the project team has introduced delays to the VRA project and the Safe Site Visits is Amber due to tight timescales. The plan to start VRAs in the HA sector is Red, this work will begin in October. Living donation cases are increasing, along with an increase in ODT SAEARs.
Risk owner	Heads of Regulation (JP lead)	
Proximity	Ongoing	

Inherent Risk >>		>> Residual Risk	
Impact	Likelihood	Impact	Likelihood
4	4	4	2

Risk Analysis						
Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance	Assured Position
Inexperience of regulatory decision makers	Range of potential effects, including: •failure to identify or follow up a shortfall against HTA standards following inspection / audit; •incorrect interpretations by staff of statutory and regulatory requirements; and •failure to follow up with an Independent Assessor or Living Donor Coordinator leading to an incorrect decision being made and / or inconsistent decision making across the team.	Guidance on inspections, SOPs and templates for staff. Induction and ongoing training programme for RMs to include codes of practice/standards and core elements of inspection and HTA regulation. This includes QA checks of enquiries by line manager when an RM is in their probation, and periodically from that point as necessary when Head input is required. Inspection evidence workbooks across all sectors Procedures for escalating regulatory decisions.			Internal QA procedures. Training records and PDP process. Channels for receiving feedback / complaints. Monthly / weekly reports.	t.b.c

Inadequate training for regulatory decision makers	Range of potential effects, including: •inconsistent regulatory decision making; •inconsistent application of enforcement processes; •inaccurate or poor quality advice and guidance given, leading to inadvertent regulatory or statutory breaches by licensed establishments; •establishments fail to comply with Codes, directions, licensing standards and conditions; •increased risk of SAEARs and HTARIs; and •loss of public and/or professional stakeholder confidence.	Improved RM induction and training programme and work to ensure contingency for teams. Decision-making framework. Sector-specific learning resources for RMs and establishments. RM probation period and sign-off process.	Work being undertaken to review the level at which documents are signed off. Ongoing review of governance documents		HR records of induction and sign-off including new onboarding template PDP process. Channels for receiving feedback / complaints.	t.b.c
Heads' time focussed on developing new team members so less capacity to support other team members	Inadequate supervision and oversight of regulatory decision making	Regular 1:1s with staff and annual PDP process. Monthly / weekly reports. Internal QA processes. Staff training and sign-off procedures.			HR records of induction and sign-off. PDP process. Channels for receiving feedback / complaints.	t.b.c
Loss of knowledge and experience through staff attrition	Heavy reliance on remaining RMs and HoR for sector-specific knowledge. Insufficient trained staff to undertake inspections and specialised project work. Reprioritisation of business plan activities such as projects and inspections.	Handover procedures when staff leave Team meetings and sector update sessions provide opportunities for RMs to share learning Regular RM meetings to share learning Internal sector-specific guidance documents / policies / position papers Information resources such as Impact, CRM, legal advice database, etc	Training of staff to cover other areas of the business to increase resilience.		No over-reliance on particular staff members for particular issues	
Inadequate systems (including quality management systems) and processes to support effective, risk-based, regulatory decision making	Poor clarity and transparency of regulatory processes Inadequate risk evaluation resulting in inspection schedule that may not reflect risk Site visit inspections which do not provide for adequate scrutiny of licensed activities (e.g. at satellite premises or during themed inspections) Decline in professional and public confidence in the work of the HTA Quality Management processes not clearly codified Poor quality documents made public/shared with the Authority Regulatory practices not consistent with Regulators' Code Increased scrutiny by DH/Select Committees	Suite of standard operating procedures underpin regulatory processes 2-yearly compliance updates with more focused and risk-based questions across all sectors; 2 yearly inspections in the HA sector and annual activity data CRM / Impact / Teams / OneDrive / Portal Decision-making framework and tools, including escalation procedures for 'significant' regulatory action	Internet and intranet development Development of desk-based assessment processes EDRMS Office 365 functionality	Q2 20/21	Feedback from staff (e.g. staff survey) and professional stakeholders (evaluation surveys, compliance updates feedback) Project work / development programme involving Transforming Systems	t.b.c

Lack of sufficient relevant expertise, in-house or access to it externally, to support decision making	Failure to identify, adequately resolve and follow up potential regulatory issues Poor/inappropriate decision making Inefficient use of resources	Recruitment procedures and strategies to ensure relevant / diverse expertise Involvement with groups such as HWG, RASRM, TAG, JPAC, SaBTO, SCUG. RM part-time secondment with HRA Participation at EU-level meetings (where appropriate) for expertise and information in the HA / ODT sector.	HA risk project action – access to external expertise. Improved access to scientific journals. Continue to support staff to attend conferences and increased networking opportunities.	To be completed in 2020/21 business year.	Feedback we get from professional stakeholders about our expertise, for example via the professional stakeholder evaluation. Feedback received from staff via PDP process and the staff survey	t.b.c

Reference		Comments:
2	Inadequate management of stakeholder relationships Linked to Strategic Risks 1 & 3	Update Q1: with COVID-19 hitting and lockdown measures coming into effect, there was potential reputational damage through inaction, delayed action, or incorrect action in response to the national situation. Suspending scheduled on-site inspections helped mitigate this, as well as a relatively uniform approach by other regulators. Update Q2: As the country moved out of lockdown, and BAU activities came back online alongside an ambitious range of change projects, there is a risk that we don't engage stakeholders early and adequately enough, or we don't follow through and deliver on our plans once they have been communicated. We are also entering a potential second wave as we move towards Q3 and a busy period leading up to the UK Transition out of the EU, both of which bring their own unique challenges and potentuial impacts on our relationships with our stakeholders.
Risk owner	Head of Communications (MS)	
Proximity	Ongoing with potential peaks depending on the external and internal environment	

Inherent Risk >>		>> Residual Risk	
Impact	**Likelihood**	**Impact**	**Likelihood**
4	**4**	**3**	**3**

FALSE

Risk Analysis						
Potential Causes	**Potential Effects**	**Existing Controls/Mitigations**	**Actions to improve mitigation**	**Date**	**Sources of Assurance**	**Assured Position**
Ineffective relationships/communication with sponsor branch	Reputational damage and reduced confidence in our work	*Framework agreement *Good communications channels with sponsor team and press office *Communications attends various ALB communications meetings *DH sit on the HTA's stakeholder group and Authority as observers *Regular business and accountability meetings with DH *Informal communications as required	*Work with the DH to ensure that information is passed on in the most effective way *Work to ensure that the HTA is not over burdened with information requests	17/18	Positive feedback from DH at accountability meetings *Feedback from DHSC accountability meetings*	
Ineffective relationships /communications with the interested public	Reputational damage and reduced confidence in our work	*Public engagement plan agreed *Effective communications routes (website, social media, newsletter) along with SOPs *Public representation on Stakeholder Group (and other groups) *Bi-monthly public e-newsletters *Annual review publication and event *Key meetings organised with partners, comms team offered briefs *Regular surveys *Monitoring of enquiries and monthly reporting: 95% of enquiries answered in 10 days *Plan for regular website review updating - improved search,/navigation, updated content etc... *Review of public facing information and creation of cord blood pack etc. *Internal staff group to look at public engagement	*Enquiries project (from Q3 2017/18) to address process, quality, systems etc... *Implementation of style guide, key messages, templates training for staff *Refresh Stakeholder Group membership *Improve look and feel of website content (Web Survey and Content review in 17/18) *Guidance for people attending external events * Public Evaluation in 2017 (outcomes to influence the public engagement plans) *Website developments *New public information review group and online forums *Work to disseminate public communications via partner organisations *Investigate online panel solution (i.e. online community for public engagement)	17/18	Evaluation forms part of the communications quarterly report to the Authority **Results from surveys of public via the public panel, website and other channels including general enquiries, media coverage and commentary and via social media etc...**	

Ineffective relationships /communications with stakeholders, including DIs, IAs and AAs	Reputational damage and reduced confidence in our work	*Public patient engagement plan agreed *Effective communications routes (website, social media, newsletter) along with SOPs *Effective Stakeholder Group *Two monthly professional and public e-newsletters *Annual review publication and event *Key meeting organised with partners, comms team offered briefs *Regular surveys: feedback sought after inspections, events, training and other ad hoc work *Monitoring of enquiries and monthly reporting: 95% of enquiries answered in 10 days *New website and regular website updating	*Better relationships with establishments project (formerly known as the DI relationship project and DI e-learning project) *Enquiries database and survey *Triennial review action plan published *Implementation of style guide, key messages, templates training for staff *Refresh Stakeholder Group membership *Review critical incident plan *Improve look and feel of website content *Guidance for people attending external events and toolkit *2016 stakeholder survey	17/18	~~Evaluation forms part of the communications quarterly report to the Authority~~ **Results from surveys of professionals, feedback and insight from the LEEP group**	
Ineffective relationships /communications with media	Reputational damage and reduced confidence in our work	*General media approach agreed - **why is this litigation?** *Lines up to date, weekly news digest, list of media mentions, list of journalist contacts *Subscription to Meltwater *Media handling SOPs *E-newsletter *Key meeting organised with partners, comms team offered briefs *Media guidance for AMs *Media training *Out of hours rota *Contact with other press offices	*SOPS *Filming guidelines *FOI and enquiries target *Continued publication of data (transparency) *Review critical incident plan *Update media handling SOP *Continue to work on projects related to HTA regulation to build our profile	17/18	~~Evaluation forms part of the communications quarterly report to the Authority~~ **Evaluated quarterly through Authority reporting (Delivery report) and kept under review on an ongoing basis.**	
Inaccurate stakeholder analysis	Lack of understanding in the HTA about our key audiences and their concerns	*Yearly stakeholder analysis takes place	*Review contacts in CRM and Mail chimp	17/18	~~Evaluation forms part of the communications quarterly report to the Authority~~ **Need to think about how we are assured that we are accurate; Stakeholder mapping?**	
Inadequate communications tools (website, social medial, newsletter, events etc.)	Inability to communicate with key audiences	*New website developed *Social media presence maintained *e-newsletters maintained *Internal branding and design support	*Review of website content assign web pages to owners *Digital survey *Website developments ongoing *DI e-learning *Increased use of webinars and webchats	17/18	~~Evaluation forms part of the communications quarterly report to the Authority~~ **Survey results from web pop up, and other channels, to measure user experience and effectiveness of engagement and comms channels**	
Inadequate communications input into HTA work and projects (Codes and Standards, Import and Coding, Fees etc.)	Poor stakeholder understanding about HTA's work and lack of input from our audiences	*Comms team involvement in projects including Standards and Codes roll out, fees and Coding and Import	*Develop media plans *Develop publication schedule	17/18	~~Evaluation forms part of the communications quarterly report to the Authority~~ **Each project or programme has a comms representative**	
Inadequate understanding about changes in the external environment (legislation, burden reduction etc.)	Poor at influencing the external environment and lack of HTA understanding of important policy changes	*SK and the upcoming media/publications plan *SK on the DH media call and feeding back *Weekly news digest *Events in the staff newsletter *Regular meetings with stakeholders *Is SK a person if so not a mitigation*	*Establish appropriate knowledge management and horizon scanning functions for the HTA *Communications timetable regularly at SMT *Develop horizon scanning function	17/18	~~Evaluation forms part of the communications quarterly report to the Authority~~ **Establishment of a Horizon Scanning function across all areas of the HTA**	
Inadequate staffing and knowledge management of the communications team	Communications team unable to operate properly	*Cross team knowledge developed about different aspects of our work *Appropriate professional development courses and membership identified	*Head of Communications handover effective	17/18	~~Evaluation forms part of the communications quarterly report to the Authority~~ **Proactive approach to recruitment, retention, and training/development.**	

Reference		Comments:
3	Failure to deliver development and change activities Linked to Strategic Risks 1 and 4	Update for Q1: imperative for change activity driven by COVID 19 response with focus on business critical areas Update for Q2: demands for change driven through development programme which, along with COVID 19 response, has resulted in increased focus on change activity. Competing priorities mean that although there in increased focus on change risk score is unchanged. Overall risk analysis below will be reviewed in Q3 to factor in organisational changes and development programme.
Risk owner	Head of Development (AT)	
Proximity	Ongoing currently high	

Inherent Risk >>		>> Residual Risk	
Impact	**Likelihood**	**Impact**	**Likelihood**
5	**4**	**4**	**3**

Risk Analysis						
Potential Causes	**Potential Effects**	**Existing Controls/Mitigations**	**Actions to improve mitigation**	**Date**	**Sources of Assurance**	**Assured Position**
Identification of change						
Inadequate horizon scanning and stakeholder engagement to inform development	Failure to identify areas for improvement	Horizon scanning lead by Heads of function with expertise and links to key stakeholder Advisory groups Core horizon scanning team established to consolidate and review horizon scanning outputs	Horizon scanning log established to monitor issues identified	Ongoing	Horizon scanning map; Minutes of stakeholder meetings Horizon scanning log will set out measures of effectiveness.	
Inadequate use of internal data sources to inform horizon scanning	Failure to identify areas for developments	Horizon scanning is a standing agenda item at team meetings	Agreed core data sets used to inform regulatory approach	Q3 2019/20	Figures published in annual review document; Sector specific publications based on data analysis. Provides assurance that we are using internal data sources to inform our work	
Failure to act on information from horizon scanning and loss of in depth sector knowledge	Lack of informed response Unable to adapt to change Reactive rather than proactive Regulatory approach unable to mitigate sector risks	In depth review of risk in HA and PM sectors with agreed recommendations for improvement	Regular risk reviews and deep dives of each sector Agreed core data sets used to inform regulatory approach	Q3 2019/20		
Inadequate horizon scanning and stakeholder engagement to inform priorities	Failure to effectively prioritise work to meet stakeholder (internal and external) expectations and meet externally imposed outcomes or deadlines	Central horizon scanning team ; Discussion of priorities at HTAMG	Report on horizon scanning outcomes to HTAMG Strengthen systems and processes for policy and development work (policy framework)	Quarterly	monthly data report detailing HS activities	
Planning and Management						
Risk of not delivering change poorly understood	Poor resource allocation between core operational business and development projects.	Continuous business planning includes consideration of project and development work and how to balance competing work priorities - discussions via HTAMG and at SMT	Improvements to continuous business planning process to include greater emphasis on resource allocation Improve balance between delivery and development resource allocation Strengthen use of data to improve regulatory focus and target resource to risk Team workplans prioritised and balanced against inspection scheduling	Ongoing	Management information used to demonstrate effective use of resource	
Projects are not added to the business plan and/or not all change activities recognised as projects	Poor resource and skills allocation Project objectives not in line with business priorities	Oversight of business plan by Heads and Directors	Cultural change to encourage Heads to discuss items at HTAMG and add to the business plan Build on continuous business planning process to be clear about what is added to corporate and team plans Team plans linked to outputs from horizon scanning and have greater visibility	Ongoing	Business plan updated monthly; HTAMG minutes.	
Lack of management support	Project team does not have authority to achieve project objectives	Projects discussed by HTAMG and approved by SMT; SRO at Head or Director level.			SMT minutes (Projects standing agenda item)	

Poorly defined project outcomes and measures of success	Outcomes which do not meet stakeholder (internal and external) expectations or project objectives	Outcomes included in project templates reviewed by HTAMG	When reviewing milestone log, consider whether the milestone is still the right one		Project documentation in IMPACT; HTAMG papers and minutes.	
Scope is poorly defined	Scope creeps with uncontrolled changes and is no longer in line with business plan objectives Project becomes undeliverable	Project scope included in planning templates Governance arrangements (SRO/project board) for individual programmes and projects in place	Formalise 'issue logs' as part of the project planning and feed into horizon scanning		Project documentation in IMPACT; HTAMG papers and minutes.	

Required activities and tasks are missing from project plan	Project requires further resource or extension to timelines to deliver Quality of project is compromised	Project plans approved by HTAMG	Greater scrutiny of project plans by HTAMG	Ongoing	Project documentation in IMPACT; HTAMG papers and minutes.	
Required activities and tasks are not completed as part of project plan	Poor quality outcomes which leave the organisation exposed to risk	Project milestones reviewed at HTAMG Progress tracked on BP monitor Key projects reported to Authority in Development report			HTAMG minutes Business plan monitor spreadsheet Development report to Authority (quarterly) Authority minutes	
Inaccurate estimates of resource during project planning	Resource requires diverting from delivering other objectives or project takes longer to deliver Poor use of resources	Project plans approved by HTAMG			Project documentation in IMPACT; HTAMG papers and minutes.	
Frequent changes to scope	Schedule and/or budget are continually extended leading to perception that project has failed	Changes to scope approved by HTAMG			Project documentation in IMPACT; HTAMG papers and minutes.	
Poorly defined project/change process	Inconsistency in decision making		Further embed continuous business planning process and make improvements to documentation to make process accessible and more efficient	Ongoing	Completed project documentation in Programme Office area of IMPACT; HTAMG minutes.	
Insufficient resource (budget, staff) allocated or available to deliver change projects.	Delays to delivery of projects or poor quality outcomes Staff perception of change and morale affected		Greater scrutiny of resources required by HTAMG prior to project approval HoPP role to address resource allocation	Ongoing	Project documentation in IMPACT; HTAMG papers and minutes.	
Poor governance and oversight of project delivery	Delays to delivery of projects or poor project outcomes	Progress on projects reviewed at HTAMG monthly Key projects include Authority Members on project board			Project board meeting notes HTAMG papers and minutes	
Skills/resource						
Insufficient programme and project management training and/or experience and/or specific programme and project knowledge concentrated in the hands of small number of people (vulnerable to staff loss).	Delays to delivery of projects or poor quality outcomes	Central location for project information in IMPACT	Recruitment of dedicated PM role Experienced staff to share learning to develop a wider set of HTA project managers All Officers trained in project support Experienced staff to share learning to develop a wider set of HTA project managers (project management covered in lunch and learn schedule)	Ongoing	Key members of staff hold project management qualifications or have relevant experience	
Insufficient deployment of resource to development activities and lack of experience in key development areas such as systems and process changes	Delays to delivery of projects or poor quality outcomes	Continuous business planning includes consideration of project and development work and how to balance competing work priorities Project plans include scoping of systems and process changes		Q3 2019/20	Project planning documentation SRO accountability for project completion	
Ac						
Failure to communicate change effectively (internal and external stakeholders)	Reputational impact Inconsistency in application of change Change not fully embedded within organisation Lack of buy in	Member of Comms team should input into all projects Early engagement and consultation Development activities driven by affected teams			Internal and external newsletters Monday briefings Sector specific communications HTA Website	
Failure to train those affected by change (internal and external stakeholders)	Reputational impact Inconsistency in application of change Change not fully embedded within organisation	RM Training to oversee training of RMs on changes	Development projects to be subject to review post implementation		RM meeting agendas Published HTA Guidance and information	
Failure to ensure change is appropriately documented in policies, SOPs, guidance etc.	Reputational impact Inconsistency in application of change Change not fully embedded within organisation	Project plans include updates to process documents as part of scoping	Process development as dedicated part of role	Recruitment to PM and project development roles	Project planning documentation	

Dependencies on external partners outside the HTA's control	Poor quality outcomes which leave the organisation exposed to risk	Clear lines of communication with key project partners, with escalation routes identified if required Ongoing relationship management with key partner organisations			Contracts with third party providers specify agreed service level provision	

Ongoing review and feedback						
Failure to evaluate change against initially agreed outcomes and measure success, or failure to feed back from lessons learned	Loss of staff morale from not implementing identified areas of improvement or feeding back why Future projects do not benefit from lessons learned Reputational impact	Project not closed until review/lessons learned carried out Discussion of lessons learnt at HTAMG Sharing of project lessons-learned at all-staff events and with Authority where appropriate	Ongoing review of project milestones and deliverables built into project delivery. Agreed processes for evaluating and adjusting outcomes and deliverables built into project management	Ongoing as part of project management	Lessons learned/review documents in IMPACT; HTAMG minutes Project planning documentation	

Risk		Comments:
4	Failure to manage workforce capability and staff turnover effectively Linked to Strategic Risk 4	**Update for Q1 -** The pandemic response put considerable pressure on the organisation's ability to manage the workforce effectively. This is the result of uncertainty in the external environment and the dramatic changes to ways of working (moving to remote working entirely) and job content (removal of site visit inspections and new pressure e.g. in the PM sector). Delivery continued and turnover was significantly reduced. **Update for Q2 -** The position continued to stabilise during the quarter as remote working became normalised. There is considerable effort being put into new activity (safe site visits, virtual regulatory assessments, development programme and other change projects - office move, website development and EU transition. There is some evidence that the business plan for Q3 and Q4 will be difficult to deliver with the resources allocated as they are at present and there will be work undertaken on this in early Q3. Staff turnover continues to be low.
Risk owner	Head of HR (SC)	
Proximity	Ongoing	

Inherent Risk >>		>> Residual Risk	
Impact	Likelihood	Impact	Likelihood
5	**4**	**4**	**4**

Risk Analysis

Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance	Assured Position
Workforce skills and behaviours not aligned with the needs of the business	Weakened ability to deliver the HTA's statutory remit	* People Strategy in place for 2019 to 2021 * Comprehensive suite of HR policies * Clearly articulated organisational values	* HTA Competence Framework in development * Formal mechanisms for the assessment of capability needs and identified routes to fill capability gaps	* Will be completed in Q3 2020 * Immediate needs for 20/21 to be assessed in Oct 2020. Longer term needs will be addressed as part of the development programme	* Published People Strategy * Suite of HR policies available on Wave * Refreshed organisational values widely communicated and branded	The HR policies are fit for purpose, but a number of published policies have passed their review dates. This will be addressed xxxx
Ineffective recruitment practices	*Insufficient staff capacity and capability *Recruits with the wrong skills *Recruits who are not a good fit for the HTA	*HTA Capability Development Framework *Well developed recruitment processes including to business critical posts *Use of testing for Head roles and above	* Organisational capability assessment to become a formal part of SMT terms of reference	* October 2020	* HTA Capability Development Framework approved * Recruitment policy published	HTA Capability Development Framework has been approved, but mechanisms need to be put in place to communicate the content to staff and managers.
Ineffective induction	* Lack of knowledge about what is expected of objectives or behaviours leading to poor performance	* Induction workbook and new starter process * Structured feedback sought on the induction process for new starters at six month anniversary	* Continuous improvement the induction process and pack	* Ongoing	* Induction policy is in place * Induction workbooks in place for RMs * Induction workbooks in place for all other posts	Feedback on remote induction has been positive. Induction policy needs to be reviewed and updated
Inadequate leadership and management	* Lack of understanding and buy-in to the HTA Strategy * Poor understanding of business objectives and priorities * Poor motivation	* Standard management leadership objective for Heads and Directors to be measured against, including holding regular 121 meetings. * Development plan introduced for HTAMG	* Active steps to improve the skills and relationships within the wider leadership team supported by external adviser.	* Q3 and Q4 2019/20 and then ongoing	* PDP process to identify management and leadership development needs * Staff Survey and staff forum feedback * Annual Exit Interview reporting	Assessment by Fiona Reed Associates identified the key areas that require development. Feedback has been provided to the entire team and a plan of action is in place for further individual and team interventions.
Inadequate utilisation of the skills, knowledge and experience of individuals	* Individual demotivation * Failure to capitalise on opportunities	* Well established PDP process * Revised PDP forms and support for 2017/18 to focus on development * Skills matrix made available via Wave	* Continuous improvement	* Ongoing	* Staff forum chair meeting regularly with ARAC chair * Staff survey feedback	This is certainly a risk at present where RMs in particular are not undertaking inspections - which is a core part of their role. This will also evolve as we become clearer on the capability needs as part of the future operating model.
Poor management of workloads	* Uneven or unfair distribution of activities * Stress on individuals	* Regular discussion between staff and line managers at 121s	* Increased scrutiny by HTAMG and SMT	* Monthly	* HTAMG and SMT scrutiny	This cause is potentially heightened during the pandemic as the fundamental nature of some of our work is altered.
Inadequate involvement and communication of what is needed from staff	*Poor understanding of objectives, priorities and decisions * Belief that an individual's voice or concerns are not heard	Variety of mechanisms for two-way communication *Newsletter *Monday briefing and regular staff meetings * SMT drop in *Quarterly business away day *Staff survey *Staff forum	* Development of strengthened internal communications function as part of the HTA Communications Strategy	* Due to be in place during Q3 209/20	* Staff forum chair meeting regularly with ARAC chair * Staff survey and pulse survey feedback	This cause is heightened both due to the move to remote working and in a period of considerable organisational change. Pulse survey suggests that staff are getting what they need, but conversely some evidence that key messages are not getting across.

Inadequate learning and development	* Insufficient skills and knowledge to deliver business objectives * Poor personal and professional development leading to poor motivation	* Learning and development framework * Learning and development plans for each member of staff	* Continuous improvement	* Ongoing	* Annual reporting of learning quality through bespoke evaluation forms * Staff survey feedback	Staff survey feedback suggests there is more to do here, but this is not necessarily borne out in the outputs from the development discussions with line mangers.

Reference		Comments:
5	Inadequate management of finances Linked to Strategic Risk 5	**April - June update:** Small positive variance against budget. The impact of the COVID-19 pandemic has seen deferment of our billing which may have an impact on cashflow in quarters 2 and beyond**.** The residual risk has been amended to reflect this. **July - August update:** Currently still within budget. There still remains a risk to income collection and an impact on our cash as we approach the September run. This has been reflected in its probability and impact score. September - As of above. A detailed review of expenditure plans to be undertaken in October. A reversal of provisions made at the end of 2019/20 will impact on available funds.
Risk owner	Head of Finance and Governance (MA)	
Proximity	End of 2020/21 business year.	

Inherent Risk >>		>> Residual Risk	
Impact	Likelihood	Impact	Likelihood
5	**4**	**4**	**3**

Risk Analysis						
Potential Causes	**Potential Effects**	**Existing Controls/Mitigations**	**Actions to improve mitigation**	**Date**	**Sources of Assurance**	**Assured Position**
Unsophisticated budget setting process.	Breaching mandatory obligations and running out of cash	Budgetary control framework and budget holders manual.	Budget Holder training – attach to meetings	In line with policy review dates	Quarterly finance meetings, noted back to directorates. Monthly reports submitted to Directorates.	Finance Reports and quarterly review highlighted the trending increase in underspend.
Inadequate budget management skills across the HTA.	Where overspend exists, inability to respond to demanding changes (lack of flexibility).	Monthly/Quarterly finance meetings attended by heads of directorates and directors.		Quarterly throughout business year		
Fraudulent activity goes undetected for a period of time	Loss of financial resources, reputational damage where we publish under FLR	Reconciliations and independent review of financials	High level risk assessment to be conducted across the organisation. Action plan to work towards meeting the Basic GovS 013 (Fraud Functional Standard)	Quarterly throughout business year	Cabinet Office Functional Standards published annual as part.	
Ineffective reporting system for managers to compare performance against budget.		Monthly management accounts with accompanying transaction listings. Quarterly review meetings		5 days after end of each month, so ongoing		
Failure to disseminate the budget and delegated authorities.	Consumption of finance resource unplanned. If significant affects cash flow	Budget training and meetings to be held.	Delegation letters issued annually confirming financial responsibilities - Completed Q1			
Reduction in license fee collection (unable to increase price again).	Failure to deliver statutory remit and operational plans.	Credit control system and supporting SOPs in place.	Detailed quarterly reviews carried out enabling us to re-forecast	July, October, December of each financial year	ALB Monitoring returns to DH quarterly	Positive Cash reserves

Unresponsive to sector changes	Reputational damage.	Legal support for debt recovery process.	Income predictions at least twice a year 2nd prediction carried out in July-18	Prior to invoice runs (March, August)	Finance commentary for SMT and Authority reporting	
Poor financial controls.	Slippage of delivery of BP.	Financial Forecasting.			Internal Audit – Financial Controls audit	No losses reported; no high/medium audit recommendations received
Spending restrictions imposed by central government.	Underspend due to inadequate forecasting.	Monthly meeting with DoF to review spends and planned income. Monthly reporting to Authority, SMT, and Audit Committee.			Quarterly finance reports to Authority	
	Lose legal status and get taken over by another regulatory body.	Returns to DHSC on quarterly basis.				
Failure of Great Plains	Inability to comply with statutory reporting.	Backup of Great Plains.		Backups are taken to a replicated server		
Non use of GPS frameworks	Missing out on government rates therefore not obtaining the best possible price.	Procurement lead attending forums Procurement and tender policy in place. DH CCS controls including Business Case requirement).	Procurement lead to update staff on all new relevant Government Frameworks - No change to framework agreements as of June-18	Annual - staff email	Returns submitted to DH monthly on spends by category.	Mandated CCS Framework agreements
		Adoption of Crown Commercial Services (CCS frameworks (HoF)			*Attendance at Procurement ALB Forum*	
NHS Trusts experience financial difficulties; special measures and panels prioritising payments.	Significant reduction in cash flow affecting business ass usual operations	Robust credit control process;	Possibly offer terms to pay monthly; horizon scanning; networking to keep abreast of changes NHS/Monitor	Terms offered to 2 orgs currently.		
Impact of COVID-19 pandemic - deferment of invoicing of establishments	May significantly reduce cash flow affecting business ass usual operations	Robust credit control process; DHSC made aware of current situation	Possibly offer terms to pay monthly; horizon scanning; networking to keep abreast of changes NHS/Monitor			

Reference		Comments:
6	Inadequate management and utilisation of data and business technology Linked to Strategic Risk 4	Update Q2: As we continue to operate in a fully remote way and having moved to Office 365 at the start of the business year, the risk focus continues to be around our new ways of working and the inherent risk arising from a lack of knowledge in how to use the new platform, alongside the elevated threat from opportunistic malicious actors taking advantage of the uncertainty and anxiety caused by the external environment. System level monitoring is in place and active threat hunting is undertaken on a regulr basis.
Risk owner	Head of Business Technology (DT)	
Proximity	Ongoing	

Inherent Risk >>		>> Residual Risk	
Impact	**Likelihood**	**Impact**	**Likelihood**
5	**3**	**4**	**3**

Risk Analysis								
Potential Causes	**Potential Effects**	**Existing Controls/Mitigations**	**Actions to improve mitigation**	**Date**	**Sources of Assurance**	**Assured Position**		**SPF**
No knowledge transfer	Lack of operational resilience due to reliance on knowledge of single individual.	Information captured in IT systems in a way that is retrievable and searchable including HTA wiki, IMPACT and CRM. See also: Risk 1 - Capability & Capacity Risk 9 - Governance *SOPs, training and guidance on HTA systems.*	*Consolidate guidance into wiki. Encourage use of wiki to capture more informal knowledge.* *Review list of systems and related guidance* *Remove out of date guidance from all systems.*	Year end	Systems guidance and SOPs Wiki	The HTA still relies on informal knowledge transfer but, along with regularly reviewed SOPs, the wiki has the potential to make existing guidance more accessible and to capture more informal organisational knowledge.	1	
No information maintenance	Not compliant with -Data Protection Act/GDPR -FOI Act -Public Records Act Inefficient use of resources Inefficient HTA operations	Information asset register defines retention periods. *Staff clear out of personal data complete.*	*Review actions against information assets and continue to add new information assts.* *Consider retention periods and housekeeping with IAOs.*	Year end	Information Asset Register on the wiki	The information asset register goes some way to defining what should happen to assets, and when. At present this is done on an ad-hoc, when needed basis. The HTA has undertaken an exercise with all staff to clear out personal data no longer needed. The IQ project will continue to address this.	1	
No information strategy	Inconsistent development of information systems and processes leading to no control or oversight of information assets. Information not stored in most efficient or reusable way leading to duplication and poor analysis of buried/hidden data which in turn can lead to poor decision making.	IT Strategy updated annually. BCC IT, CRM and LAN support, contracts. Webcurl support contract.	*Develop an 'information strategy' with an overarching view and road map of how to store and make best use of information. Strategy to include* *-Information architecture* *-Information capture/consolidation* *-Information processing* *-Information analysis*		IT strategies and HTAMG papers. Quarterly meetings with BCC Quarterly meetings with Webcurl	The HTA has a good idea of where it is going from an ICT point of view but needs to remain flexible and open to new developments.	1	
Information Risk Management Regime								

No governance framework Inappropriate risk appetite No SMT or Authority engagement No risk management policies No lifecycle approach	Increased exposure to risk Inappropriate levels of decision making Ineffective policy implementation Duplication of risk management activities	Information assurance framework in place including protective marking scheme. Information risk appetite defined in Information Governance policy Authority kept engaged with information risk through Strategic risk register SMT engaged with information risk through strategic and operational risk registers and HTAMG HTA has overall risk policy Risk register reported on monthly and updated if necessary Risk register and policies reviewed annually. Caldicot guardian appointed.	*Ensure risk policy covers information risk*	Year end	Information governance policy HTA risk policy HTAMG meeting minutes SMT meeting minutes Authority meeting minutes Operational and Strategic risk registers Caldicott Guardian logs & reports.	The HTA's approach to information risk is set out in the IG policy and the HTA has a risk policy. The Authority and SMT are sufficiently engaged in information risk and at this time a recognised standard would potentially add more burden without significant benefits. There are risks that accepting traceability records may lead to the HTA receiving records not related to traceability. This is mitigated through the SOP for receiving such records. The Caldicott Guardian will have a register of all records received on the wiki.	1, 2
Secure Configuration							
No update or patch policies in place No lockdown of operating systems or software No vulnerability scans	Unauthorised changes to systems Exploitation of unpatched vulnerabilities Exploitation of insecure system configurations Increase in number of security incidents	All servers patched and updated as necessary. Laptops do not have optical drives. Installation and configuration permissions restricted. Scanning folder wiped daily and abandoned printouts put in confidential waste. Printer and scanning controls in place. Assurance templates now being received from all key suppliers.	*Consider automated tool to manage and audit ICT assets and software, including updates.* *Consider tools to conduct vulnerability scan against HTA network. Portal and website.*	End of quarter two.	Email reports of patch updates from webcurl/BCC. Nagios reports from WebCurl being agreed. Standard assurance template now being completed quarterly by WebCurl and BCC. BBD have indicated they will use it from first quarterly review.	Management of servers and infrastructure is outsourced to BCC for the HTA's internal network, to webcurl for the Portal and to the website supplier for the website. As such the HTA is reliant on these 3rd parties patching and configuring servers and networks appropriately. It is important that the HTA gets timely and sufficient assurances. A standard assurance template is now being used for key suppliers. This has a high inherent risk and impact but is considered to be adequately mitigated.	2
Network Security & Monitoring							
Network perimeter not policed No protection of internal network No intrusion monitoring in place No testing of security controls No monitoring strategy or policies No monitoring of ICT systems No monitoring of network traffic	Leakage of sensitive corporate information Import or export of malware Denial of service Damage or defacement of website or portal. Attacks not detected. Attacks not responded to appropriately. No accountability.	New firewall installed March 2016 and IDS in place for HTA network, Portal and website. Websense filters email and web traffic to HTA network. HTA network segregated appropriately from internet and internal IPs not visible. VPNs in place to portal. Corporate Wi-Fi protected by password. Separate guest Wi-Fi not connected to HTA network. Administration only carried out over secure channels. HTA network and servers monitored. PWC penetration test. Server health and storage monitored.	*Firewall reports from Webcurl* *Firewall reports from Website supplier* *Consider frequency of penetration tests.* *Consider log server.*	Q	Fortnightly firewall report from BCC. List of monitored servers and services maintained by Martin. Network diagram maintained by Martin. PWC penetration test report and recommendations. System documentation on wiki.	Like secure configuration, network security is outsourced and the HTA needs to rely on 3rd party assurances that the appropriate measures are in place. And similarly, this has a high inherent risk and impact but is considered to be adequately mitigated.	2
Manage User Privileges							

No effective account management processes Number and use of privileged accounts not limited Users not monitored	Misuse of privileges Increased attacked capability Negating established security controls	Starter and leaver SOP. There are limited admin accounts and Martin does not use an admin account as his primary account. HR conduct pre-employment checks. Only S&Q have access to transplant approval systems and folders. Only authorised finance and HR users have access to employee systems and folders. Password complexity policy in place on HTA servers: 8 characters, 8 previous passwords remembered, 90 days. Remote access pinsafe two factor authentication. Only authorised suppliers have access to system logs.	*Review starter and leaver SOP.* *The IQ project should consider how to document user access and audit trails.* *Consider Portal user account creation and deletion SOP.* *Tidying up the CRM contacts will make Portal account management (via CRM) more simple and easier to track.* *Consider password policy on portal* *Relevant guidance and SOPs on wiki*	*Year end*	Martin maintains folder with signed out laptops. Emails with requests to change accounts/permissions to bccadmin	Generally, changes to user accounts are managed by Martin or BCC with an email (or CRM IT support case) providing an audit trail. Portal accounts are linked to CRM contacts. Access and usage of files is not currently audited across all systems as this would require development and cost money and is not considered necessary. Key systems track key decisions and changes to information (e.g. CRM history and IMPACT previous versions) This is not considered a major risk.	2
User Education and Awareness							

No user security Policy No staff Induction Process Users not aware of threats No formal assessment of IA Skills	Unacceptable use Use of personal removable media and devices may lead to security incidents. (e.g. malware) HTA subject to legal and/or regulatory sanction. Increased impact of incidents. Misuse of system may lead to compromise. User becomes means of external attack. User becomes source of attack.	IT systems policy (covering acceptable use) Social Media policy Information Governance policy covering information assurance, data protection, forensic readiness, incident response and records retention (actual periods listed in information asset register). Disciplinary policy. Induction process and documents. CSL courses for Information assurance. BSC data protection course. Ad-hoc newsletter updates. Ad-hoc all staff meeting updates. System guidance. Internal audit survey. Policy acknowledgements now being received by email.	*Promote formal IA qualifications and courses.* *Promote awareness of Information asset register.*	*Quarter two* *Throughout the year.*	IT Systems Policy Information Governance Policy Social Media Policy. Disciplinary Policy. Guidance on HTAlk. CSL records. BSC records. Newsletters and all staff meeting minutes. CRM Incident cases.	Staff are generally aware of cyber risks but it would be good to get additional assurances that the message is getting out to all staff and that they remain aware. HTA staff and suppliers are required to annually acknowledge the IG and Cyber risk policy by email.
Incident Management						
No senior management approval and support No incident response and DR capability No specialist training	Major and/or continual disruption of business operations. Non-compliance with legal and regulatory reporting requirements.	SMT approval of Information Governance Policy which covers incident response and forensic readiness. Business continuity plan with defined roles and responsibilities. Business continuity plan updated yearly in line with business plan. Incidents captured and tracked in CRM. Server and data backups to BCC DR site. Lessons learned following major incidents. New CIRP now in place aligning critical incidents and business plans and training in place.			Ad-hoc DR test report emails from BCC Fortnightly backup report emails from Martin. CRM incidents. Full business continuity tests including DR site.	Information is backed up and replicated to an offsite DR site. The DR site was tested fully in October 2014 with a good awareness of DR procedures shown by all staff. We now have a new critical incident response plan which covers business continuity, DR and critical incidents. This has clear links from day to day SOPs and clear responsibilities for handling and escalating incidents.
Removable media controls & Malware Prevention						
No removable media corporate policy No limits on use of removable media No scanning of removable media for malware No corporate malware policies No anti-malware defences No scans for malware	Loss/leakage of information through theft, loss or neglect. Introduction of malware via: -Email -Web browsing and social media -Removable media and personal devices. Reputational damage. Financial loss or fines.	IT Systems policy covers use of removable media and personal devices. Websense scans email and webtraffic before it enters the HTA network. Websense blacklists websites. (The firewall can blacklist IP addresses.) Microsoft Forefront protects laptops from malware. Laptop baseline build HTA encrypted USB keys available for staff. USB devices are blocked by default on HTA laptops.	*Consider CESG end user device configuration guidance (covers all points above)*	*Quarter 3*	Websense logs. Quarantined emails. Forefront logs.	The HTA is comprehensively covered across the internal network and the risk of malware is small. The PWC tests recommended that malware scanning should take place on the portal server itself. The HTA has mitigated the risks of malware entering the network via the portal and does not consider this necessary. CESG provide detailed guidance around the configuration of end user guidance which will be considered. The greatest risk in this area is users so awareness is important.
Home and mobile working						

The columns for the three content rows also contain a final risk-score column showing: 2, 3 / 4 / 1 respectively.

No risk assessments or mobile working policy Users not educated or aware No secure baseline build	Loss or theft of device. Being overlooked in public spaces. Loss of credentials. Tampering.	Home working policy. Remote users have secure login and do not work on non HTA devices. BSC home working course and self-assessment. GOOD server central control of mobiles Access to office controlled by pass. Laptops locked in pedestals when not in use. Laptops encrypted with McAfee endpoint encryption. Direct Access now in place providing secure access from HTA laptops that are external.			Home working Policy. BES server logs. Physical asset register. Martin keeps list of mobile phones by user.	There is a risk of home users either printing information out and not securing or disposing of it appropriately. In theory it is also possible that HTA information may be emailed to personal accounts and worked on non-HTA devices as we do not have assurance that this does not happen.	1
No risk assessments or mobile working policy Users not educated or aware No secure baseline build	Loss or theft of device. Being overlooked in public spaces. Loss of credentials. Tampering.	Home working policy. Remote users have secure login and do not work on non HTA devices. BSC home working course and self-assessment. GOOD server central control of mobiles Access to office controlled by pass. Laptops locked in pedestals when not in use. Laptops encrypted with McAfee endpoint encryption. Direct Access now in place providing secure access from HTA laptops that are external.			Home working Policy. BES server logs. Physical asset register. Martin keeps list of mobile phones by user.	There is a risk of home users either printing information out and not securing or disposing of it appropriately. In theory it is also possible that HTA information may be emailed to personal accounts and worked on non-HTA devices as we do not have assurance that this does not happen.	1

Reference		Comments:
7	Business plan is not the right plan to delivery strategy, and business plan is not delivered Linked to Strategic Risk 4	**August update:** business planning has been disrupted so far this year by COVID-19 uncertainty, and there are now some risks to delivery of the big projects. Project plans are being developed/amended and a new form of resource planning is to be trialled for Qs 3 and 4. Risk remains unchanged for the moment.
Risk owner	Head of Planning & Performance	
Proximity	Ongoing	

Inherent Risk >>		>> Residual Risk	
Impact	Likelihood	Impact	Likelihood
4	**4**	**3**	**3**

Risk Analysis

Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance
Planning					
Lack of buy-in to business plan means staff continue to work on non-priority items	resource is not used in the agreed way and the business plan is not delivered	New business planning process has involved all Heads, communication of the business plan at all staff awayday, monthly progress reporting in place	Heads/directors maintain a view on their teams' delivery against the business plan - ongoing Learnings from business planning process last year are gathered and built in to improving the process this year	ongoing	Monthly report - all held to account for delivery in their 1-2-1s with their line managers
Lack of understanding of time demands for different pieces of work leads to an undeliverable business plan	Elements of plan are not delivered, or quality is affected	resource model generated, business plan contains estimates of resource, monthly report now shows workload flows, problem definition sheet for project work includes resource counts	Activity resourcing to be properly scoped through project planning and links to project plans to be made into business plan. New resource calendar view to be trialled and Heads to track and amend in weekly HTAMG	Starting Q2	HTAMG meetings and minutes. Revision to inspection and audit schedule as required.
COVID 19 changes mean business plan is unclear and changing	We don't deliver to the best of our ability	weekly and monthly reporting to allow agile decisions, weekly HTAMG to allow shifting of priorities and resource, comms to staff and general staff understanding of the need for agility	Maintain a watch on business plan delivery	ongoing	weekly and monthly reports, revisions to business plans
Resources need to be allocated to other unplanned activity - e.g. EU exit, new licensing challenges	We aren't able to deliver the planned activity	EU weekly meetings; weekly HTAMGs to allow conversations about new work and shifting resource; PM in place for office move/web redevelopment/EU exit to maintain focus on those areas	project management to be ramped up again as EU exit approaches; project management approach now being adopted for desk based assessment piece and return to site visit piece		As above plus project meeting minutes and workplans
Monitoring				Cultural shift underway	
Poor reporting and management information means that SMT and Heads fail to manage their resource effectively to deliver the plan	Business objectives and targets are not met. Lack of revaluation / reprioritisation of business plan (review and adapt).	Business plan updates now in place; Monthly reporting now in place; weekly reporting in place (may be replaced by dashboards); some dashboards set up	Role of HTAMG/SMT in managing performance to be clarified; Not delivering the business plan seen as a performance issue and is addressed by SMT/Heads/Managers in team meetings and 1-2-1s where applicable		Business plan updates and monthly reports and dashboards

			As above -		
Lack of organisational awareness of strategic priorities and business plan means work done in teams is not aligned to strategy	Failure to deliver strategic objectives.	Key objectives for 2021 agreed as part of business planning cycle			
Resources					

Audit and Risk Assurance Committee paper

Date	15 October 2020	**Paper reference**	AUD (14/20)
Agenda item	9	**Author**	Louise Dineley
			Director of Data, Technology and Development
Protective Marking	OFFICIAL		

Development Programme Report

Purpose of paper

1. This paper aims to provide an update on the HTA's Development Programme and to set out the scope of work for the next six months.

Decision-making to date

2. The priorities in the development programme continue to reflect and drive forward core themes of the HTA's Strategy and the vision to support and maintain the delivery of its purpose.

3. This paper was reviewed and approved by the Director of Resources on 9 October 2020.

Action required

4. The committee is asked to note the paper and the action that has been taken to incorporate outstanding actions and recommendations from internal audits into development plans over the next six months.

Background

5.   For the last three years the HTA Strategy has been committed to strengthening the
use of data and developing our technology to support the delivery of effective
regulation. Progress in the achievement and realisation of the intended benefits had
been constrained due to the availability of resources (financial and people). In quarter
four 2019/20 there was a renewed drive to realise the developments of the strategy
through the successful cloud migration, implementation of O365 and establishing a
baseline on our current and future data, intelligence and information requirements.

6.   The coronavirus pandemic presented an opportunity to reset our plans and use our
resources.   In quarters one & two activity levels across the business have been
generally lower than in previous years. This offered the opportunity to focus on
progressing developments previously constrained by resources through targeted
investment.

7.   At the July Authority meeting we shared an update on the Development Programme
confirming the priority projects and their scope. Since then the focus has been
planning the projects in detail which has included embracing outstanding actions from
internal audit recommendations and bringing long standing issues into scope. This
alignment of actions will help in future proofing some of the proposed developments
and establishing a sustainable HTA Target Operating Model for the next three year
strategy.

Table 1 provides a matrix of actions and alignment to the Development programme priority
projects.

	Development Programme - priority projects 2020/21					
	Develop the HTA Operating Model	**Strengthen the use of data and intelligence**	**Implement an EDRMS**	**Optimise O365 functionality**	**Horizon scanning for future regulation**	**Organisational Preparedness**
Outstanding ARAC actions						
Action 2: To review and sign off the Records Management Policy at the October 2019 meeting.			X			
Action 6: HA risk update and progress with remaining actions to be provided at the June ARAC meeting.	X	X				
Action 3: The leaver's and starters process to be reviewed at the June meeting.						X
Action 5: To present a dashboard style report relating to cyber security risks.			X	X		

Update on the Priority Projects

8.   The focus of the projects in quarter two has centred planning and scoping the delivery and implementation of the developments. This planning has included:
     a.   Project planning
     b.   Mapping interdependencies
     c.   Identified benefits
     d.   Management of resources

In addition, we have also mapped a critical path for each project for the remainder of this financial year with business as usual / operational developments. This provides ongoing assurance on the foundations to support the HTA Strategy 2021-24 as well as what we need to achieve in year.

9.   *Strengthening the use of data & intelligence* : Following the commissioning of Transforming Systems in August, further progress has been made in the development of how the HTA uses data and intelligence in the delivery of effective regulation. The commission includes support to draft a Data & Intelligence Strategy and the identification of a core data set based one existing data collection. This data set will then be used to develop a proof of concept model that utilises existing systems and data sources to help identify potential areas of risk and target the HTA's regulatory response. It is anticipated that there will be a further commission following the evaluation of the proof of concept to realise the end state for strengthened data and intelligence capability in the HTA.

10. *Developing the HTA Operating Model:* The early scoping of the Operating Model has confirmed the core functions and provided a high level view on proposed changes to past methodologies. In scoping the future purpose of the functions, licensing, data, assessment (previously inspection), corrective action and authoritative voice, there are a number of changes to our systems, processes and people that will be needed. A critical interdependency to the development of a future operating model is the development of data and how this is used as part of an updated regulatory offer and the assessment of compliance in licensed establishments. A key change from the current regulatory approach will be the use of a range of assessment tools. Site visits will continue to be an option and will be supplemented by ongoing insight assessments and targeted virtual assessments.   As work progresses in quarters three and four our aim will be to test the proposed changes internally and engage the views of external stakeholders.

11. *Implementing an Electronic Document Record Management System (EDRMS):* The planning for the EDRMS project has built on the requirements gathered in quarter four 2019/20 and active actions including past internal audit recommendations. In preparation for the implementation of the EDRMS solution there have been a number

of key actions that have needed to be completed. A key action has been establishing a state of readiness for document migration from IMPACT. In parallel to these housekeeping arrangements, the identification of a preferred solution has continued to be progressed. To support this decision and aligned to the project to optimise O365 functionality, there has been a strategic focus on the HTA's future IT requirements. The draft IT strategy provides a framework and a set of principles for future investment and development that ensures interoperability of our systems as well as phased developments against a central vision. This is particularly relevant to the scoping of the EDRMS project with phase one focused on the replacement of IMPACT and subsequent phases considering the future use of CRM.

12. *Optimising O365 functionality:* The adoption of Office 365 at the end of quarter four provided the HTA with a wealth of functionality. The added functionality of Teams as a collaboration and communication tool has been a significant factor in the successful transition to remote working in the last six months. Looking forward, there is an appetite to build on the strong early uptake and utilise more of the functionality offered through O365 to support collaboration in the development projects and as part of business as usual. The project actions focus on embedding of O365 and the tools available. Examples of how this will be achieved include the development of a series of guides, the identification of internal champions and "super users" to encourage adoption across peer groups and the use of personal activity data to identify and suggest to individuals additional apps and opportunities for use.

13. *Horizon Scanning & future regulation*: The insight from internal horizon scanning has acted as a key source of insight to the development programme design to date and to the early thinking for the HTA Strategy 2021-24. There are a number of areas currently being explored including:

   - Approval of living donation cases (driver- requirement for Board approval for what are now seen as routine cases)
   - Consent provisions for imported material (driver – current area of focus as a result of the MMD Bill)
   - Adaptive licensing models (driver – COVID and Transition Period licensing changes)
   - Information sharing and partnership and innovative ways of working (driver - better regulation initiatives, burden reduction and busting bureaucracy)

14. *Organisational Preparedness*: The emerging developments and details from each of the projects share a common theme of change. The developments identify changes to what we do, how we do it and the potential for additional skills and expertise in the delivery. In August we successfully appointed an experienced Change Manager to help and prepare the organisation for the scale of change anticipated over the next 6 months. This change is not limited to the Development Programme and encompasses the move of the office to 2 Redman Place and the extension of remote working as part

of an ongoing response to COVID -19 and with existing planned changes to employment contracts. In the first six weeks of appointment the Change Manager has made good progress in setting a foundation with staff for the changes ahead. Actions include the introduction of a change management framework and change impact assessments for priority projects, a change management workshop for Heads of function and the alignment of changes irrespective of the programme to ensure staff hear a consistent and single message.

Next steps

15. Over quarter three there are a number of planned deliverables. These include:
    - Completion of an initial proof of concept on the data and intelligence model and commissioning of next steps including the commission of external data collection testing.
    - Agreement of the recommended EDRMS solution and implementation with aim for completion in early January.
    - High level design for the future Target Operating Model including a detailed profile of core functions (licensing, data and assessments)
    - Completion of change impact assessments for all projects
    - Implementation of external engagement strategy of stakeholders in proposed changes to the regulatory model

Audit and Risk Assurance Committee paper

Date	15 October 2020	**Paper reference**	AUD (15/20)
Agenda item	10	**Author**	David Thomson, Head of Business Technology
Protective Marking	OFFICIAL		

Cyber Security Update

Purpose of paper

1. To provide an update to the Audit and Risk Assurance Committee (ARAC) on progress made against the HTA Cyber Security strategy.

Decision-making to date

2. This paper was reviewed and approved by the Director of Resources on 9 October 2020.

Action required

3. To note the Head of Business Technology's report of actions taken to date.

Background

4. The Head of Business Technology holds operational responsibility for managing the cyber security risks to the HTA and for recommending and implementing improvement and mitigation actions in line with the HTA Cyber Security strategy.

5. The HTA Cyber Security strategy was approved by the ARAC at the 16 June 2020 meeting.

6. The Government Internal Audit Agency has carried out a review of the HTA Cyber Security strategy. This has been reported on separately.

Report

7.   The HTA Cyber Security strategy is focused on the five core objectives of: Identify, Protect, Detect, Respond and Recover.

8.   The bulk of the improvement actions taken since June have centred around the Protect and Detect objectives.

9.   Actions taken to meet the Protect objective include:

   a.   In September, all staff have completed mandatory eLearning modules covering Using email and the internet securely and Phishing awareness
   b.   Enabling a sign-in risk policy to ensure that suspicious sign-ins are challenged for multi-factor authentication
   c.   Enabling a user risk policy to detect the probability of a user account being compromised
   d.   Enabling password hash synchronisation between the on-premise and cloud active directories to limit the number of passwords that a user is expected to remember
   e.   Disabling clear text credential exposure
   f.   Disabling legacy protocol communication
   g.   Disabling weak cipher usage
   h.   Blocking unsecure end-user credential impersonation
   i.   Removing dormant accounts
   j.   Protecting local administrator accounts with access control lists
   k.   Reducing lateral movement pathways between non-sensitive and sensitive accounts
   l.   Removing unsecure security identifier history attributes
   m.   Resolving unsecure account attributes
   n.   Blocking the ability for users to grant consent to unmanaged applications
   o.   Configuring cloud app security to detect anomalous behaviour
   p.   Configuring automated notification of new cloud application usage
   q.   Configuring cloud app security to detect shadow IT application usage
   r.   Limiting the number of administrative roles
   s.   Limiting weak security protocol usage

10.   Actions taken to meet the Detect objective include:

   a.   Reviewing email transport rules to detect auto forwarding of email to external domains
   b.   Reviewing account provisioning activity
   c.   Reviewing application usage

d. Ensuring no users have had their email privileges automatically restricted due to anomalous activity

e. Reviewing self-service password reset activity

f. Reviewing spoofed domains report

g. Reviewing user role group changes

h. Threat hunting using Azure Sentinel

11. In addition to Protect and Detect actions we have also taken action to meet the Recover objective by adding an Office 365 backup capability to our existing on-premise backups.

12. The next phase of activity will focus on the Identify objective and further work to meet the Protect objective. Activities will include identification and classification of the sensitive information types in use at the HTA and applying metadata labels to the information types to enable the Office 365 environment to take appropriate action upon detecting sensitive information types in transit. Other activities will focus on protecting end user devices and managing the internal threat.

Audit and Risk Assurance Committee paper

Date	15 October 2020	**Paper reference**	AUD (16/20)
Agenda item	11	**Author**	Nicky Harrison, Director of Regulation
			Robert Watson, Head of Regulation
			Louise Knight, Regulation Manager
Protective Marking	OFFICIAL		

HA Risk Project Update

Purpose of paper

1. To provide an update to ARAC on the progress/status of the HA Risk project.

Decision-making to date

2. The previous update to ARAC was in November 2019.

Action required

3. None.

Background

4. HA Risk project work has continued since the previous ARAC update in November 2019.

    In relation to the Preparation Process Dossier (PPD) work the following actions have been completed:

    *   There are documented procedures for:

        –   the mandatory tracking of relevant information at different time points during PPD assessment and decision (PO1).
        –   managing PPD related RDMs (e.g. where these take place, their outcomes and pending/future actions) (PO4).

- managing conditional authorisations (PO7).
- auditing PPD information relating to assessment and decision. A pilot audit has been completed by the quality forum and the process is acceptable (PO2).
- Benchmark review templates have been established for 28 tissue types based on internal and external information; the templates include critical quality attributes (CQAs) and critical processing parameters (CPPs) (PO5).
- The investigation of alternative IT systems to manage PPDs and associated data have been incorporated into Development programme work (PO9).

- Two actions remain open:

  - A review of existing established processes which do not have a PPD submission has been completed. A paper relating to 'deemed authorised' preparation processes has been drafted and is awaiting review by SMT. The paper recommends that a subset of deemed authorised preparation processes are submitted for review, but that this process be deferred to Q1 21/22.
  - The HTA PPD guidance to establishments has been reviewed and updated to clarify the HTA's expectation of the information to be submitted as part of a PPD. A decision has been taken not to include benchmark criteria within this document until the GAPP project has concluded (PPD5); this will enable us to determine how best to disseminate this information and to remain aligned with developments in the sector.

- Regarding Inspection work the following actions have been completed:

  - Changes made to inspection workbook to formally capture procurement and/or processing. Serious Adverse Events and Reactions (SAEARs) discussion slot included in timetable templates. Procurement will not be observed (IO1).
  - Procedures relating to SAEARs, PPDs etc. have been updated to ensure operational changes and risk indicators are considered during inspection scheduling and planning (IO2).
  - Training is a standing agenda item at HA team meetings (IO10).
  - The HTA's Data Analyst provides shortfall data for discussion at HA team meetings (IO7).

- Two actions remain open:

  - Plans are in place to resume Technical Liaison group meetings with the MHRA in Q3, and progress has been made to generate a list of establishments jointly licensed and regulated with the HFEA. Work is ongoing to generate an updated list with the MHRA (IO3).

- No further work has been undertaken on the enhanced use of external experts in the delivery of our regulatory functions within the sector. We are exploring whether this can be addressed in the Development programme as part of the work package on the operating model (IO6).

- No separate work has been undertaken on the following objectives as they will be addressed as part of the development programme, which includes work packages on a risk based and data and intelligence led approach to regulation:

  - A model for a risk-based approach should be adopted which is based on known information concerning the establishment complexity and updated as required (I1).
  - The frequency with which an establishment is subjected to a full site visit inspection should be based on risk (I2).
  - More use should be made of inspections to look at major changes and SAEARs (I3).
  - The inspection of satellite premises should be reviewed and made more consistent (I4).
  - The use of self-assessment reports should be considered as part of the inspection preparation process (I5).
  - A series of operational changes should be implemented to strengthen the conduct of the inspection process by clarifying focus and strengthening resource (I6).

- The following pieces of work have not been taken forward as they are not considered priorities for the organisation at this time:

  - The HA standards should be reviewed so that they are better targeted at assessing compliance with the requirements of the legislation (I7).
  - RM training and qualifications should be reviewed in line with the technical knowledge required of the sector and the recommendations set out in ViStart inspection Guidelines (I8).
  - The inspection of testing laboratories should be reviewed to consider the roles of the HTA and UKAS (IO4).
  - The inspection of microbial testing and testing of tissue/cell parameters should be clarified (IO5).

Audit and Risk Assurance Committee paper

Date	15 October 2020	**Paper reference**	AUD (17/20)
Agenda item	12	**Author**	Matthew Silk
			Head of Communications
Protective Marking	OFFICIAL		

Licensed Establishment Engagement Programme (LEEP) Update

Purpose of paper

1. To update ARAC on the work and status of LEEP.

Decision-making to date

2. N/A

Action required

3. None.

Background

4. LEEP began in 2017 under the title "Improving Relationships with DIs (Designated Individuals)', then 'Relationships with people working at licensed establishments', primarily focusing on engagement with DIs.

5. The aim of this project was to take a view on how well the HTA was engaging DIs, and to explore new areas of work to improve relationships and engagement.

6. Following the departure of the then Director of Policy, Strategy, and Communications and the then Stakeholder Engagement Manager, after a short pause in activity the project was picked and up by the Head of Communications and the new Stakeholder Engagement Manager.

7. Rebranded as the Licensed Establishment Engagement Programme, this new overarching initiative – following up on feedback from work undertaken in 2017 – sought to establish both an internal and external group to consider engagement with all licensed contacts at HTA-licensed establishments.

8. The internal LEEP group comprised a number of HTA Regulation Managers and members of the Communications Team. The external group comprised two Authority Members, professionals from licensed establishments, and ad hoc attendance from those leading work at the HTA as and when required.

9. The aims of the LEEP were to provide advice, guidance, and steering for ongoing and new work in relation to engagement with licensed establishments. One reason for calling this a programme, rather than a project in its own right, was because it incorporated work undertaken in a variety of other projects.

10. The three aims/benefits of LEEP were:

    i. **Increased input into the development of new processes, policies, and projects**
        Resulting in higher quality products, outputs, and outcomes

    ii. **Encouraging greater understanding of how to achieve compliance**
        Looking at training packages for professionals at establishments and increasing engagement with Persons Designate and Corporate Licence Holders

    iii. **Sharing learning and best practice**
        Looking at how to use our finite resources to share learning and best practice more widely and actively, for the benefit of professionals working at licensed establishments.

11. The main areas of work/consideration for the LEEP were:

        a. Training materials
        b. Evaluating the impact of engagement work
        c. Scoping the potential development for an online forum
        d. Inputting into policy and process development
        e. Exploring the value of existing HTA stakeholder groups
        f. Looking at potential engagement events
        g. Exploring the concept of HTA relationship managers

12. These areas of work evolved over time, for example:

        a. After a meticulous exploration into the pros and cons of training packages and different mediums, with an options appraisal, the decision was taken not to progress with this as a project due to other resource demands.

b. After working closely with colleagues at what was then the Department of Health Digital Team, and having worked through a Discovery period to establish users needs, feedback from professionals working at establishments did not evidence a need for an online forum.

Current status of LEEP and the continuation of engagement work

13. The founding principles of LEEP are still relevant to the work of the HTA, but it was clear as we moved through the 2019/20 business year that the group had made as much progress as it could in its current form.

14. Outstanding pieces of work – notably looking at a programme of webinars – were not considered as a priority against other work that had to be delivered, and so following discussions with the wider management group, it was decided not to dedicate further resource to progressing these.

15. As a result, LEEP was suspended – as an active group that meets regularly – temporarily, in order for individual members to be able to devote their time to other project and regulatory work.

16. Work continued on an ad hoc basis amongst group members, particularly on some of our older digital content, in correspondence and via ad hoc meetings, which looked to update and develop existing web content and functionality during 2019, such as:

    a. Updating our licensing flowcharts on the HTA website.
    b. Establishing the external HTA blog as an additional engagement channel.
    c. Adding a "follow" function on licensed establishment pages, to notify users when an inspection report is published.
    d. Following the decision not to follow through with the production of a training provision, working with the LEEP group we developed and published a series of online tests for professionals to self-assess their knowledge of our requirements. These were very positively received and by the end of 2019/20 had been taken, over 3000 times.
    e. Working in collaboration with other Regulators and key stakeholders to produce shared resources, such as new e-learning modules on research tissue banks with colleagues at the Health Research Authority.

Looking ahead

17. With the focus of the 2021/21 Business Plan on a suite of change and development projects, members of the LEEP group are engaged in a variety of activities which may

once have fallen under the purview of LEEP, but due to the volume and scale of the work, sit better as individual projects and programmes in their own right.

18. One of the original work packages back in 2017 was to look at establishing a "Relationship Manager" role at the HTA, something which our 2020 professional stakeholder evaluation found to be a popular potential development.

19. As we develop a new Communications and Engagement Strategy during the 2020/21 business year, we will revisit the work, principles, and aims and objectives of LEEP, to see what we might usefully adopt moving into our new ways of working in 2021 and beyond.

HTA
Human Tissue Authority

Audit and Risk Assurance Committee paper

Date	15 October 2020	**Paper reference**	AUD (18/20)
Agenda item	13	**Author**	Richard Sydee
			Director of Resources
	OFFICIAL		

Reserves Policy

Purpose of paper

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

Decision-making to date

2. This policy was last reviewed by the Committee in October 2019 at which point it was confirmed that we were unsuccessful in gaining DHSC approval to use our reserves. Since then, the global pandemic has required us to make decisions around our billing of establishments that could impact on our cash reserves.

3. Also at the October 2019 meeting, the Committee agreed that the HTA should maintain an ongoing minimum cash balance of £900k to facilitate its usual cash flow requirements plus a £600k buffer for exceptional events. We continue to monitor our cashflow for early warning indicators of significant reduction in our cash balance.

4. 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 billing all sectors in September, the attached policy remains unchanged.

Action required

5. ARAC Members are required to note the un-amended policy.

HTA

Cash flow forecast

Year ended 31 March 2020

	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
	Actual	**Actual**	**Actual**	**Actual**	**Actual**	**Actual**	**Forecast**	**Forecast**	**Forecast**	**Forecast**	**Forecast**	**Forecast**	**Forecast**
Opening Balance	4,250,007	3,696,468	3,400,649	2,622,602	2,512,960	2,120,376	1,679,546	1,545,030	1,579,465	1,721,147	2,153,424	2,640,824	3,020,833
Revenue Receipts													
Government Grant in Aid	-	-	-	176,000	-	-	211,000	-	-	223,000	-	161,000	-
Licence fees and other income	47,213	32,601	-	87,681	-	80,641	86,782	428,706	583,965	668,776	948,447	718,459	333,730
Other cash receipts	1,799	40,495	494	2,885	-	-	-	-	-	-	-	-	-
Total receipts	*49,012*	*73,096*	*494*	*266,566*	*-*	*80,641*	*297,782*	*428,706*	*583,965*	*891,776*	*948,447*	*879,459*	*333,730*
Payments													
Trade creditors	232,135	233,177	478,115	111,506	82,634	273,828	129,296	134,481	139,281	156,497	158,047	196,449	255,387
Other Cash payments	4,080	2,667	46,665	5,934	3,770	1,040	-	-	-	-	-	-	-
Salaries	136,710	133,070	142,145	137,596	131,667	134,732	183,638	140,425	183,638	183,637	183,637	183,637	183,636
PAYE & Niers & Pension	229,626	-	111,617	121,171	174,513	111,870	119,364	119,364	119,364	119,364	119,364	119,364	119,364
Total Payments	*602,551*	*368,914*	*778,542*	*376,208*	*392,584*	*521,471*	*432,298*	*394,271*	*442,283*	*459,498*	*461,048*	*499,450*	*558,387*
Net Revenue Receipts/(payments)	*(553,539)*	*(295,818)*	*(778,047)*	*(109,642)*	*(392,584)*	*(440,830)*	*(134,516)*	*34,435*	*141,682*	*432,278*	*487,399*	*380,009*	*(224,657)*
Total Revenue Cash Flow	**3,696,468**	**3,400,649**	**2,622,602**	**2,512,960**	**2,120,376**	**1,679,546**	**1,545,030**	**1,579,465**	**1,721,147**	**2,153,424**	**2,640,824**	**3,020,833**	**2,796,176**

Reserves Policy

Version number	15.5	**Date last approved**	September 2019
Reference	HTA-POL-049	**Next review due**	September 2020
Author(s)	Head of Finance	**Owner**	Director of Resources
Reviewed by	HTA SMT	**Distribution**	HTA SMT & Authority
Approved by	Audit and Risk Assurance Committee		

Purpose

1. The purpose of this policy is to ensure that both the Executive and Authority of the HTA 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 taken into account 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 on 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 2019/20, there is an increase in the level of reserves, primarily as a result of the increase in income we are recovering from regulated establishments and static expenditure base in 2019/20. 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 80% 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, 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 £300k. A reserve of two months would therefore be £600k.

Minimum reserves

13. The HTA's minimum level of reserves for 2019/20 will be maintained at a level that provides £600k for unforeseen difficulty, and meets the cash flow volatility requirement of £0.9m. The minimum cash reserves required for 2019/20 is therefore calculated as £1.5m. These reserves will be in a readily realisable form at all times.

14. Each quarter the level of reserves will be reviewed by the Director of 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 able to 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

19. Document each version or draft providing a simple audit trail to explain amendments.

Date	Version	Comments
30.07.09	0.3	Approved by the Authority
12.11.10	0.4	Approved by the Authority
31.01.12	0.5	Reviewed - minor change
31.12.12	0.6	Reviewed - minor change
07.02.13	0.6	Approved by Audit Committee
14.10.13	0.7	Amended
02.01.15	0.8	Amended
04.02.15	15.0	Approved by ARAC
22.01.16	15.1	Reviewed and amended
27.01.17	15.2	Reviewed and updated
14.01.18	15.3	Reviewed and updated
28.06.18	15.4	Amended reserves level as per ARAC
12.09.19	15.5	Small amendments to dates and roles

Audit and Risk Assurance Committee paper

Date	15 October 2020	**Paper reference**	AUD (19/20)
Agenda item	14	**Author**	Morounke Akingbola
			Head of Finance and Governance

Protective Marking	OFFICIAL

Gifts and Hospitality Register

Purpose of paper

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

Decision-making to date

2. None.

Action required

3. The Committee is requested to note the attached register which has not changed since it was last tabled in January 2020.

Register of Gifts / Hospitality Received and Provided

Version:	HTAG0001
	Oct-20

DIVISION / DEPARTMENT: HTA

FINANCIAL YEAR(s): 2017/18 - onwards

	Details of the Gift or Hospitality						Provider Details			Recipient Details	
Type	Brief Description of Item	Reason for Gift or Hospitality	Date(s) of provision	Value of Item(s)	Location where Provided	Action on Gifts Received	Name of Person or Body	Contact Name	Relationship to Department	Name of Person(s) or Body	Contact Name
Receipt	Bottle of Champagne	Leaving gift for Staff member	12/04/2017	£30	HTA Offices	Accepted, staff member allowed to retain as gift was deemed to of a personal nature	BCC	D Atha	IT services supplier	Jamie Munro	
Receipt	Lunch	Lunch paid for by one of our suppliers of legal advice during a meeting	12/06/2017	£15 each	Not disclosed	Hospitality refused	Blake Morgan	Eve Piffaretti	Legal supplier	Victoria Marshment Sarah Bedwell	
Receipt	Dinner and drinks reception	Stakeholder	27/09/2017	Unknown	Not provided	Declined	NHSBT Cardiff	Ian Trenholm	Licensee and stakeholder	Bill Horne	
Receipt	Financial payment £150/£250	Participation in survey	21/11/2017	£150/£250	Not provided	Declined	SIS International Research	Cedric Marin	Cold call	David Thomson	
Receipt	Decorative plaque	As a thankyou for hosting the delegation	27/11/2017	Unknown	HTA Offices	Accepted	Ghuizhou Medical University	Amy Li	Visiting Academics	Amy Thomas	
Receipt	2 1,2kg tins of Quality Street	Christmas gift for staff	05/12/2017	Less than £15	HTA Offices	Accepted, distributed to all staff	BCC	D Atha	IT services supplier	David Thomson	
Receipt	Cinema screening - Star Wars	Registration to an event	13/12/2017	Less than £20	Not disclosed	Declined	Nutanix	Noor Ughratdar	None - sales call	David Thomson	
Receipt	Eye Masks, Biscuits, Cake	Thank you from	13/04/2018	£20	HTA Offices	Accepted	University of Tokyo	Dr Kayo Takashima	Visiting Research Fellow	Suet-Ping Wong, Julie Edgeworth, Adam Morris	Regulation, Comms Directorates
Receipt	Hamper	Non given	12/12/2018	Less than £20	HTA Offices	Accepted, distributed to all staff	BCC	D Atha	IT services supplier	D Thomson	
Receipt	Logo'd USB stick	Non given	21/12/2018	Less than £5	HTA Offices	Accepted, placed in stationery cupboard	Frontier Software	D Patel	Payroll Bureau	M Akingbola	
Receipt	Light refreshment	Provided for attendees at launch event	22/01/2019	Between £2-£3	Celtic Manor Resort	Accepted	Westfield Health British Transplant	Not given	Not given	Bill Horne	Authority Member
Receipt	Lunch	Research/fact finding on flexible working	04/04/2019	£8	Facebook	Accepted	Facebook	Not given	Not given	Bill Horne	Authority Member
Receipt	Lunch	Research/fact finding on flexible working	04/04/2019	£8	Facebook	Accepted	Facebook	Not given	Not given	Allan Marriott Smith	CEO
Receipt	Dinner	The DHSC Care 100: Lessons for the future event	16/07/2019	£25	Pig and Goose	Accepted	Strand Group 38	Matin Stolliday	Not given	Nicolette Harrison	
Receipt	Lunch	Lunch provided on inspection	09/07/2019	Unknown	On site	Accepted	Cytec Limited [L/N 11083]		Licenced establishment	A Whiaker/V Stratigou	
Receipt	Lunch	Lunch provided on inspection	11/07/2019	Unknown	On site	Accepted	Cytec Limited [L/N 22671]		Licenced establishment	A Whiaker/V Stratigou	
Receipt	Lunch	Lunch provided on inspection	31/07/2019	Unknown	On site	Accepted	Oxford DRWF [L/N 22496]		Licenced establishment	A Shackell/R Barallon	
Receipt	Lunch	Lunch provided on inspection	28/08/2019	Unknown	On site	Accepted	B'Ham Women & Childrens NHS FT [L/N 40051]		Licenced establishment	A Whitaker/R Barallon/J Scherr	
Receipt	Lunch	Lunch provided on inspection	05/09/2019	Unknown	On site	Accepted	Future Health Technologies [L/N 22503]		Licenced establishment	A Whiaker/N Harrison/P Bergin	
Receipt	Lunch	Lunch provided on inspection	11/09/2019	approx £30	On site	Accepted	King's College Hospital [11006]		Licenced establishment	A Vossenkaemper/V Stratigou	
Receipt	Lunch	Lunch provided on inspection	12/09/2019	Unknown	On site	Accepted	Anthony Nolan [L/N 22527]		Licenced establishment	H Tang/R Barrallon	
Receipt	Lunch	Working lunch and tea - NHSBT Strategy workshop	26/09/2019	Unknown	On site	Accepted	NHST		Licenced establishment	N Harrison/A Marriott-Smith	
Receipt	Lunch	Lunch provided on inspection	10/10/2019	Unknown	On site	Accepted	Royal Sotke [L/N 22593]		Licenced establishment	A Shackell/H Tang	
Receipt	Reception	EU Organ Donation day	10/10/2019	Unknown	House of Lords	Accepted	NHSBT		Licenced establishment	A Gibbon/A Marriott-Smith	
Receipt	Lunch	Lunch provided whist delivering training SNOD's	14/10/2019	Unknown	On site	Accepted	NHSBT		Licenced establishment	A Whitaker/R Barallon/J Scherr	
Receipt	Lunch	Lunch provided on inspection	16/10/2019	approx £35	On site	Accepted	Tissue & Cells Technologies Ltd [L/N 11020]		Licenced establishment	A Whitaker/A Vossemkeamper	
Receipt	Lunch	Lunch provided on inspection	30/10/2019 31/10/2019	Unknown	On site	Accepted	The London Clinic [11052]		Licenced establishment	L Knight/S Wong/M MacRory	
Receipt	Sweet treats	Christmas	17/12/2019	Unknown	HTA Offices	Accepted	Softcat		IT services supplier	D Thomson	
Receipt	Lunch	Lunch provided on inspection	11/12/2019	Unknown	On site	Accepted	Royal Free [L/N 12406]		Licenced establishment	A Shackell/A Vossenkaemper	
Receipt	Lunch	Lunch provided on inspection	14/01/2020	Unknown	On site	Accepted	Microbiotica L/N [12694]		Licenced establishment	J Merrimen-Jones	
Receipt	Lunch	Lunch provided on inspection	16/01/2020	Unknown	On site	Accepted	Belfast City Hospital		Licenced establishment	A Whittaker/J Edgeworth/R Barallon	
Receipt	Lunch	Lunch provided on inspection	23/01/2020	Unknown	On site	Accepted	Cannock Chase Public Mortuary L/N [12303]		Licenced establishment	H Tate/J Merrimen-Jones/L Carter	
Receipt	Lunch	Lunch provided on inspection	29/01/2020	Unknown	On site	Accepted	Alderhey Hospital [L/N 22595]		Licenced establishment	H Tate/H Vossenkaemper	
Receipt	Tea and Biscuits	Lunch provided on inspection	29/01/2020	Unknown	On site	Not accepted	Alderhey Hospital [L/N 22595]		Licenced establishment	H Tate/H Vossenkaemper	
Receipt	Networking Events	Opportunity to meet	05/02/2020	Unknown	House of Lords	Not accepted	Transforming Systems		Potential supplier	L Dineley	
Receipt	Lunch and taxi	Lunch provided on inspection	05/02/2020	Unknown	On site	Accepted	Replimune Ltd [L/N 12697]		Licenced establishment	C Perrett	
Receipt	Lunch	Lunch provided on inspection	25/02/2020	Unknown	On site	Accepted	Leeds General Infirmary [L/N 12231]		Licenced establishment	L Carter/M Lancaster/R Mogg (day 2 only)	
Receipt	Lunch	Lunch provided on inspection	11/02/2020	Unknown	On site	Accepted	Wessex BMTU [L/N 22526]		Licenced establishment	L Knight/A Vossenkaemper/J Edgeworth	
Receipt	Lunch	Lunch provided on inspection	25/02/2020	Unknown	On site	Accepted	Tissue Regenix [L/N 22670]		Licenced establishment	V Stratigou/H Tate	
Receipt	Lunch (days 1&2)	Lunch provided on inspection	09/03/2020				London Bridge Hospital [L/N 11069]		Licenced establishment	H Tang/A Shackell	