

Audit and Risk Assurance Committee Agenda

Date 22 October 2019
Time 10:30 – 14.05
Venue Portrait Suite, Double Tree by Hilton Hotel, 2 Bridge Place, SW1V 1QA

Private Members Session:

ARAC Members private session (10:15 – 10:30)

Meeting:

Main ARAC meeting (10:30 – 13:35)

Lunch:

Lunch (13:35 – 14:05)

Agenda

1.	Welcome and apologies	
2.	Declarations of interest	Oral
3.	Minutes of 12 June 2019	(AUD 11/19)
4.	Matters arising from 12 June 2019 and forward plan	(AUD 12/19)
5.	ARAC Chair's Update	Oral
	Internal Audit (Confidential)	
6.	Internal Audit update	(AUD 13/19)
	• Capability Audit	Annex A
	Audit Tracking	
7.	Audit Tracker Update	(AUD 14/19)
	External Audit	
8.	NAO update	Oral
	Cyber security	

9.	Cyber Security Update	Oral
	Records Management	
10.	Records Management update	(AUD 15/19)
	<ul style="list-style-type: none"> Records Management and Retention Policy 	Annex A
	Risk Update	
11.	Risk Update	(AUD 16/19)
	<ul style="list-style-type: none"> HTA Strategic Risk Register 	Annex A
	<ul style="list-style-type: none"> UK exit from the European Union 	Oral
	Exploration of risk area:	
12.	Licensing Fees Review	(AUD 17/19)
	<ul style="list-style-type: none"> Overview of HTA Fees Model 	Annex A
	<ul style="list-style-type: none"> Establishment Numbers 	Annex B
13.	HA Risk project update	Oral
	Policy / Procedures updates	
14.	HTA Gifts and Hospitality Register	(AUD 18/19)
	<ul style="list-style-type: none"> Gifts and Hospitality Register 	Annex A
15.	Counter Fraud Strategy	(AUD 19/19)
	<ul style="list-style-type: none"> Draft Strategy 	Annex A
16.	HTA Reserves Policy	(AUD 20/19)
	<ul style="list-style-type: none"> HTA-POL-049 	Annex A
17.	ARAC Handbook update	(AUD 21/19)
	<ul style="list-style-type: none"> ARAC Handbook 	Annex A
	Regular reporting and updates	
18.	Reports on grievances, disputes, fraud and other information	Oral
19.	Topics for future risk discussions	Discussion
20.	Topics for future ARAC training	Discussion
	Any other business	
21.	HTA Office relocation update	Oral

Meeting close -13.35

No afternoon training.

Minutes of Audit and Risk Assurance Committee

Date	12 June 2019
Venue	Rovos Suite, The Grosvenor Hotel, 101 Buckingham Palace Road, Victoria, SW1W 0SJ
Protective Marking	OFFICIAL

Present	
Members Amanda Gibbon (AG, Chair) Glenn Houston (GH) Prof. Andrew (Andy) Hall (AH) Dr. Stuart Dollow (SD) William (Bill) Horne (BH)	In attendance Allan Marriott-Smith (AMS, Chief Executive) Richard Sydee (RS, Director of Resources) Nicolette Harrison (ANH, Director of Regulatory Delivery) Morounke Akingbola (MA, Head of Finance and Governance) David Thomson (DT, Item 10) Antony Wright (AW, item 13) Nima Sharma (NS, Board Secretary)
Apologies Roger Wallis (RW, DHSC) Jacky Cooper, (JC, DHSC) Jeremy Mean, (JM, DHSC) Dr Hazel Lofty, (HL, Director of Regulatory Development)	External Attendees Jeremy Nolan (JN, Government Internal Audit Agency) Tony Stanley (AS, Government Internal Audit Agency) Jill Hearne (JH, National Audit Office) George Smiles (GS, National Audit Office) Dan Howard (DH, HFEA) (item 10)

Item 1	Welcome and apologies
	<ol style="list-style-type: none"> 1. Amanda Gibbon (the Chair) welcomed Members, HTA staff, Government Internal Audit Agency (GIAA) and the National Audit Office (NAO). 2. The Chair noted apologies from external observers at the Department of Health and Social Care and Dr Hazel Lofty, Director of Regulatory Development.
Item 2	Declarations of Interest (Oral)
	<ol style="list-style-type: none"> 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 7 February 2019 (AUD 01/19)
	<ol style="list-style-type: none"> 4. There were two points of factual accuracy raised in regards to the minutes of the meeting of 7 February 2019. These were: <ul style="list-style-type: none"> • GS attended the February meeting on behalf of NAO and not Sarah Edwards as stated. • Under Paragraph 14, a business case 'had already been submitted' as opposed to 'has been submitted'.
Item 4	Matters arising from minutes of 12 February 2019 and forward plan (AUD 02/19)
	<ol style="list-style-type: none"> 5. The Chair noted that the actions arising from the meeting on 12 February 2019 were resolved, are noted on the forward plan or would be addressed within the relevant agenda items of the meeting.

6. An update was provided about the Transformation Programme. AMS clarified that the business case for funding would not be assessed by the Department of Health and Social Care (DHSC), and had, therefore, not been formally rejected. The Executive's focus is on prioritising and preparing for the move to the new premises.
7. Members questioned whether a re-submission of the business case would be accepted by DHSC in the future. RS informed the Committee that this discussion will form part of the negotiation for HTA requirements from the proposed 2020/21 spending review process. Current internal focus is on establishing what spending is essential in 2019/20. RS reassured the Committee that there is no critical impact at present. The Committee were of the opinion that the DHSC should be informed about the impact and risks posed by the failure of the business case to progress once this has been assessed.
8. The Committee was informed that the contract with BCC has been signed.
9. The Committee was informed that a successful appointment has been made to the Head of Performance and Planning post, with the appointee expected to commence their new role at the HTA on 27 August 2019.
10. The Committee was informed that the HR software migration has not gone as smoothly as hoped. However, data has now been extracted from the current system. This piece of work is ongoing and the migration should be completed by the end of June.
11. AMS informed the Committee that two complaints had been received by the HTA. The first was dealt with under the complaints procedure and related to an individual who was not able to attend an HTA event. The complaint was not upheld. The second related to the IA reaccreditation process and the additional information requested by the HTA when considering living donation cases. The complaint was partially upheld and internal training was delivered as a result.

Item 5 ARAC Chair's Update (Oral)

12. The Chair (AG) confirmed that since the last meeting she had:

- held telephone conversations with GS from NAO and JN from GIAA in preparation for the ARAC meeting;
- met with Claire Wend-Hansen, Regulation Manager at the HTA in her role as staff Freedom to Speak Up champion;
- attended the deemed consent faith roundtable event;
- attended the NHSBT/British Transplant Society congress in Harrogate and
- been involved in the recruitment process for HTA Member appointments.

Item 6 Internal Audit Update (AUD 03/19)

13. JN provided an update to the Committee following the HTA audits carried out.

14. JN confirmed that as a result of the Records Management audit GIAA were only able to offer limited assurance. The Audit made 8 recommendations, 5 of which (the finalisation of a records management policy, the linking of the policy to the Information Asset Register, the development of a risk assessment methodology, the provision of training for staff and the appointment of a Departmental Records Officer) were classified as high priority. He explained that the remaining area of concern is that records, except for those handled under Human Resources (HR), are not being destroyed within an appropriate timescale. JN informed the Committee that during the audit it was identified that the risks relating to records management were not clearly set out in the HTA's risk registers.

15. Members were asked to note that paper and electronic records on the current HR software are now compliant with the new HR software and migration can commence shortly.

16. The committee noted that good progress had been made in completing many of the high priority recommendations made by internal audit. RS noted that the most difficult recommendation to implement was that concerning the appointment of a Departmental Records Officer (DRO). For an organisation of the HTA's size it is difficult to justify making a specific appointment to

this role. The committee discussed other ideas suggested by executive colleagues as to how this role could be discharged, possibly by splitting it across a number of different individuals such as the Heads. It was agreed that SMT would revert with a firm proposal in due course.

17. GH raised concerns about the records management audit report as there are unresolved issues and questioned whether it is possible to engage with Information Governance consultants to strengthen this area. He also questioned how this aspect would be evidenced in the strategic risk register and whether an additional risk would need to be created. AMS asked ARAC to note that strategic risk four could appropriately capture the records management risk.

18. Members noted that GIAA would follow up on the recommendations in this audit and that they would be in a position to review progress at the October meeting. In particular it was agreed that Members would review the Records Management policy at the October meeting. This would include a firm proposal about fulfilling the DRO role.

19. JN informed the Committee that he was able to offer substantial assurance following the key regulatory processes audit where only two low priority recommendations had been made. Members extended their congratulations to the team over the results of this audit.

20. JN reported the results of the GDPR compliance audit and confirmed that good progress has been made and that there is a strong risk management and control framework in place covering a range of issues. He explained that the remaining areas for improvement include the development of a documented process as to how the SIRO and DPO gain assurance. The relevant SOP will be finalised by the next ARAC meeting in October. The other recommendation made by this audit is in relation to a comprehensive policy on records retainment and relates in particular to HR records. Members congratulated the Executive on achieving a positive outcome for the GDPR compliance audit.

21. JN confirmed that an overall moderate assurance rating was given in the Internal Audit's Annual Assurance Report which is the same

	<p>as last year. JN confirmed that against the 2019/20 plan there is one audit in progress with an expected date of completion by the end of June.</p> <p>22. The Committee noted the content of this update.</p> <p>Action 1: An update on progress against internal audit recommendations will be provided at the next ARAC meeting in October 2019.</p> <p>Action 2: To review and sign off the Records Management Policy at the October 2019 meeting.</p>
Item 7	Audit Tracker Update (AUD 04/19)
	<p>23. MA asked the Committee to note that the implementation of actions from four internal audits is ongoing and that the cyber security audit is almost complete.</p> <p>24. The Committee reviewed progress with actions and agreed that all actions would remain on the tracker until GIAA had had an opportunity to review them.</p> <p>25. The Committee noted the content of this update.</p>
Item 8	Information Risk Management - SIRO Report (AUD 05/19)
	<p>26. RS presented this report to the Committee.</p> <p>27. RS noted that a great deal of work had been done to ensure compliance with GDPR including the development of the policy. Although the records management audit had highlighted some weaknesses in the HTA's documentation of procedures, it had not uncovered any failure to store or retrieve records. RS informed Members that, as the SIRO for the HTA, he has no concerns about the HTA's management of information. He confirmed that DT also feels assured that the HTA is in a stronger position following the introduction of new policies and procedures over the last year.</p>

	<p>28. The Chair noted that the SIRO report had highlighted issues with the recent penetration test and asked DT to provide a summary of what these were. DT reported that the 23 high impact issues revealed by the test mostly reside in systems that the HTA no longer uses and have since been switched off. Six of the 23 issues are on the HR server and, when the migration is complete, will no longer be present. Four of the 23 issues reside on the software for room bookings; this machine is undergoing testing currently. The remaining two of the 23 issues exist on virtual servers.</p> <p>29. The Committee noted the content of this paper.</p>
Item 9	Cyber Security (Oral)
	<p>30. DT had no further updates on Cyber Security as these aspects had been discussed at item eight.</p>
Item 10	Update from Data Protection Officer (AUD 06/19)
	<p>31. DH attended the meeting to present the annual Data Protection Officer (DPO) update.</p> <p>32. DH noted that he had made three recommendations in relation to data protection refresher training, Office365 and the development and review of Information Governance and Assurance Policies. The Committee noted that it is important that the HTA continues to prioritise GDPR training as well as records management processes. DT informed the Committee that Office365 is cloud-based and provides extra functionality around security and compliance.</p> <p>33. The Chair asked DH to provide the Terms of Reference for the Data Protection Officer role at the October ARAC meeting.</p> <p>34. The Committee noted the content of this paper.</p> <p>Action 3: DH to provide the Terms of Reference for the DPO role at ARAC meeting in October.</p>

<p>Item 11</p>	<p>Approval of Annual Report and Accounts (AUD 07/19)</p>
	<p>35. RS provided an overview of the HTA Annual Report and Accounts for 2018/2019.</p> <p>36. RS clarified that Grant in Aid is treated as financing and is therefore not included within the income figures provided on the Statement of Comprehensive Net Expenditure in the accounts . One significant adjustment had been made to the accounts since the draft was presented to the Authority. This was to reverse £147k of accrued income which related to VAT on rental payments for space at 151 Buckingham Palace Road which is due from NHS Resolution. The Committee thanked MA for the timely preparation of the accounts and the smooth progress with the annual audit.</p> <p>37. GS presented the outcome of the audit to the Committee. He confirmed that an unqualified audit opinion has been given on the 2018/19 report and accounts. He noted the audit adjustment in relation to the £147k accrued income and highlighted that slide number 4, in relation to audit adjustments is incorrect and should state '£147k' not '£172k'.</p> <p>38. GS noted the CRM upgrade and confirmed that the audit had not identified any expenditure which had been incorrectly capitalised. In relation to Exiting the EU, the auditors did not consider that any further disclosures were required.</p> <p>39. GS referred the Committee to slide eight of Annex B, summarising the list of adjusted misstatements. Apart from the accrued income adjustment noted above, the only other adjustment was within balance sheet accounts and had no effect on net income/expenditure.</p> <p>40. Members asked whether DHSC is aware of the issue over VAT on rents at 151 Buckingham Palace Road and raised concerns about writing off this income. RS confirmed that the DHSC Finance team is aware of this issue and that, from a managerial perspective, the HTA would continue its efforts to recover the income.</p> <p>41. GS referred the Committee to Annex C, Draft Letter of</p>

	<p>Representation. He informed that Committee that standard information has been included and that pages 18-19 include the draft audit certificate. He highlighted that a new standard will be coming into effect from 2020.</p> <p>42. MA informed the Committee that note e on page 61 of the Draft Annual Report and Accounts document was not included due to a formatting issue. AG agreed to liaise with MA over some minor drafting comments.</p> <p>43. The Committee thanked NAO and MA for their contribution and thanked RS for circulating the Annual Governance Statement early in the process to enable Members the opportunity to comment in good time.</p> <p>44. The Committee noted the content of this update and agreed that they were content, subject to final minor amendments, to recommend the Annual Report and Accounts be signed by the Accounting Officer. GS confirmed that NAO will aim to certify the report by 27 June 2019.</p>
<p>Item 12</p>	<p>Risk Update (AUD 08/19)</p>
	<p>45. RS presented this item to the Committee.</p> <p>46. RS confirmed that there has been no substantial change in risks three, four and six. All three risks are rated as amber.</p> <p>47. RS informed the Committee that the HTAMG discussed whether the records management audit should be regarded as a separate operational risk. He informed the Committee that the SMT's view was that, while this may be an operational risk, it does not, however, affect the delivery of the HTA's strategic objectives.</p> <p>48. Members discussed whether the approach taken to considering risks relating to records management requires further review to ensure it is appropriately captured. AMS reassured Members that Risk 4, which relates to effective data management sufficiently covers this risk. Members felt that there needs to be greater emphasis on this risk in the risk register as this was not clear to</p>

	<p>auditors.</p> <p>49. There were no further comments on the operational risk register and no further updates regarding EU Exit.</p> <p>50. The Committee noted the content of this paper.</p> <p>Action 4: Records Management risks to be sufficiently captured under Risk Four on the Strategic Risk Register.</p>
<p>Item 13</p>	<p>Designated Individual Engagement - Exploration of Risk (AUD 09/19)</p>
	<p>51. ANH presented this item and provided a summary of the Regulation Directorate's responses to the questions provided by Members to assist the Committee in their deep dive of DI Engagement. She informed the Committee that AW was in attendance to answer specific questions. ANH thanked Members for providing their deep dive questions in advance.</p> <p>52. AW confirmed that the DI has main responsibility for discharging responsibility under the Human Tissue Act and can nominate a Person Designate (PD) to assist in achieving compliance under their direction.</p> <p>53. Members inquired as to the range of individuals that are selected to carry out the role of DI. AW confirmed that DIs are normally in a position of seniority and are expected to have the ability to influence change within their organisation. He clarified that very few DI applications have been rejected on the basis of the individual not being suitable.</p> <p>54. ANH confirmed that there has been a good uptake of online tests with over 1500 participants who have completed these, including DIs. Members enquired whether the HTA is able to see how well the individuals taking the tests have performed. ANH informed Members that, whilst the HTA receives data on the scores from tests taken, it is not able to identify which individuals have undertaken these tests. Emerging themes are being tracked to indicate whether changes might be needed to the tests or to indicate awareness gaps.</p>

	<p>55. Members raised queries about the risk that a DI, who has been deemed unsuitable, applies to be a DI in another application to the HTA. ANH and AW confirmed that they were not aware of any cases where this has happened. AW added that the suitability of all DIs is assessed by a Regulation Manager. In the rare event that the Regulation Manager declines the DI application any objection to a refusal to accept the unsuitability of a DI could be dealt with through the complaints procedure.</p> <p>56. AW noted that approximately 5% of DI variations take place retrospectively, for example, where the DI has left and another individual is being appointed to undertake the role. AW informed Members that all DI variations must be approved by the HTA.</p> <p>57. Members thanked ANH and AW for their responses during the deep dive and noted the content of the paper.</p>
Item 14	Review of Gifts and Hospitality Policy (AUD 10/19)
	<p>58. MA presented the Gifts and Hospitality Policy for the Committee's information. She informed the Committee that the register had not been included as there were no new entries made. No comments or changes were made.</p> <p>59. Members noted the content of this update.</p>
Item 15	Reports on grievances, disputes, complaints, fraud and other information (Oral)
	<p>60. AMS provided an update about two complaints during agenda item 4. (paragraph, 11.)</p>
Item 16	Topics for future risk discussions (Discussion)
	<p>61. AG asked Members for suggestions for future risk discussions and in particular asked what they wished to discuss at the October meeting.</p>

	<p>62. BH suggested that Members should not have a deep dive session to enable them to focus instead on the outcome of the licensing fees review. The committee agreed that this would be appropriate.</p>
Item 17	Topics for future ARAC training (Discussion)
	<p>63. AG asked Members if there are any current training needs. Members agreed that no further formal training is required at the October meeting.</p>
Item 18	Any Other Business
	<p>64. MA presented a paper on Government Fraud Standards.</p> <p>65. MA apologised to the Committee for the late circulation of this paper. She informed Members that there are 12 functional standards being rolled out across Government Departments and ALBs. Our initial assessment is that the HTA is not currently compliant with these standards. She explained what the HTA will need to do in order to achieve compliance by the deadline of 2 September 2019.</p> <p>66. MA informed the Committee that a copy of the Government Counter Fraud documents was circulated with the paper and advised the Committee that the HTA needs to agree the Accountable individual within the organisation who can manage and oversee fraud prevention. The Committee discussed this and agreed that RS would be best placed to oversee this activity.</p> <p>67. MA informed the Committee that the HTA will be drafting a Fraud strategy and welcomed any advice from the Committee on how to proceed with this. The Committee advised that content for this could be based on a generic Fraud strategy document and BH confirmed that he would be happy to provide some guidance on how to proceed. Furthermore, JN informed MA that he can provide her with the contact details of an individual at another ALB who has dealt with this recently.</p>

68. The Committee agreed that a fraud risk assessment, which focusses on the activity across the entire business, will need to be carried out by the HTA. The Committee also discussed the issue of regulatory fraud and, although it agreed this is low risk, were of the opinion that this should be looked at in parallel with the financial risks.

69. JN confirmed that an anti-fraud audit would be carried out in quarter three. AMS highlighted to the Committee that the HTA does have mechanisms to report fraud directly to the Department of Health and Social Care's Fraud Unit.

70. The Committee discussed the staff training needs that will need to be met in order to achieve compliance with the standards and agreed that all staff should receive appropriate anti-fraud training as part of their induction.

71. The Committee were in favour of planning a deep dive session about Fraud in the Public Sector and lack of oversight by Boards at a future meeting.

72. The Committee noted the content of this update, were in support of MA seeking input from Members and agreed that a further update should be brought to the October meeting.

Action 5: MA to draft a paper which outlines the HTA's progress in meeting the Government's Fraud Standards.

The next meeting will take place on 22 October 2019.

HTA Audit and Risk Assurance Committee

Matters arising and forward plan

Tuesday 22 October 2019

HTA Audit and Risk Committee Matters arising

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
75	19 June 2018	Action 10: ARAC to review a copy of the HTA's Assurance map at its meeting in February 2019.	Director of Regulatory Development	June 2019	This item has been added to the Added to the ARAC forward plan. Training session to take place at June 2019 meeting. Ongoing.	Live
107	12 June 2019	Action 1: An update on progress against internal audit recommendations will be provided at the next ARAC meeting in October 2019.	Director of Resources	01 October 2019	To be presented at the October ARAC meeting by Internal Audit.	Live
108	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.	Live
110	12 June 2019	Action 4: MA to draft a paper which outlines the HTA's progress in meeting the Government's Fraud Standards.	Head of Finance	01 October 2019	To be presented at the October ARAC meeting by Head of Finance.	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 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 2018 ARAC Meeting, the Committee agreed to postpone its investigation of the HTA's Licensed Establishment Relationship Programme, which was scheduled for 23 October 2018 ARAC meeting. The Committee elected instead, to explore the risks and assurance associated with the HTA's staff induction process.
The risks and assurance associated with the HTA's staff induction process.	October 2018	At 19 June 2018 ARAC Meeting, the Committee elected to explore the risks and assurance associated with the HTA's staff induction process.
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	30 January 2020	

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
	February 2020	TBC	
	June 2020	TBC	

Forward plan **Forward Plan**

Standing items	<p>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)</p>	
Meeting		
February 2019	<p>Review and approval of the Internal Audit proposed Audit plan for the financial year 2019/20</p> <p>Review of the Audit & Risk Assurance Committee's performance including Members' skills and training</p> <p>Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting)</p> <p>Review gifts and hospitality register</p> <p>Update on the review of the risk management policy and strategy</p>	
June 2019	<p>Approval of the Annual Report and Accounts</p> <p>Review of the External Auditors ISA 260 report (management letter)</p> <p>Consider key messages for the Audit & Risk Assurance Committee's report on its activity and performance (to the Authority)</p> <p>Review and approval of the Internal Audit proposed Audit plan for the financial year</p> <p>Internal Audit Annual statement. (Draft Note: RS to discuss the approach to this with PF, invite</p> <p>Information Risk management - SIRO report</p> <p>Annual review of the Operational Risk Register</p>	<p>To consider a draft update of the HTA Gifts and Hospitality Policy</p> <p>Incorporation of draft proposals to address the Caldicott Review within the annual review</p>
October 2019	<p>Review of HTA Reserves Policy</p> <p>Review of ARAC Handbook- Annual refresh</p> <p>Review of Gifts & Hospitality Register</p> <p>Risk in the Human Application Sector- general update to be provided</p>	<p>Update on complaints and complaints handling at the HTA</p> <p>Management proposals for the cross-referencing of inspection findings with compliance updates</p> <p>Review of ARAC Handbook</p> <p>At the 19 June 2018 ARAC meeting, The Committee agreed to invite the HTA's Data protection Officer Dan Howard to attend the 23 October 2018 ARAC meeting.</p> <p>At the 19 June 2018 ARAC meeting, The Committee requested a follow-up review of the revised Operational Risk Register at its meeting on 23 October 2018.</p> <p>At the 19 June 2018 ARAC meeting, The Committee requested that Executive to present an updated version of the Critical Incident and Response Plan at the 23 October 2018 ARAC meeting.</p>
January 2020	<p>Review and approval of the Internal Audit proposed Audit plan for the financial year 2020/21</p> <p>Review of the Audit & Risk Assurance Committee's performance including Members' skills and training.</p> <p>Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting)</p> <p>Review gifts and hospitality register</p> <p>Update on the review of the risk management policy and strategy</p> <p>Annual review of the Operational Risk Register</p>	<p>At the 19 June 2018 ARAC meeting, The Committee requested a follow-up report on the development of an oversight strategy for Third Party Agreements within the Human Application Sector, at the ARAC meeting in February 2019.</p> <p>At the 19 June 2018 ARAC meeting, The Committee asked to review a copy of the HTAs Assurance map at its meeting in February 2019</p>

Internal Audit Update- Confidential



Audit and Risk Assurance Committee paper

Date	22 October 2019	Paper reference	(AUD 14/19)
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. One audit has been undertaken and completed since the June 2019 meeting.

Action required

3. 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.

Update

4. Committee to note the update on the two on-going **red** recommendations (Cyber and Records Management recommendations). The latest Capabilities audit has some amendments to target dates.

Summary of all 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	Not started or N/a
IA – GDPR Compliance	3	2	0	1	0	0	0
IA – Key Regulatory Processes	2	0	0	2	0	0	0
IA – Records Management	8	8	0	0	0	0	0
IA - Cyber security	2	0	2	0	0	0	0
IA – Utilisation of Capabilities	6	0	0	2	0	0	4
COUNT	21	10	2	5	0	0	4

IA – Internal Audit – PwC/DH

EA – External Audit - NAO

HIGH	7	5	0	2	0	0	0
MEDIUM	12	5	0	3	0	0	4
LOW	2	0	0	2	0	0	0

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)		
SIRO to develop a documented process on how assurance will be gain from across the organisation and how the report will be developed	Agreed – a Standard Operating Procedure will be developed that captures the assurance process for a number of Information Governance areas, including GDPR, for all relevant roles. Target date – June 2019	June 2019 SIRO report sets out the changes to the process for gaining assurance in response to GDPR and Records Management Audit. This will form the basis for the SOP that will be drafted by the end of June October 2019 Evidence of completion to be provided to GIAA	Richard Sydee COMPLETE
DPO to develop a documented process on how assurance will be gained from across the organisation and how the report will be developed.	As above – we feel these recommendations are one and the same	June 2019 As above October 2019 Evidence of completion to be provided to GIAA	Richard Sydee COMPLETE
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	Richard Sydee ON-GOING

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
2018/19			
Key Regulatory Processes			
Where policies and procedures are not adhered to, the Authority may not identify non-compliance and cannot take action to prevent its			
<p>The HTA should carry out a review of the SOPs to identify any opportunities to streamline and condense the information, to ensure they are as user friendly and functional as possible.</p>	<p>The HTA will define the approach it will take to incorporating this into existing business-as-usual activity to review governance documents and streamline processes to improve efficiency and aid induction.</p> <p>Target date – December 2019</p>	<p>June 2019 Heads of Regulation are continuing to review SOPs in line with the Quality Management schedule and Head of Regulation are considering how best to undertake a more coordinated cross-sector approach to the core regulatory delivery SOPs. The HTA Quality and Corporate Governance Manager has also established a Quality Forum with representatives from across the business, which will provide another mechanism for improving our approach to managing and updating SOPs.</p> <p>October 2019 We have done an audit of what needs to be updated and drafted to a consistent format, and the Quality Forum looking at how to develop a framework for prioritising work on SOPs based levels of risk.</p>	<p>Nicolette Harrison ON-GOING</p>
<p>The HTA should provide formal training on the Human Tissue Act to ensure that all Regulation Managers are familiar with all relevant legislation.</p>	<p>The HTA will include training in the HT Act (and training in other legislation under which we regulate, such as those governing use of tissue for Human Application or organ donations and transplantation) in the updated approach to induction and training that it is already developing and which will be led by the newly created posts of RM-Training.</p> <p>Target date – December 2019</p>	<p>June 2019 A new 12-month post of Regulation Manager (Training) has been developed with a RM (Caroline Kerridge) being appointed to the role with effect from 1st May. She has already developed an initial outline plan for taking forward the findings from the recent work on RM induction as two project streams, which includes incorporating training in legislation.</p> <p>October 2019 The RM (Training), Caroline Kerridge, worked with the Head of HR, Sandra Croser, to organise an initial workshop with colleagues on 2 October 2019, to</p>	<p>Nicolette Harrison ON-GOING</p>

		identify the scope of the training need and use that to develop a training plan.	
RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Records Management – Risk 1			
<p>1 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 the Audit and Risk Assurance Committee. Once agreed, this should be circulated to all HTA staff.</p>	<p>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</p> <p>Target date – May 2019</p>	<p>June 2019 Draft has been attached to Annual SIRO assessment.</p> <p>October 2019 Policy is completed to the extent that is possible. A number of areas of the policy will not be complied with until DRO resource is in place and decisions taken about the priority of this work relative to other business needs.</p>	<p>Richard Sydee ON-GOING</p>
Records Management			
<p>2 The FOI guidance should be reviewed and updated as soon as possible</p>	<p>Completed as part of GDPR work</p>	<p>N/a October 2019 Evidence of completion to be provided to GIAA</p>	<p>COMPLETE</p>

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
<u>Records Management - Risk 2</u>			
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			
3 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 COMPLETE
<u>Records Management</u>			
HTA's records management strategy and policy are not sufficient to ensure compliance with statutory obligations			
4 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 up to date information as well as links to relevant policies. Target date – May 2019	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 COMPLETE

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
<u>Records Management - Risk 3</u>			
5 The revised records management policy should include a clear risk assessment methodology, including how records management risks can be incorporated into the strategic and operational risk registers, as well as guidance on how records management issues should be escalated.	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 COMPLETE

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
<u>Records Management - Risk 4</u> The accountability and oversight arrangements used to monitor delivery of records management policy and progress are not effective			
6 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 Revised target date – Not yet agreed	June 2019 This is part of the agenda for the All staff away day in July. October 2019 With elements of the policy still unsupported by process and infrastructure, SMT took the decision to postpone awareness raising until more definitive guidance has been completed on appointment of DRO and Data Analyst.	DRO ON-GOING
7 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 Development and Head of Business Technology to discuss requirement and advise SMT of appropriate response Target date – June 2019	June 2019 Definition for DRO and local records managers have been drafted. We would like to discuss the practicalities of implementing this with ARAC October 2019 Policy reflects decision to appoint the new Director as DRO and that the new Data Analyst role has a job description which encompasses the operational responsibilities on the DROs behalf.	Allan Marriott Smith COMPLETE
<u>Records Management – Risk 4</u> The accountability and oversight arrangements used to monitor delivery of records management policy and progress are not effective			
8 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	June 2019 Job descriptions to be updated in line with drafted PDP objective. October 2019	Richard Sydee ON-GOING

	standing IAO objective added to the PDP of those with IAO responsibilities Target date – June 2019	SMT has take the decision the job descriptions will be updated as they become vacant and are advertised. In the meantime, this responsibility is covered in PDP objectives.	
RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
<u>Cyber security</u>	Security – lack of forensic readiness That in the event of an external or internal attack or information security incident on HTA’s IT infrastructure, there is an inability to effectively secure appropriate digital evidence to ensure there is a robust audit trail, and for use in support of any resulting legal or disciplinary action.		
We recommend that HTA develops and applies a system of forensic readiness which ensures they can provide an appropriate level of capability to collect, preserve, protect and analyse digital evidence of any unwanted or unforeseen event impacting its IT systems. We further recommend this should be in accordance with the NHS Digital ‘Forensic Readiness Good Practice Guide’.	David Thomson to create a forensic readiness specification that can be agreed with a number of providers <i>Target date - January 2018</i> <i>New target date – Difficult to say as work is complex</i>	May 2018 – Forensic readiness policy has been written into the HTA’s contract with BCC. The next stage is to compse a plan to implement the policy. October 2018 - Contract has been re-tendered. On award, work will begin on forensic readiness spec. February 2019 Contract variation with BCC is to be finalised by the end of February. June 2019 Contract variation has been agreed and signed with BCC and includes the Forensic Readiness Policy. October 2019 Evidence of completion to be provided to GIAA	David Thomson COMPLETE

<p><u>Cyber security</u></p>	<p>Policy – notification of access permission changes That staffing changes such as leavers and role changes are not made known by Human Resources to IT services to allow the timely amendment or termination of access permissions on the effective date of the change. Where an appointment is made to a post which has access to HTA’s most sensitive information there is no form of enhanced vetting</p>		
<p>We recommend that HTA Human Resources develop and implement a formal system which notifies IT services of staff leaving or moving roles so that any required amendments to access permissions can be made in a timely manner.</p>	<p>David Thomson and Diane Galbraith to agree a pro forma for all starters, leavers and job role changes to ensure that accounts are created, suspended or amended as their employment with HTA changes or ends</p> <p><i>Target date – January 2018</i></p> <p>New target date – March 2019</p>	<p>May 2018 – This has been included as part of the GDPR work scheduled on the next six months</p> <p>October 2018 -Documentation has been drafted and process agreed. Documentation awaiting sign-off</p> <p>February 19 Implementation and communication plan to be agreed in February with target launch of new process in March</p> <p>June 2019 Our last Civil Service fast streamer designed a Joiner/Mover/Leaver process which we have been working to, albeit in a manual way, over the past few months. Once we have completed the implementation of the new HR system, due by the end of June, we will systematise that process allowing us to have a centralised control with notifications and authorisations distributed to relevant parties <i>via automated workflows.</i></p> <p>October 2019 New HR system is in place however, we continue to work to the manual process whilst reviewing options (Service Desk or using HR System – Cascade workflows).</p>	<p>Diane Galbraith David Thonpson</p> <p>ON-GOING</p>

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
<u>Utilisation of Capabilities (Risk 1)</u>			
(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 where possible. Target date — End September 2019 Revised target date – End December 2019	<u>October 2019</u> 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.	Sandra Croser & SMT In progress
(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	<u>October 2019</u> As recommendation 1	
(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	<u>October 2019</u> Work has not yet commenced and we suggest a revised target date of end of March 2020.	Sandra Croser & SMT Not started

<u>Utilisation of Capabilities (Risk 2)</u>	Resourcing plans do not effectively identify, present or articulate current skills and new skills requirements		
<p>(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 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.</p>	<p>Corporate and individual training needs are currently identified from the PDP output which then drives the individual and corporate 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.</p> <p>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.</p> <p>In addition, a bi weekly Lunch and Learn has been initiated to enable the sharing of skills and experience along with general information sessions.</p> <p>Target date – End November Revised target date – End March 2020</p>	<p><u>October 2019</u> 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.</p>	<p>Sandra Croser & SMT Not started</p>

<u>Utilisation of Capabilities (Risk 3)</u>	Resourcing plans do not effectively identify, present or articulate current skills and new skills requirements		
<p>(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.</p>	<p>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.</p> <p>Target date – End November 2019 Revised target date – End March 2020</p>	<p><u>October 2019</u> 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.</p>	<p>SMT & Head of HR Not started</p>
<p>(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.</p>	<p>A capability framework will be developed which will also identify the key people and key roles across the organisation. Knowledge and experience required for each role will be documented along with training expectations for that role. Where possible a nominated deputy will be identified. However, given the size of the organisation and the recent stress audit, workload and overstretch will need to be carefully considered.</p> <p>Target date – End November 2019</p>	<p><u>October 2019</u> Further work has not yet commenced. An SMT discussion will be scheduled to agree what further action should be taken in light of our comments in Agreed Actions.</p>	<p>Sandra Croser Not started</p>

Audit and Risk Assurance Committee paper

Date	22 October 2019	Paper reference	AUD (15/19)
Agenda item	10	Author	Allan Marriott Smith Chief Executive

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Records Management update

Purpose of paper

1. To present the ARAC with an update on the progress on responding to the recommendations of the Records Management internal audit which was presented at the June meeting.
2. Paper AUD 14-19 Audit Tracker Update presents an overview of progress. This paper sets the issues out in more detail and the rationale for the approach taken.

Decision-making to date

3. None.

Action required

4. The Committee is requested to note the progress and provide any comment.

Progress

Role allocation

5. Since the last ARAC meeting the Director of Regulatory Development post became vacant. As is the case with all HTA vacancies, this was used as an opportunity to review the focus of the role to ensure that it best builds on the capabilities required by the HTA. As a result, the HTA has now recruited a Director of Data, Technology and Development to strengthen senior level leadership on data and technology issues. The

new Director will be accountable for the HTA's data, information, records and knowledge arrangements and development. As part of this the new Director will take on responsibility as Departmental Records Officer (DRO).

6. In parallel, SMT had already taken the decision to recruit a new Data Analyst role. The job description for this role also contains many of the operational responsibilities set out for DRO with a view to these being delegated.
7. As both of these posts are currently vacant and the Senior Team has needed to prioritise activity based on risk over the summer months, progress against the remaining recommendations has been made, but has been modest.
8. It is envisaged that by the time of the Authority away day in January, the senior team will be in a better position to set out a clearer view on what further action should be prioritised to bring the residual risk to a tolerable level.

Records Management and Retention Policy

9. A further draft of the Records Management and Retention Policy has been produced (an annotated version can be found at Annex A). This draft formally fulfils the requirements of the internal audit recommendations, but as discussed at the last ARAC meeting does not mean that it can fully be deployed at present.
10. A gap analysis has been undertaken and those aspects of the policy which we are not in a position to fulfil at present are highlighted in grey. These grey sections and the issues raised will be set out orally at the October meeting.

Additional work

11. Additional work has been undertaken over the summer to assess how well we are currently complying with the Records Management and Retention Policy.
12. The register of records has been reviewed, and potential gaps have been identified.
13. An assessment has been of how readily these records can be accessed for review, archiving and deletion.
14. Further work is required to map out a path to full compliance with the Policy, which will not be undertaken until the DRO and Data Analyst are in post.



HTA Policy

Reference	HTA-POL-XXX	Date approved	Xx Month 2019
Author(s)	David Thomson	Next review due	XX Month 2020
Reviewed by	Allan Marriott-Smith	Owner	Director of Data, Technology and Development
Approved by	SMT	Distribution	All staff, Authority Members, third parties, contractors, consultants and visitors using HTA Information Systems

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Records Management and Retention Policy

Revision history

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

Date	Version	Comments
June 2019	0.1	Initial draft
October 2019	0.2	Revisions by CEO in light of ARAC discussions

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Records Management and Retention Policy

Introduction

1. Having accurate and relevant information and records is vital to the efficient management of the HTA's work. This contributes towards the overall corporate knowledge, which is the combined tacit, tribal, documented and undocumented knowledge within an organisation.

A record is information or documents (paper or electronic) created, received and maintained as evidence and information by an organisation or person, in pursuance of legal obligations or in the transaction of business. (Source; BS ISO 15489)

2. As a public body, the HTA is required by law to manage its records properly. We need to balance our statutory obligations under Data Protection, Freedom of Information and Public Records legislation, and our stated aim of acting transparently, with our duty of confidentiality for personal data and other sensitive records. It is important to bear in mind that records have a specific meaning in the context of our statutory obligations and that records can be viewed as a subset of the wider information held by the HTA.
3. We create and manage information and records efficiently – making them accessible whenever appropriate to do so – and protect and store them securely and ensure they are safely disposed of at the appropriate time.
4. This policy aims to make sure all HTA staff understand what they must do to protect and manage records effectively and efficiently and in compliance with our legal obligations to manage personal data securely.
5. We will review our policy annually to ensure it continues to be relevant.

The purpose of good records and information management

6. Good records and information management practices help us meet our statutory objectives and overall business responsibilities. Whatever form the record takes, knowledge and information must be protected. It must also be accurate, ordered, useful, up to date and accessible whenever it is needed.

7. Records constitute a major part of the HTA's knowledge. Managing records well makes it easier to find and reuse the information and knowledge we already hold, and to develop our business and improve our services.

8. Having accurate records is critical to the HTA's success because they:

- help us carry out our day to day regulatory activities;
- support our policy and project work;
- help us make informed decisions;
- enable us to have accurate management information;
- enable us to maintain continuity and consistency in management and administration;
- provide audit trails to meet business, regulatory and legal requirements;
- make sure we can comply with legislation such as the Freedom of Information Act, the Data Protection Act 2018, the General Data Protection Regulation and the Public Records Act; and
- ensure we are transparent and responsive.

9. Good records and information management relies on the key principle that a record is managed through its full lifecycle – from creation or receipt to maintenance, storage and accessibility, to retrieval and finally disposal of the record (or transfer to the National Archives).

10. Records, once created or received, should therefore be:

- stored in a methodical, accessible yet secure manner;
- reviewed at regular intervals;
- stored in a controlled and accessible manner for set periods where they retain value; and
- disposed of securely when they no longer have any value.

11. Everyone at the HTA creates records and information, and everyone at the HTA is therefore responsible for managing the records they create in the course of their work.

12. This document sets out:

- who is responsible for the management of records and information;

- how we can create records and information in a methodical, secure and accessible manner;
- when to review records;
- how long to keep records; and
- when to dispose of records.

What constitutes a record or information?

13. Documents or data in all technical or physical formats or media, either created or received by the HTA while carrying out business activities, constitute information and may constitute records. Below are examples of the information HTA staff are likely to use that need to be properly managed:

- documents (handwritten and typed)
- paper-based files
- electronic (computer) files
- e-mails
- faxes
- forms
- inspection reports

Who does this policy apply to?

14. This policy applies to all permanent and temporary employees, contractors, consultants, secondees and Civil Service Fast-Streamers who have access to the HTA's information, regardless of form (electronic or hard copy).

Regulatory environment

15. All records (paper and electronic) created and received by the HTA must be managed in accordance with the provisions of the legislation governing the records of public bodies. The main statutory provisions affecting the HTA can be seen at [Appendix 1 – Legal Framework](#).

16. This legislation places a duty on the HTA to manage its records in such a way that the access provisions of these laws are complied with. It is essential that the HTA's records are properly captured, well managed and accounted for and are readily retrievable until they are either destroyed or transferred to the National Archives.

17. Finally, our records should also be managed in accordance with the expectations of our stakeholders on what constitutes acceptable business practice and behaviour.

Roles and responsibilities

18. The HTA owns all records created by staff carrying out work for or on behalf of the HTA. Records received by the HTA's staff relating to the HTA's work are also owned by the HTA. Individual staff members do not own records but they do have responsibilities for managing records.

Management responsibility

19. The Director of Data, Technology and Development maintains overall responsibility for the records management policy and standards, and for promoting their application throughout the HTA. The Director will also act as the Departmental Records Officer.

Commented [AM1]: Not yet in post. Part of the restructured job description.

Departmental Record Officer

20. The HTA Departmental Records Officer (DRO) is accountable for the overall development and maintenance of records management practices throughout the HTA, in particular for drawing up guidance for good records management practice and promoting compliance with the Records Management policies in such a way as to ensure the easy, appropriate and timely retrieval of information. In practice the DRO will delegate a number of their responsibilities to the HTA's Data Analyst.

Commented [AM2]: Still being recruited but contained within the current job description.

Responsibilities:

- ensure there are policies and processes to support compliance with information legislation
- identify information worthy of historical preservation in line with The National Archives Records Collection Policy
- appraise selected records under the [Section 46 Code of Practice](#) for the Freedom of Information Act and Environmental Information Regulations
- oversee the transfer of records to The National Archive or a place of deposit, in line with legislative obligations
- seek assurance on compliance with the HTA Records Management and Retention Policy from all local record managers
- report the assured position to the Senior Information Risk Owner

Information Asset Owners as record managers

21. The responsibility for local records management is devolved to the relevant HTA staff. HTA-POL-056 Information Governance and Cyber Risk Policy establishes the role of Information Asset Owners and sets out their duties. The Information Asset Register sets information assets held by the HTA and identifies the owner for each of asset. Where an information asset is also a record, the Information Asset Owner is also responsible for ensuring that records controlled within their area are managed in a way which meets the aims of the HTA's Records Management Policy.

Responsibilities:

- know what information is being created and held
- understand the value of the records held, what it is needed for, and the technology needed to support it
- determine how long records should be kept and ensure that records are disposed of in line with disposal policy
- implement digital continuity principles into departmental record-keeping process, as well as identifying and escalating risks to the availability and completeness of information arising from changes in technology or the business

Responsibilities of individuals

22. All HTA staff who create, receive and use records have records management responsibilities. In particular all staff must ensure that they keep appropriate records of their work in the HTA and manage those records in keeping with the HTA Records Management and Retention Policy and with any SOPs and guidance subsequently produced.

Creating information or records

23. Information and records are created by individual staff members and saved in locations such as Impact and CRM (electronic records), or in filing cabinets (paper records), together referred to as systems of record.

24. It is essential that the HTA's systems of record are well managed and properly maintained if information is to be stored in an accessible way. Key to this is adhering to naming conventions set out by the Quality and Governance Manager and reviewing the content at regular intervals.

Access to and security of records

Commented [AM3]: This has been subject to an initial assessment

25. Information Asset Owners (IAOs) are responsible for setting access permissions to information and records in their areas of responsibility.
26. All staff are required to handle information appropriately. New documentation should possess, wherever appropriate, a protective marking so that others know what the appropriate method of handling and sharing the information is. In general, information that is of an Official nature does not require a protective marking, although it is still good practice to include one. Please refer to the HTA Data Classification Policy [DN: include a link to the policy once published] for more information.
27. Documents and records must be protected against unauthorised disclosure, including to those within the HTA who are not authorised to access them. All staff are responsible for ensuring that documents are stored or saved in appropriate cabinets or folders, applying restrictions where appropriate.
28. In making records available outside of the HTA, the HTA will comply with data protection legislation and the Freedom of Information Act.
29. Refer to the HTA Information Governance and Assurance Directive for further information about how to process information and data securely.

Management of records and information

30. The management of information and records falls into a number of categories, each requiring certain actions at particular times.
31. Different categories of records will be subject to different procedures and different retention or destruction timetables.
32. Certain records that will be of interest to the National Archives and will need to be stored securely until the National Archives is ready to receive the records – 20 years after their creation.

Reviewing information

33. In order to ensure we do not hold more information or records than is necessary, it is essential that all records are reviewed at regular intervals, except when there are set timetables for their destruction. There are many advantages of doing this including:

- the records in shared areas are only ones that are of use to you or of likely future value to the HTA;
- we avoid having shared areas full of redundant records that simply make the task of finding what you want harder;
- we minimise the amount of physical space dedicated to filing cabinets, freeing it up for other uses;
- we keep to a minimum the costs of storing and backing up electronic data;
- we reduce our risk of being in breach of data protection law; and
- we reduce the amount of material we may be required to search following a request under the Freedom of Information Act.

34. As a public body, our records are deemed public records under the Public Records Act, and the National Archives may wish, in time, to transfer some of these records to their collection for permanent preservation.

35. When reviewing records therefore, it is important to consider whether they are likely to be of future interest to researchers and historians. However, it is also important to bear in mind that some of this information is already in the public domain through our website, and the National Archives takes regular snapshots of our entire website for preservation in their Web Archive. Their principal areas of interest are:

- Records about the constitution and initial establishment of the HTA;
- Agendas and papers of Authority meetings;
- Records – such as policy or programme management records – which record key decisions that resulted in a particular policy or legislative changes or significant operational changes, if these are not already otherwise available;
- Records of the appointment processes for Chairpersons, Authority members or the Chief Executive; and
- Any other particular records we may hold on file that will have influenced the HTA's work.

36. The National Archives have however indicated that they do not envisage taking “case files”. This would therefore preclude, for example, regular correspondence with licence contacts or enquiries.

Retaining and reviewing records

Commented [AM4]: This has been subject to an initial assessment

37. Many of the HTA’s records have a limited and defined shelf life. Such records should have their destruction date set on the date they are created.

38. The categories of records which have agreed destruction dates are set out in the HTA’s Records Retention and Disposal Schedule, [DN: need to include an impact link once retention schedule published].

39. No records should be retained indefinitely.

40. For those categories of records where the decision is not so clear cut, the decision around retention, disposal or long-term archiving for transfer to the National Archives needs to be made when carrying out the regular review of records.

41. Any records identified for disposal at that time should be deleted or destroyed in a safe and secure manner.

42. Records identified for retention or long-term preservation and eventual transfer to the National Archives should be stored in a discrete and secure place.

43. When the agreed retention period for retained records expires, records should be re-reviewed and:

- Retained for a further period if required for business purposes;
- If merited, preserved for eventual transfer to the National Archives; or
- Destroyed.

Archiving records

Commented [AM5]: No underlying process or architecture at present.

44. Records that are the subject of retention for a set period of time or have been earmarked for future transfer to the National Archive should be archived, providing they do not need to be accessible for the HTA’s regular business activities.

45. Electronic records earmarked for archiving should be moved to the “HTA Archive”, where they will be protected from accidental changes or deletions.

46. Paper records earmarked for archiving should be identified to the HTA's DRO who will make arrangements for long term secure storage.

47. IAOs are responsible for maintaining a register of the records that have been archived.

Destroying records

48. When records have reached the end of their lifecycle – i.e. when they no longer have a business purpose, are no longer required for audit purposes and are not due to be transferred to the National Archives – they should be destroyed in a safe and secure manner.

49. Electronic records can be deleted in a straightforward manner. If, for whatever reason, you are unable to delete a file that has reached the end of its lifecycle, please refer to the HTA's Head of Business Technology.

50. Paper records kept in the HTA's offices should be destroyed by using the confidential waste facilities.

51. Paper records stored with an offsite storage provider will be destroyed by that provider who will provide a certificate of destruction.

52. The HTA's DRO will ensure that records held offsite are destroyed at the end of their retention period.

53. IAOs are responsible for maintaining record destruction register that records details of all destroyed records that could have been subject to audit.

Commented [AM6]: Limited process and architecture at present.

Appendix 1 - Legal framework

- The Human Tissue Act 2004 and associated Regulations
- The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)
- The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended)
- The Public Records Acts 1958 and 1967
- The Data Protection Act 2018
- The EU General Data Protection Regulation
- The Freedom of Information Act 2000
- The Environmental Information Regulations 2004
- Civil Evidence Act 1995
- Value Added Tax Act 1994
- Companies Acts 1985 and 1989
- Financial Services Act 1986
- Limitation Act 1980
- Unfair Contract Terms Act 1977
- Latent Damage Act 1986
- Working Time Regulations 1998 Part II
- The Statutory Maternity Pay (General) Regulations 1986 as amended
- The Equality Act 2010
- The Defamation Act 1996
- The Public Interest Disclosure Act 1998
- The Employment Rights Act 1996
- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) (SI 1995/3163) as amended
- Health and Safety (First-Aid) Regulations 1981
- Fire Precautions (Workplace) Regulations 1997
- Health and Safety (Consultations with employees) Regulations 1996
- H&S Information for Employees Regulations 1989
- The Control of Substances Hazardous to Health Regulations 1999 and 2002

Audit and Risk Assurance Committee paper

Date	22 October 2019	Paper reference	AUD (16/19)
Agenda item	11	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 October 2019.

Decision-making to date

2. None.

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 Senior Management Team (SMT) monthly, and the register is updated. The strategic risk register that was updated at the beginning of October is at Annex A.
5. In June, we reported that three risks were amber rated: failure to manage regulatory expectations (risk three); failure to utilise our capabilities (risk four) and failure to achieve the benefits of the organisational transformation programme (risk six).
6. The risk of failing to manage regulatory expectations (risk three) has seen no change to the overall rating. Over this period we continued to monitor and manage perimeter

issues for the HTA, such as taphonomy, as well as managing the escalation of activity in preparation for Brexit. This remains an area of significant activity for the HTA; however, at this point SMT does not feel that the overall risk has increased. We will continue to monitor this risk, and in particular the Brexit outcome and the potential impact on regulatory expectations.

7. Risk 4, failure to utilise capabilities effectively, has seen increases and decreases in perceived risk since June 2019. Although workload and pressure continue to be monitored closely by SMT, an action plan is in place to deal with the recommendations of the stress survey and audit. Good progress has been made on improving our induction procedures that is being further built on by the appointment to the Regulation Manager -Training post, which has responsibility for induction, learning and development. Additional funding released, as a result, of the resolution of the rent dispute means that some funding can be used during this financial year which will support smarter working initiatives and improved data use. Overall SMT are of the view that the trend in this risk is downward.
8. Risk 6, failure to achieve the benefits of the organisational transformation programme, has decreased since ARAC's June meeting. As a result, of the revised funding position we anticipate some progress in implementing necessary change associated with the office relocation. In addition, the pending start date for the new Director and PM resource point to downward pressure against this risk at this time.
9. SMT is content that the strategic risk register is complete and that the planned actions to mitigate the risks to the levels reported are taking place.

HTA Strategic Risk Register October 2019

Overview: Risks reflect the strategy for 2019 - 2022. Our highest scored risks are the failure to manage expectations of regulation, which reflects the fast-pace of change within the sectors we regulate and the low likelihood of legislative change in the foreseeable future, and failure to utilise our capabilities effectively. Our Regulation Manager cadre is now more experienced with all now signed off to lead and support inspections. This has had a mitigating impact on risks 1 and 4. At the beginning of October, three posts are vacant, Project Manager, Data Analyst and Business Analyst, although plans are underway to appoint an interim Project Manager to mitigate risks of carrying this vacancy. The Director level vacancy is now filled, with the successful candidate likely to start in late October. SMT will continue to provide support for this Director's responsibilities whilst the new incumbent gets up to speed.

Other notable risks: Internally, planning for the ongoing uncertainty posed by EU Exit has increased, planned activity has been reviewed and limited to priority areas with resources having been identified to be redeployed at short notice if required later. The Head of Planning and Performance has commenced, bringing our Regulatory Delivery function back to full strength and will further mitigate R1.

Progress on development activity has slowed further as a result of carrying out work relating to EU exit, the opt-out consent Code of Practice and the loss of the Director in this business area. Work is continuing to scope the development priorities for the coming two years. Additional funds have been released as a result of the resolution of a long standing rent dispute, although they will need to be utilised by the end of this financial year. Work has begun to identify parts of the Development Programme that support our office move and could be delivered in this tight timescale. This will inevitably bring management overhead in terms of oversight and the administrative burden of letting appropriate contacts in short timescales. DHSC spending controls are likely to place continuing pressures on ALBs to make savings. We still await confirmation of GIA funding for the 2020/21 financial year and anticipate that we will continue to be unable to access reserves to fund our wider development project ambitions - we will need to consider the options to provide some contingency funding next financial year to enable the completion of the development work we undertake from now until March 2020.

Risk	July 2019	Aug 2019	Sept 2019	Oct 2019	Comments
1 - Failure to regulate appropriately (Risk to Delivery a-d & f and Development a-d)	↓	→	→	↓	A good regulatory framework and processes are in place, with a strong assured position on our key regulatory processes confirmed in the recent internal audit of these processes. Further continuous improvement is planned through mechanisms such as the recently introduced quality forum and the investment in the new one-year role of Regulation Manager - Training. All new Regulation Managers recruited during the preceding year have now been signed-off to lead inspections, increasing the organisation's capacity and strengthening our regulatory capability. A range of training activities and the new RM induction programme have been overseen by the new RM-Training. Regular training sessions coupled with work to improve and standardise reporting processes along with an increasing focus on using data and data quality is also improving this area. Given the work done to date, we consider the overall risk level is now falling, although we note that churn amongst the Authority, including the Chair, potentially leaves some gaps in oversight and support on regulatory and transformation issues. The introduction of the new Inspection Report templates reduces the risk of inconsistencies in reporting which we feel has a positive impact on this risk.
2 - Failure to manage an incident (Delivery, Development and Deployment)	→	→	→	→	Plans are in place to manage an incident. These plans are complete and were tested during Q4 of 2016/17. The Critical Incident Plan (CIP) was utilised to manage a building power outage during March 2018 and a regulatory issue in April 2018. Lessons learnt papers were discussed at ARAC, but the incidents were managed well. We are currently finalising the scope of an internal audit review of our Business Continuity and Critical Incident management arrangements, which will be undertaken during quarter 3. We are aware that if there is a 'no deal' EU Exit, this could affect our ability to respond or regulate effectively. We feel the plans in place are adequate.
3 - Failure to manage expectations of regulation (Risk to Delivery e and Development c)	→	→	→	→	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. The number of perimeter issue shows no sign of decreasing. These issues and the planning for EU exit continue to occupy regulatory resource. We are conscious that we have staff operating in the frontline who may be challenged about issues beyond our control, which would be heightened in a 'no-deal' EU Exit.
4 - Failure to utilise our capabilities effectively (Delivery a-e) (Development a-d) (Deployment a, c and d)	→	↑	→	↓	We are now using the skills of our more recent recruits more fully. Some specialist posts have been harder to fill successfully, but as yet we have not had to leave posts vacant with no suitable appointable candidates. Workload and pressure continue to be monitored closely by the management team and an action plan is in place to deal with the recommendations of the stress survey and audit. We achieved our planned position relating to GDPR by the end of March 2019 and have received moderate assurance from internal audit. Good progress has been made on improving our induction procedures and this is being built on by the appointment of the RM-Training, with responsibility for induction, learning and development. Additional funding released as a result of the resolution of the rent dispute means that some funding can be used during this financial year which will support smarter working initiatives and improved data use. Overall we are of the view that the trend in this risk is downward.
5 - Insufficient, or ineffective management of, financial resources (Deployment b)	→	→	→	→	Partial funding from DHSC was secured to cover increase in Employers' Pension contributions for 2019/20 along with non-cash income to cover our depreciation costs. Budget pressures this financial year have been alleviated due to the settlement of a longstanding rent dispute, this has released c£350 of additional funds that can be utilised through to the end of the March 2020. The lack of funding for Transformation programme beyond this financial year will limit the activity that can be initiated now was not approved in the current business year. We await final confirmation of the GIA settlement for the 2020/21 financial year from DHSC finance colleagues, we hope this will be received in time to inform budget and fees setting for the next financial year, in particular the ongoing funding of the NHS Pension contributions increase is a key concern
6 - Failure to achieve the benefits of the HTA Development Programme (Development objectives a-d)	↑	→	→	↓	The impact of 'high' recognises that aspects of the programme in particular IT related could have significant impact on the business should service be disrupted. DHSC did not agreed funding for this Programme in the current business year which has delayed the planning and project initiation. Some funding is now available for the remainder of this financial year and we anticipate some progress in implementing necessary change associated with the office relocation. As a result of the revised funding position and pending start date for the new Director and PM resource we have indicated downward pressure against this risk.

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

Risks are assessed by using the grid below

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

Lines of defence are:

- 1 - Embedded in the business operation
- 2 - Corporate oversight functions
- 3 - Independent of the HTA

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			
1	<p>Failure to regulate in a manner that maintains public safety and confidence and is appropriate</p> <p><i>(Risk to Delivery objectives a-d & f Development objectives a-d)</i></p> <p>Risk Owner: Allan Marriott-Smith</p>	<p>Causes</p> <ul style="list-style-type: none"> 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 Risk based approach to implementing Import and Coding regulations ahead of 31 March 2018 deadline Failure to deal with regulatory consequences of EU exit Uncertainty regarding the appointments to and composition of the Board. <p>Effects</p> <ul style="list-style-type: none"> 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	5	1		1	2	3				
						<p>Regulatory model</p> <p>HTA Strategy 2018 to 2021 clearly articulates the HTA's regulatory model</p> <p>Regulatory decision making framework</p> <p>Annual scheduled review of Strategy</p> <p>Approved HTA Business Plan 2018/19 identifies a balanced programme of regulatory activity and continuous improvement</p> <p>Well established processes support our core regulatory business.</p>					X		Preventative	Authority developed and approved the HTA Strategy	HTA Strategy published in May 2019
									X			Preventative	Reports to Authority of key decisions in Delivery Report	Satisfactory report made in July 2019	
								X	X			Preventative	Outputs from annual strategy review translate into revised annual Strategy	Annual strategic planning away day completed in September 2018	
								X	X	X		Preventative	Sign off of the business plan by the Chair on behalf of the Authority and by sponsor Department	HTA Business Plan to be published in April and approved by the Department of Health and Social Care	
											X	Detective	Internal audit conducted on Key Regulatory Processes, receiving substantial assurance and noting good areas of best practice	Final report received April 2019	
						<p>Quality management systems</p> <p>HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model</p>				X			Preventative/Monitoring	Individual staff Member responsible for QMS, automated review reminders, management oversight of progress on updates	Management are aware of limitations in the QMS - HTAMG took a report of proposed improvements in March 2019 and a Quality Forum is now in operation to improve the QMS.
						<p>People</p> <p>Adherence to the HTA People Strategy which has been substantially amended and approved by the Authority</p>			X				Preventative	Management information and assessment presented to the Authority quarterly as part of the Deployment report	Quarterly report made at July 2019 Authority meeting
						<p>Training and development of professional competence</p> <p>Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas</p>			X				Preventative	Annual PDPs, RM proposals to SMT	End of year PDP process was completed July 2019.
						<p>EU Exit</p> <p>Close liaison with DHSC and contingency planning for a range of outcomes including no-deal</p>			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
						<p>EU Exit</p> <p>Close liaison with DHSC and contingency planning for a range of outcomes including no-deal</p>							Preventive / Detective / Monitoring	Weekly reporting by ANH to SMT under standing item on SMT agenda. Notes and actions from weekly Brexit meetings. Recruitment of Brexit Project Manager (temporary contractor) has started - interviews started w/c 30/9/19.	Readiness Assessment completed and sent to DHSC August 2019 showed strong assured position across all areas. Brexit Project Manager due to start 15 October.
						<p>Use of existing regulatory model to manage the outcomes of 'no-deal'</p>							Detective / Monitoring	We are contributing, via DHSC, to planning around clinical trials involving tissue and cells – this makes sure consistent information is being provided and that we are reaching an appropriate network of stakeholders.	We have looked at which MS tissues and cells are imported from to work out what policy issues may arise because of how the legislation has been interpreted; we have also used data to identify where an incident arises in one establishment, how we would be able to use our data to work out the extent and/or impact of the issue.
						<p>Board</p> <p>Experienced Authority Member appointed as interim Chair Future appointments pending - have requested that the Department expedite recruitment for Chair and additional members</p>									
						<p>Regulatory model</p> <p>Delivery of Licensing and inspection review projects and outcomes of HA Risk and PM Development work to strengthen our regulatory model. Agreed action plan to end Q1 2019/20 (AMS)</p>			X				Preventative		
						<p>Consideration of Import licenced establishment in HA inspection planning. Establishments assessed in order of existing risk profile and level of activity</p>			X				Preventative		
						<p>Other</p> <p>Strengthening horizon scanning arrangements</p>			X				Preventative		
						<p>Embed Better Regulation initiatives in the regulatory model</p>			X				Preventative		

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			
2	<p>Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:</p> <ul style="list-style-type: none"> 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 <p>(Risk to all Delivery Development and Deployment objectives)</p> <p>Risk owner: Nicky Harrison</p>	<p>Cause</p> <ul style="list-style-type: none"> 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 Consequences of 'no-deal' EU Exit affecting supply routes, staff availability or multiple incidents <p>Effect</p> <ul style="list-style-type: none"> Loss of public confidence Reputational damage Legal action against the HTA Intervention by sponsor 	5	3	Future, should event occur	<p>Filled identified business-critical roles</p> <p>Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff</p> <p>Media handling policy and guidance in place, including regular media training for key staff & Members with relevant scenarios, to supplement media release and enquiries SOPs</p> <p>Accessible lines to take and key messages for likely scenarios</p> <p>Availability of legal advice</p> <p>Fit for purpose Police Referrals Policy</p> <p>Onward delegation scheme and decision making framework agreed by the Authority</p> <p>Regulatory decision making framework</p> <p>IT security controls and information risk management</p> <p>Critical incident response plan regularly reviewed and tested</p> <p>Evaluate test exercise of incident and feedback to all staff.</p> <p>Plan to develop and strengthen the relationship with DIs</p> <p>EU exit plans in place</p>	3	2		1	2	3	Preventative	<p>Monthly reports to HTAMG</p> <p>Policies etc. reviewed annually, training specification and notes after incident reviews</p> <p>Policy reviewed annually, training specifications</p> <p>Reports on media issues in Delivery Report</p> <p>Documented, incidents reported to Chair and in Delivery Report</p> <p>Lawyers specified in Critical Incident Response Plan, SMT updates</p> <p>Annual review of policy (minimum), usage recorded in SMT minutes</p> <p>Standing Orders and Authority minutes</p> <p>Reports to Authority of key decisions in Delivery Report</p> <p>SIRO annual review and report Internal audit reports</p> <p>Critical Incident Response Plan and notes of test, reported to SMT</p> <p>Process has been utilised twice in 2018, lessons learned papers to be presented to ARAC June 2018</p> <p>Blog and DI training</p> <p>Paper on EU Exit plans to be reviewed by SMT in January, and considered by Authority at February meeting.</p> <p>Updated EU Exit readiness assessment completed in August 2019 and considered by SMT and DHSC.</p> <p>Daily SitRep structure planned and arrangements put in place for their organisation and for monitoring and escalation of arising issues.</p> <p>Completion of daily cover rota with colleagues knowing expectations of their roles over this period.</p> <p>Awareness-raising across HTA at all-staff meeting on 14/10/19.</p> <p>EU exit response planner developed to ensure that if an incident arises, we all know what to do.</p>	<p>MontAMSy reports on vacancies by the Head of HR to HTAMG and KPI requiring exception reporting if there are more than two vacancies at the end of each month, although without reference to specific business-critical posts. Last report April 2018.</p> <p>Reviewed by ARAC October 2018</p> <p>Media policy to be reviewed.</p> <p>Delivery report to Authority meeting May 2019</p> <p>In place</p> <p>Policy reviewed by Authority July 2018</p> <p>SO reviewed and agreed in 4 May 2017 (next review May 2019)</p> <p>RDMs summarised in Delivery Report to Authority Meeting in May 2019.</p> <p>Cyber security review - standing agenda item at ARAC June 2018</p> <p>CIP was used to manage a power outage during March 2018 and a regulatory incident arising in April</p> <p>Project on business plan</p> <p>EU Exit planning is a standing item on the weekly Senior Management Team Meeting and was covered in detail at the February, May and July Authority Meetings.</p> <p>Mostly green operational readiness assessment reported to DHSC August 2019.</p> <p>Further consideration of HTA's Operational Readiness at SMT on 11/10/19 and assurance on operational readiness to be reported to DHSC by 16/10/19.</p>

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION					
			I	L			I	L		1	2	3								
3	<p>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</p> <p>(Risk to Delivery objective e, and Development c)</p> <p>Risk Owner: Allan Marriott-Smith</p>	<p>Cause</p> <p>External factors</p> <ul style="list-style-type: none"> 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 <p>Matters which certain stakeholder groups believe require review</p> <ul style="list-style-type: none"> 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 <p>Matters which stakeholders/public may expect to be inside regulatory scope</p> <ul style="list-style-type: none"> 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 <p>Effect</p> <ul style="list-style-type: none"> Diminished professional confidence in the adequacy of the legislation 	5	4	Ongoing	Log of issues known to the HTA with respect to the legislation to inform DH and manage messages	4	3		1	2	3		Ongoing log	Log in place and reviewed at HTAMG quarterly. New issues identified in causes and effects Reviewed by HTAMG in September 2019					
						Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope						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 January 2019; Transplant Advisory Group May 2019		
						Active management of issues raised by the media – including the development of the HTA position on issues						X				Preventative/Detective	Quarterly reports to Authority on communication (including media) activities	Last report to Public Authority Meeting in May 2019		
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence										X		Monitoring	Quarterly Accountability meetings with DH	Full year accountability meeting in May 2019
						Action where we believe it will support public confidence (e.g. publication of pregnancy remains guidance)										X		Preventative	Published guidance for particular issues (e.g. pregnancy remains, and cord blood)	Pregnancy remains guidance published March 2015 Cord blood guidance issued in March 2016 Guidance is still current. Cryopreservation information for public published September 2018
						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	Letter to Minister re. import and consent requirements for public display Advice and guidance continues to be provided.
						Legal advice now gives a clearer view of our Schedule 2, s. 20 powers										X		Preventative	Legal advice to be followed	Legal advice September 2016. No change to position.
						Codes of practice and standards – provide greater clarity on matters inside and outside of regulatory scope were published April 2017. Circulation of principles within Code A to wider stakeholders was undertaken Quarter 3 2017/18										X		Preventative	Codes published on website	Supplementary guidance on PM standard on traceability issued Feb 2019
						Partial implementation of triennial review recommendations March 2017										X		Preventative and remedial	Recommendations form part of business plan	Good progress, most complete with only benchmarking to be finalised
						Public research - gaining a better understanding of public confidence and the factors which impact it - complete Q2 2017/18										X		Preventative		Authority undertook review of headline messages at strategic awayday October 2017. Public forum and review of public guides
						Proactive horizon scanning and development of policy in emerging/complex areas Project complete Q3 2017, now business as usual										X		Preventative	HTAMG Minutes	Horizon scanning map in use and reviewed quarterly by HTAMG Horizon scanning standard agenda item at all stakeholder group, TAG, HWG
																X		Preventative	Programme monitored by SMT and HTAMG	Programme underway Licensed establishment engagement programme established to inform work New ToR for internal group to agree focus for next business year

	<ul style="list-style-type: none"> • <i>Reduced public confidence in regulation of matters relating to human tissue</i> • <i>Reputational damage</i> 				<i>Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners, ORG, Comms sub-group) to inform planning for EU Exit and plan in place, including for a 'no-deal' scenario</i>	x		<i>Preventative</i>	<i>Meetings diarised and actions recorded. Internal EU Exit lead identified. Quarterly updates provided to Authority in Development report, and substantive paper at February 2019 meeting</i>	<i>On track, but uncertainty remains. Guidance to sector published Feb 19. ORC assessment of preparedness as green. Extension period agreed to 31 October 2019; frequency of meetings reduced pending outcome of further Govt negotiations</i>
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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	<p>Failure to utilise people, data and business technology capabilities effectively</p> <p><i>(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)</i></p> <p>Risk Owner: Allan Marriott-Smith</p>	<ul style="list-style-type: none"> 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 Heads 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 <p>Effect</p> <ul style="list-style-type: none"> 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		<p>People</p>	4	3							
						Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle			X	X		Preventative/Monitoring	QMS reminders as policies due for review. SMT review of all revised policies	Regular review cycle recommenced in late summer	
						Established annual Performance Development Planning (PDP) process supported by mandated in year processes (1-2-1s and mid year review) Standard objectives for all line managers			X	X		Preventative/Monitoring	PDP guidance reviewed annually and approved by SMT, newly introduced countersigning officer check	Guidance issued April 2019. End of year guidance has been issued and process commenced.	
						Regular review of HTA organisational structure and job descriptions			X	X		Preventative	Recruiting to the currently agreed organisational structure and approved job descriptions	Job descriptions reviewed as posts become vacant and recruitment to new vacant posts almost complete.	
						Feedback from HTA people about work, management and leadership			X	X		Monitoring/Detective	Staff survey, exit interviews, staff forum (attended by SMT Member and Head of HR)	Staff Survey action plan largely complete at end March 2019. ARAC chair regularly discusses staff issues with chair of staff forum.	
						Revised People Strategy 2019 to 2021			X			Preventative/Monitoring	Authority approval of the Strategy	Authority approved the Strategy at its meeting in February 2019.	
						Data									
						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.	
						Business technology									
						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	
						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 2018	
						Business technology									
						Identify refresher training and targeted software specific training needs.			X			Preventative			

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	<p><i>Insufficient, or ineffective management of, financial resources</i></p> <p><i>(Risk to Deployment objective b</i></p> <p><i>Risk Owner:</i></p> <p><i>Richard Sydee</i></p>	<p>Cause</p> <ul style="list-style-type: none"> • 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 <p>Effect</p> <ul style="list-style-type: none"> • 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 <p>Leading to:</p> <ul style="list-style-type: none"> • Inability to deliver operations and carry out statutory remit • Reputational damage and non payment of fees 	5	4	Ongoing	Budget management framework to control and review spend and take early action	2	3		X	X		All	Budgetary control policy reviewed annually and agreed by SMT	Last review January 2019
						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 April 2019	
						Licence fee modelling						Preventative	Annual update to fees model	Update agreed by the Authority January 2019 meeting	
						Rigorous debt recovery procedure			X			Preventative	Monthly finance reports to SMT and quarterly to Authority	Last quarterly report July 2019	
						Reserves policy and levels reserves			X			Monitoring	Reserves policy reviewed annually and agreed by ARAC	Last agreed by ARAC October 2018	
						Delegation letters set out responsibilities			X	X		Preventative	Delegation letters issued annually	Issued in May 2019	
						Prioritisation when work requirements change			X			Preventative	Agreed business plan, monthly HTAMG and SMT reports	Last HTAMG report July 2019 Last SMT update June 2019	
						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 2018.	
						Annual external audit					X	Detective	NAO report annually	Last report in June 2019 - 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 2019	
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 <i>DHSC Finance wrote in September indication confirmation of GIA funding sometime in October 2019</i>									
Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards	X	X		Preventative											

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			
6	<p>Failure to achieve the benefits of the HTA Development Programme</p> <p>(Development objectives a-d)</p> <p>Risk owner</p> <p>Allan Marriott-Smith</p>	<p>Causes</p> <ul style="list-style-type: none"> • 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 <p>Effects</p> <ul style="list-style-type: none"> • 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			4	4		1	2	3			
						SMT experience of organisational change, programme and project management			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 PRINCE2)			X			Preventative			
						A number of trained project managers among HTA staff			X			Preventative			
						Experience of procurement and contract management			X			Preventative			
						Existing mechanisms for engaging staff			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			X			Preventative			
						Obtain external advice on programme design and implementation									
						Implementation of external advice on programme design and governance			X			Preventative	PPL presentation to SMT April 2019		
						Embed Benefits Realisation Management methodology within programme			X			Preventative			
						Introduce a Programme Management Office			X			Preventative			
						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		
						Training plan to encompass project and change management and HTA approach			X			Preventative			
						Development of procurement plan to deliver the DDAT Strategy			X			Preventative			
						SROs identified for Programme and individual projects			X			Preventative			
						Schedule a regular programme of staff engagement events			X			Preventative			
						Establish an external stakeholder communications and engagement plan			X			Preventative			
						Recruitment of new Authority Member(s) with digital and organisational change experience				X		Monitoring			
						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	22 October 2019	Paper reference	AUD (17/19)
Agenda item	12	Author	Richard Sydee Director of Resources
Protective Marking	OFFICIAL		

License fees and income – ARAC discussion paper

Purpose of paper

1. To provide the committee with an overview of the recent fees review and activity since the September 2019 Authority discussion.

Decision-making to date

2. None.

Action required

3. The committee are asked to note the paper.

Background

4. The HTA sets its fees using a model, the most recent iteration of which was reviewed and developed in 2016. As the committee will recall the model allocates overhead costs as an equal charge to all licence holders and apportions the remainder to “pots” for each sector dependent on the level or regulatory activity each sector utilises.
5. These sector pots are then recovered via a main licence fee and a number of sub fees for satellite sites and activities. Some sectors, for example Human Application (HA), have a more complex recovery model than simpler sectors, such as, Public Display (PD).
6. A schematic overview of the HTA fees model is contained in Annex A.

Current licensing position

7. During this financial year, we have continued to see a reduction in the number of licensed establishments in the Human Application sector and an increase in the Research sector. Trends in establishment numbers since 2014/15 are contained in Annex B.
8. Although in overall numbers this may appear balanced this can have a negative impact on sector fees:
 - The fee model recovers an overall amount from each sector based on regulatory effort, as there is no change in the proportion of regulatory activity in each sector the model would increase the fees for an HA licence (the sum recoverable divided by a smaller denominator) whilst reducing fees in the Research sector (due to the increased denominator). Although in theory this ensures that we would recover the same overall amount in fees it would lead to an increase materially above CPI for HA sector licenses.
 - The alternative is to increase all fees by a fixed percentage (as per last year) but given the significant difference between Research and HA sector fees limiting this to CPI would result in a real terms reduction in the overall level of fees recovered.

Fees for complex satellites

9. The Authority discussed the recommendation for the introduction of this fee at the September meeting. There was general agreement that for the Post Mortem (PM) sector the activity of undertaking a PM was an appropriate delineation between a complex and non-complex satellite. In the HA sector there was some discussion as to whether processing alone was sufficient to clearly distinguish satellites as complex. The Authority asked that we discuss this with the Stakeholder and Fees Group (SFG) and we will be providing an update on this at the ARAC meeting.
10. It is important to note that to make the introduction of such a fee we would wish to use existing activities as indicative of complexity, any approach that suggested further work be required to analyse satellite sites would in our view be counterproductive – likely to cost more to introduce than it would recover.
11. To inform the Authority's discussion we had modelled a scenario which charged a significantly higher fee for a complex satellite than the existing satellite fees. As suggested at that time this was based on an assumption that such a scenario would look to introduce a charge that went a considerable way to charging a complex

satellite a fee akin to that of a main site. It was also modelled at this level to deliver a material increase in fees recovered to provide a demonstrable offset for non-complex satellites.

12. As this would be a new fee we would have some discretion as to the level at which such a fee would be set. If we proposed the introduction of complex satellites a new standalone fee, rather than counterbalanced by a reduction in non-complex satellite fees, then we could set the fee at a lower level and increase total recovery from fees.

Overall fee increases

13. The fee increase for 2019/20 saw a move away from amendment to the fees model to determine fees increases to a fixed percentage point increase to all fees, agreed as the September 2018 CPI rate of 2.x%.
14. Between the issuing of this paper and the ARAC meeting SMT will be discussing proposal for the annual fee increase for 2020/21. As with last year the proposal will likely be linked to a percentage point increase to all fees, SMT will indicate to the Authority the level at which it believes fees could be increased – but provide Authority with the modelling data to inform their discussion.

Other fee changes

15. The proposal to introduce a new temporary fixed period licence was also presented to the Authority during the October Licensing Fees meeting. This was agreed in principle and we will include recommendations for the level at which that fee will be set to the November Authority meeting.
16. Proposal to make modest adjustments to the weighting of some activities within the fees model, primarily the activities of Import and Processing, will also be included in the November paper.
17. We will provide relevant feedback from discussions at SFG to the ARAC meeting.

Third Party Agreements

18. This proved to be a complex area during the fees review process. Although it is acknowledged there is inherent risk in the current approach to Third Party Agreements (TPAs) at this time the HTA has not finalised its approach to regulation of such agreements. It is difficult therefore to quantify the amount of regulatory effort which might be expended in this area in the future; we are therefore limited in our ability to calculate an amount to be recovered.

19. A further complicating factor is the different nature of TPAs, we have summarised below a few scenarios:

- A licensed establishment holds a large number of TPAs with individuals who are able to acquire tissue samples at various sites.
- A licensed establishment holds a single TPA with a non-licensed establishment to undertake some activity. This third party might be licensed by another regulator.
- A licensed establishment holds a TPA with another licensed establishment
- A licensed establishment provides a number of services under numerous TPAs to other licensed establishments

20. During our discussion it was clear that there was no simple one size fits all solution to charging for TPAs. As we finalise the HTA's regulatory approach it will become clearer how much work we will undertake to review and possibly licence such arrangements. It is hoped that this will also provide a clearer position from which we might consider who might meet the cost of this regulation and how it might be charged for.

Future landscape

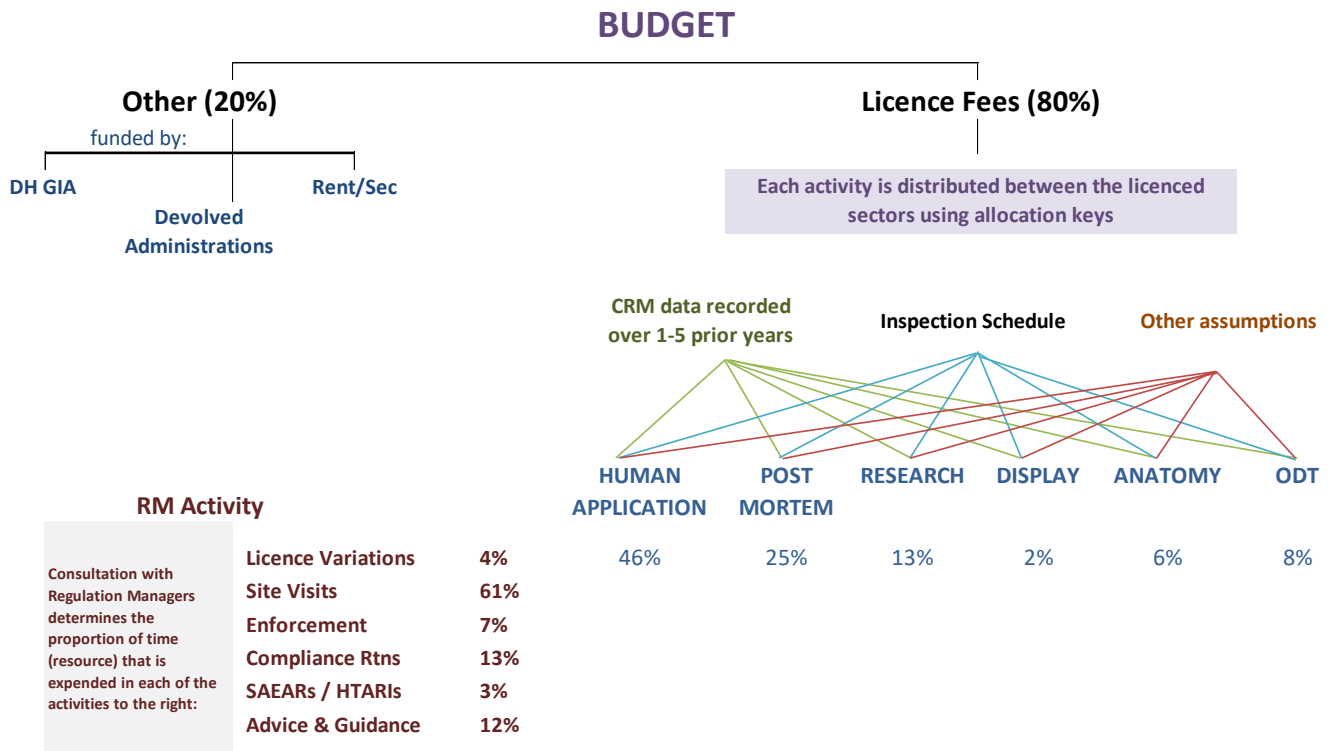
21. The fees model, as historically operated, has looked to recover a set budgeted amount. Through the majority of this decade the restraint on public sector expenditure has required the HTA to at first reduce the amount sought to recover and in recent years limit where possible increases in budget.

22. This scenario has been deliverable in the medium term, whilst we have been able to rely on existing systems and assets to support our operational delivery. Moving forward the shift towards cloud based IT will require a different funding model – one far more reliant on revenue budget for annual subscriptions than the historic capital investment in physical assets. If coupled with a desire to improve systems and processes this will likely require increased budget, as there are very limited options available for further internal efficiencies.

23. The current operating landscape is difficult to predict. Research remains the only sector where we have seen growth in recent years with both the HA and PM sectors having seen reductions in overall number of licensed establishments over the same period. There is little firm evidence on which we might base any forecast growth or contraction in any of the sectors we regulate and as an organisation we will need to ensure we are able to fund and maintain the work of the HTA moving forward.

24. Without growth in activity (number of establishments) or additional funding from our sponsor Department we may need to consider fee increases above inflation if we are to deliver and then sustain process and system improvement.

Annex A – Overview of HTA fees model



The fees model first determines the amount of licence fee income that should be generated from each sector, taking a percentage of the recoverable budget based on RM activity and then apportioning that amount based on the percentage share of the activity undertaken in each sector. The sector total from these calculations becomes the figure that will be recovered from that sector. This ensures full recovery of the budget and that each sector bears the full weight of the cost of regulation based solely upon the level of regulatory activity in their sector - eliminating the previous cross subsidisation between sector.

FEES STRUCTURE

Once the total to be recovered from each sector has been calculated the fees model then calculates licence fees. These are based on a number of factors that our Regulation Directorate believe indicate the likely complexity and therefore resource that is required for different types of licenced activity/number of sites etc.

	HA	PM	R	PD	A	ODT
Main Fee	X	X	X	X	X	X
Activity fees						
Activity	X					
Activity		X				
Activity						X
Satellite (1-4)	X	X	X	X	X	
Satellite (5+)	X	X	X	X	X	

Licence fees are calculated using a weighting process.

- Within each sector a main licence carries a weight of 1.
- Activities (Processing, Storage, Distribution etc.) are given a weighting in relation to the main fee for that sector, related to the amount of additional resource required to regulate it. For example processing within HA might carry a weighting of 0.5 compared to a main fee.
- Satellites are given a weighting in proportion to the main fee, again related to the additional burden a satellite brings to regulating a licenced organisation
- The weighting for each activity is multiplied by the number of licence holders who undertake it to provide an "Applied weighting". The Applied weighting for the activity is then divided by the Total weighting for the sector to provide the percentage of the Sector's total cost will be recovered from that activity. This is then divided by the number of licence holders to arrive at a fee for the activity.

Example (illustrative, not real figures) - The HA licence Main Fee is weighted at 1, there are 100 HA licence holders.

The Total weighting for the sector is 200, therefore 50% (100/200) of the sector's total cost will be recovered from the main licence.

The total sector cost is £2m, 50% of which is divided by the number of licence holders (100) to arrive at a main licence fee of £10k.

Annex B – Establishment numbers 2014/15 to date.

Establishment numbers

	Human Application		Post Mortem		Research		Anatomy		Public Display		ODT
	Main	Sat	Main	Sat	Main	Sat	Main	Sat	Main	Sat	
2014/15	159	89	198	66	142	108	37	14	14	4	37
2015/16	150	65	189	66	144	132	37	16	13	5	37
2016/17	148	64	182	65	163	152	36	16	14	6	37
2017/18	146	62	180	68	162	139	37	15	14	6	36
2018/19	136	50	180	67	162	142	37	15	14	6	36
Forecast - 2020/21	133	48	178	74	169	153	38	15	16	6	35

Licence fee income recoverable

	Human Application	Post Mortem	Research	Anatomy	Public Display	ODT	TOTAL
2014/15	1,226,200	1,102,300	663,600	84,800	27,000	286,300	3,390,200
2015/16	1,365,700	1,072,500	532,300	82,000	34,400	273,000	3,359,900
2016/17	1,298,960	1,007,709	564,675	82,606	36,927	267,123	3,258,000
2017/18	1,344,484	1,061,718	599,226	87,009	48,054	274,510	3,415,001
2018/19	1,383,253	1,161,043	656,649	112,856	40,359	205,922	3,560,082

Average fee per licence

	Human Application	Post Mortem	Research	Anatomy	Public Display	ODT
2014/15	7,712	5,567	4,673	2,292	1,929	7,738
2015/16	9,105	5,675	3,697	2,216	2,646	7,378
2016/17	8,777	5,537	3,464	2,295	2,638	7,220
2017/18	9,209	5,898	3,699	2,352	3,432	7,625
2018/19	10,171	6,450	4,053	3,050	2,883	5,720

Average fee per site

	Human Application	Post Mortem	Research	Anatomy	Public Display	ODT
2014/15	4,944	4,175	2,654	1,663	1,500	7,738
2015/16	6,352	4,206	1,929	1,547	1,911	7,378
2016/17	6,127	4,080	1,793	1,589	1,846	7,220
2017/18	6,464	4,281	1,991	1,673	2,403	7,625
2018/19	7,437	4,701	2,160	2,170	2,018	5,720

Audit and Risk Assurance Committee paper

Date	22 October 2019	Paper reference	AUD (18/19)
Agenda item	14	Author	Morounke Akingbola Head of Finance and Governance

Protective Marking OFFICIAL

HTA Gifts and Hospitality Register

Purpose of paper

1. To present the latest Gifts and Hospitality Register to the Committee.

Decision-making to date

2. None.

Action required

3. Review the register and comment.

Background

4. The Register is a standing agenda item and is presented at each meeting.

Register of Gifts / Hospitality Received and Provided

Version: HTAG0001 (AUD 18-19) Annex A
Oct-19

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	

Audit and Risk Assurance Committee paper

Date	22 October 2019	Paper reference	AUD (19/19)
Agenda item	15	Author	Morounke Akingbola Head of Finance and Governance
Protective Marking	OFFICIAL		

Counter Fraud Strategy 2019-22

Purpose of paper

1. To present to the Committee the Anti-Fraud Strategy submitted to the Cabinet Office as part of the suite of documents that make up the submissions that demonstrate our adherence to the Functional Standards: Counter Fraud.

Decision-making to date

2. The Counter Fraud Strategy has been agreed in principle with the final draft shared with the Committee early in August 2019.

Action required

3. The Committee is requested to review and comment on the attached strategy (Annex A) and in particular note the high-level action plan and comment where necessary.

Update

4. On 30 August, we submitted our return to the Cabinet Office, which included our Counter Fraud Strategy, Risk Assessment and Action Plan. The documents submitted were to demonstrate that we have achieved the basic level of compliance with the standard.
5. We are awaiting a response from the Cabinet Office and in the meantime are working towards completing the tasks on the Annual Action Plan.

6. The most pressing action is that of Fraud Awareness. We aim to achieve this through on-line training. A new training package has been procured but will not be available to HTA staff until November 2019.
7. A more detailed update on progress against our Action Plan will be provided at the January 2020 ARAC meeting.

Author(s)	Morounke Akingbola	Next review due	September 2020
Reviewed by	Richard Sydee	Owner	Head of Finance and Governance
Approved by	Director of Resources	Distribution	SMT, ARAC
Protective Marking	OFFICIAL		

HTA Counter Fraud, Bribery and Corruption Strategy 2019 - 2022

Introduction

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

Purpose of the Counter Fraud Strategy, Bribery and Corruption Strategy

3. The HTA is a small organisation with a less public-facing role than some other regulators, nevertheless our activities can expose us to inherent risk of fraud from both external and internal sources. Our commissioning and procurement of goods and services, our grantig of Licences and site visits also presents inherent risks of corruption and bribery.
4. As well as financial loss, fraud and corruption also detrimentally impacts service provision, morale and undermines confidence in the HTA and public bodies more generally.
5. To date there is little evidence that these risks ('fraud risk') are a material risk for the HTA. This may be due to the established counter fraud arrangements as set

out in the 'Ant-fraud Policy', although such evidence can, of course, only be based on what is known. There is, however, strong evidence that overall, fraud risk in the public sector is increasing, due partly to more sophisticated methods of fraud but also different ways of delivering service and revised management arrangements.

6. It is therefore essential that the HTA regularly assesses its exposure to fraud risk and ensures that its counter fraud arrangements and the resources allocated to managing the risks are appropriate – that the controls are effective and aligned to best practice. Overall, the Anti-Fraud Policy commits the HTA to achieving an anti-fraud and theft culture that promotes honesty, openness, integrity and vigilance in order to minimise fraud, theft and its cost to the HTA.
7. This Strategy therefore sets out what the HTA will need to do over the period 2019 to 2022 to successfully fulfil this commitment.
8. Many controls to manage fraud risk are already in place but these need to be maintained and where necessary, improved to help keep pace with the increased level of perceived risk. There are also other controls that either are needed or may be needed, depending on the overall assessment of fraud risk and the resources available.
9. Implementation of the Strategy will help the HTA to achieve its strategic objective of improving standards through intelligence and meet the Cabinet Office Functional Standards released in 2018.

Scope

10. All references to fraud within this Strategy include all types of fraud-related offence, i.e., theft, corruption and bribery.
11. The Strategy covers all business, activities and transactions undertaken by the HTA or on its behalf, and therefore applies to all Members and all who work for the HTA¹.

¹ Employees including casual staff and agency staff, consultants, contractors and partners.

Basis – What has informed the Strategy

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

13. This standard sets out key principles:

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

14. This Strategy has been informed by a detailed assessment against these principles using the Functional Standards Maturity model and an organisational fraud risk assessment. The HTA has assessed itself as being non-compliant against the standard currently.

15. The basis of this Strategy is therefore to address those areas of the standard that must be met and developed in order that the HTA can move towards embedding the counter-fraud culture envisaged by the functional standards.

16. Not all areas of the standard are relevant to the HTA as the standard applies to organisations of varying sizes and type within the UK, and not all recommendations are therefore proportionate to the risks faced.

17. A detailed fraud assessment was carried out during the creation of this strategy. The outcome of this assessment has highlighted those areas of our organisation that are susceptible to fraud. The main area identified is within Travel and Subsistence and actions are being taken to mitigate the risk.
18. There are other areas of fraud risk, such as Cyber risk, mandate fraud and procurement which are considered to be business as usual and therefore are managed via the operational and strategic risk registers.

Objectives – Where the HTA needs to be

19. Based on the five principles of the Counter Fraud Functional Standards above, the objectives below set out what the HTA will need to be achieving by 2020 in order to fully have met the basic standard.
- a) Conduct fraud risk assessment of existing and new fraud threats to ensure appropriate actions are taken to mitigate identified risks;
 - b) Creation of a counter-fraud culture across the organisation through training and communication;
 - c) Maintain effective systems, controls and procedures to facilitate the prevention and detection of fraudulent and corrupt activity;
 - d) Effective response and investigation of suspected cases of fraud and corruption and pursue redress and effective sanctions, including legal action against people committing fraud;
 - e) Implement reporting of counter-fraud performance by establishing key metrics for reporting on counter-fraud activity and fraud cases.

Implementation

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

Accountability

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

22. Additionally, all other Directors and Heads of Directorates are responsible for ensuring that the Strategy is applied within their areas of accountability and for working with the Head of Finance and Governance in its implementation. All employees and Authority Members have a responsibility to work in line with this strategy and support its effective implementation. Details of responsibilities are set out in the Counter-Fraud Policy.
23. A report on progress on implementing this Strategy will be provided to the Audit, Risk and Assurance Committee (ARAC) in addition to the Department of Health and Social Care Anti-Fraud Unit (DHSC AFU).
24. The effectiveness of counter fraud controls is assessed in part by Internal Audit reviews, and an overview of the effectiveness of our mitigating controls are contained in the Internal Audit reports submitted to ARAC. Any strategic concerns could be raised in these reports.

Measures of success

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

Reporting and review

26. The HTA's approach to suspected fraud can be demonstrated in its Fraud Response Plan contained in the [Anti-Fraud Policy](#)
27. The responsibility for the prevention and detection of fraud rests with all staff, but Directors and Managers have a primary responsibility given their delegated contractual and financial authority. If anyone believes that someone is committing a fraud, or suspects corrupt practices, these concerns should be

raised in the first instance directly with line management or a member of SMT then the Chair of the Audit and Risk Assurance Committee.

28. The Chief Executive and the Director of Resources are responsible for ensuring the HTA has a robust anti-fraud and corruption response.
29. The Audit and Risk Assurance Committee will ensure the continuous review and amendment of this Strategy and the Action Plan contained within it, to ensure that it remains compliant with good practice and national public sector standards, primarily Cabinet Office Functional Standards: Counter-fraud.

DRAFT

Annex A: Strategic Action plan 2019-22

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

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

Prevent and Deter					
Action	Description	Core Discipline	Due date	Outcome	Owner
Policies	Refresh and promote the HTA's suite of anti-fraud related policies and procedures to ensure that they continue to be relevant to current guidance.	Leadership, Management and Strategy	Annually, each April	Updated policies.	Head of Finance and Governance
Internal Audit	Use of Internal Audit review to identify further weaknesses	Prevent	February	Assurance to ARAC	Director of Resources
Intelligence	Use of information and intelligence from external sources to identify anomalies that may indicate fraud	Prevent	TBC	Increased awareness; additional controls implemented	Head of Finance and Governance

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

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

Audit and Risk Assurance Committee paper

Date	22 October 2019	Paper reference	AUD (20/19)
Agenda item	16	Author	Richard Sydee Director of Resources
Protective Marking	OFFICIAL		

Reserves Policy

Purpose of paper

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

Decision-making to date

2. At the June 2018 ARAC meeting, a discussion took place on the implications of the HTA using its surpluses as a means of investing in the HTA's transformation programme over the next three years in order to reduce the current level of reserves.
3. 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. In addition, a business case to the Department of Health and Social Care (DHSC) would be submitted justifying the need to run a deficit for a period, thus reducing the level of reserves.
4. Since the last meeting, we were unsuccessful in gaining DHSC approval to use our reserves. The attached policy therefore remains unchanged.

Action required

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

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 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	22 October 2019	Paper reference	AUD (21/19)
Agenda item	17	Author	Morounke Akingbola Head of Finance and Governance
Protective Marking	OFFICIAL		

Audit, Risk and Assurance Committee (ARAC) Handbook

Purpose of paper

1. To present the ARAC Handbook to the Committee.

Decision-making to date

2. None.

Action required

3. The Committee is requested to review, comment and note the minor change within the plan of work, from specific months to seasons.

HTA Audit & Risk Assurance Committee Handbook

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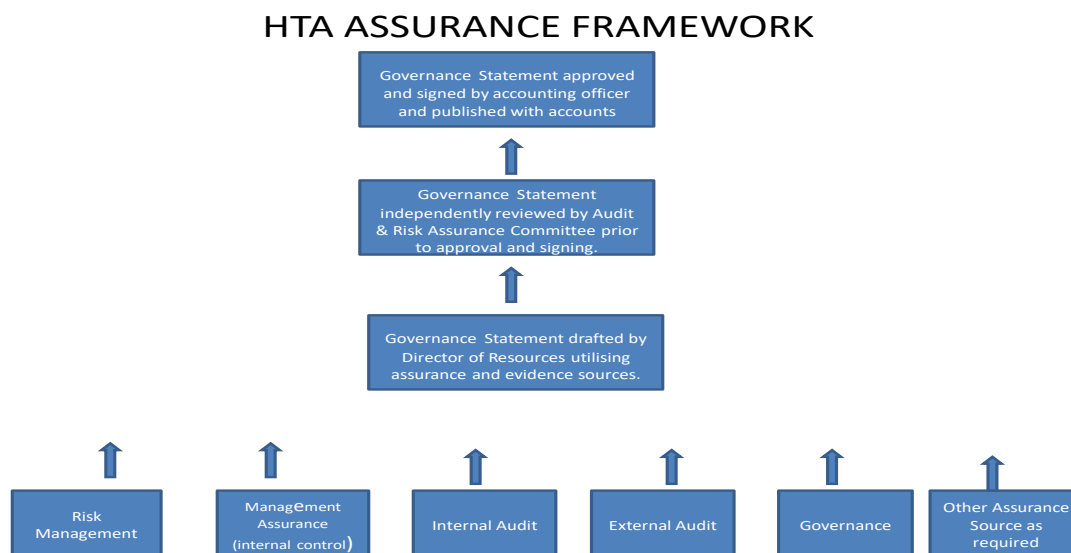
Section 1

Introduction

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

The role of the Audit & Risk Assurance Committee

- b) The Audit & Risk Assurance Committee is a committee to the Human Tissue Authority's board (the Authority) as defined by section 8 and Annex B of the Framework agreement between the DHSC and the HTA. The Committee's primary role is to advise the Authority and the Accounting Officer on the exercise of their responsibilities, by concluding upon the adequacy and effective operation of the HTA's overall internal control system and ensuring there is an adequate and effective risk management and assurance framework.
- c) It is the responsibility of the Accounting Officer (i.e. Chief Executive Officer) to ensure that the organisation properly exercises its obligations / responsibilities in relation to issues of risk, control, governance and associated assurances. As a result the Committee will review the Annual Governance Statement, - this being a primary disclosure statement within the final accounts - prior to signing by the CEO. The HTA assurance framework is illustrated below.



- d) In discharging its duties the Audit & Risk Assurance Committee will:
- a) Review the comprehensiveness of assurances in meeting the Authority's / Accounting Officer's assurance needs

- b) Review the reliability and integrity of these assurances
 - c) Review the adequacy of the Authority and Accounting Officer in discharging their responsibilities (particularly in respect to Financial Reporting).
- e) HM Treasury's Audit Committee Handbook provides further guidance on the role of audit committees, the role of the chair of the audit committee and good practice.

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

- f) In conducting their review the Committee will consider whether the Authority and the Accounting Officer are:
- a) promoting the highest standards of propriety in the use of HTA funds and encourage proper accountability for the use of those funds
 - b) improving the quality of financial reporting by reviewing internal and external financial statements on behalf of the Authority
 - c) promoting a climate of financial discipline and control which will help to reduce the opportunity for financial mismanagement
 - d) identifying and managing risk and promoting the development of internal controls systems which will help satisfy the Authority that the HTA will achieve its objectives and targets
 - e) operating in accordance with any statutory requirements for the use of public funds, within delegated authorities laid down within the Authority's Standing Orders and the HTA's own rules on what matters should be referred to the Authority and in a manner which will make most economic and effective use of resources available

Section 2

Terms of reference of the Audit & Risk Assurance Committee Constitution

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

Duties and functions

3. The ARAC will advise the Accounting Officer and Authority on:
 - a) the strategic processes for risk, control and governance and the Annual Governance Statement;
 - b) the accounting policies, the accounts, and the annual reports of the HTA. This includes the process for review of the accounts prior to submission for audit, levels of error identified, and management's letter of representation to External Audit;
 - c) the planned activity and results of both Internal and External Audit;
 - d) adequacy of management response to issues identified by audit activity, including External Audit's audit completion report;
 - e) assurance relating to corporate governance requirements for the HTA;
 - f) the remuneration report for staff and Members as presented in the annual report and accounts
 - g) (where appropriate) proposals for tendering for either Internal or External Audit services or for purchase of non-audit services from contractors who provide audit services; and
 - h) where necessary, anti-fraud policies, whistle-blowing processes, organisational culture and arrangements for special investigations.

Rights

4. The ARAC has the following rights:
 - a) it may co-opt additional participants, for a period not exceeding a year, to provide specialist skills, knowledge and experience (these additional participants must be recruited in line with paragraph 15 of this document);
 - b) it may procure independent specialist ad-hoc advice, at the expense of the HTA, subject to budgets agreed by the Authority; and
 - c) it may seek any information it requires from HTA staff, who are expected to assist the Committee in the conduct of any enquiries.

Access

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

Information requirements

6. As appropriate to the meeting the ARAC will be provided with:
 - a) a report summarising any significant changes to the organisation's Risk Register;
 - b) a progress report from Internal Audit summarising: work performed (and a comparison with work planned); key issues emerging from Internal Audit work;
 - c) management response to audit recommendations;
 - d) changes to the Internal Audit Plan;
 - e) details of any resourcing issues affecting the delivery of Internal Audit objectives. Requests for work and reports received will be channelled through the Accounting Officer, to whom Internal Audit reports;
 - f) a progress report from the External Audit representative summarising work done and emerging findings; and
 - g) progress reports from the Executive, including periodic in-depth reports on areas of potential uncontrolled risk as identified by the ARAC.
7. As and when appropriate the ARAC will also be provided with:
 - a) the Internal Audit Plan;
 - b) Internal Audit's annual opinion and report;
 - c) External Audit's annual report and opinion
 - d) the draft accounts of the organisation;
 - e) the draft Annual Governance Statement;
 - f) a report on any changes to accounting policies;
 - g) a report on any proposals to tender for audit functions;
 - h) a report on co-operation between Internal and External Audit; and
 - i) a report on any fraud or financial misdemeanour and any whistleblowing.

Reporting to the Authority

8. The Authority will receive the minutes of meetings of the ARAC for information. The circulation of any confidential minutes will be at the discretion of the Committee Chair.
9. The ARAC will formally report back (either verbally or in writing) to the Authority after each of its meetings.
10. The ARAC will provide the Authority with an Annual Report, timed to support the finalisation of the accounts and the Annual Governance Statement. The report will summarise the conclusions from the work it has undertaken during the year.

Reviewing effectiveness

11. The ARAC will undertake annual reviews of its own effectiveness and agree actions for improvement based on the National Audit Office's [self-assessment checklist for Audit Committees](#). The ARAC will report the results of the review to the Authority.

Recruitment and membership

12. The ARAC will be chaired by a lay Authority Member, who is not the Authority Chair, and who preferably has relevant experience and expertise.
13. All other members of the Committee should be Authority Members, but not Authority Chair. Including the ARAC Chair, there will be a minimum of three Authority Members and a maximum of five Authority Members on the Committee at any time.
14. At least one Authority Member, who is not the ARAC Chair, must be a member of both the ARAC and the Remuneration Committee, to provide assurance over remuneration matters.
15. Recruitment of Authority Members to the ARAC will be through 'expressions of interest' with personal statements in application. The applications will be reviewed by the Authority Chair and the Chief Executive, who will decide on the appointments. Should an insufficient number of expressions of interest be received to fill an available role, the Authority Chair will appoint the Member who has the most appropriate skills and experience to the role.
16. The ARAC Chair and the other ARAC members will be appointed for a set term of three years, which will not exceed their tenure as Authority Members. It should be noted that Authority Members may be reappointed to the ARAC in accordance with the HTA's business needs.
17. Members of the ARAC must disclose the existence and nature of any personal or material interest before the discussion of that interest at any meeting. They must be free of any relationship that may compromise their independence or interfere with the exercise of their judgement.

Attendance

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

20. Authority Members who are not members of the ARAC have the right of attendance at Committee meetings. Authority Members attending meetings shall be entitled to speak with the permission of the Chair of the meeting, but in no case shall they be entitled to vote.
21. If the ARAC Chair is not present at a meeting, an alternative Authority member will be co-opted to chair that meeting.
22. The Chair of the Authority may attend Committee meetings, say once per year and not so frequently as to compromise the independence of the Committee. An Authority Member who is not a member of the ARAC may be co-opted as a member of the ARAC for a specific meeting if necessary to ensure a meeting is quorate.
23. The Chief Executive in his or her role as Accounting Officer (as defined in the Framework Agreement), the Director of Resources, and any other officer (at the discretion of the Chair) and Internal and External Audit (or equivalents) will also attend meetings of the Committee.
24. Up to two observers from the Department of Health will normally be invited to attend meetings of the Committee.
25. The ARAC may ask any other officials of the Authority to attend to assist it with its discussions on any particular matter.
26. The ARAC may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters by the Committee.

Frequency of meetings

27. The ARAC will meet three times per calendar year, with meetings timed to ensure effective and timely conduct of business and reporting to the Authority.
28. The Chair of the ARAC may convene additional meetings, as they deem necessary.
29. External Audit may request a meeting of the Committee if they consider one necessary.
30. The Accounting Officer or the Authority may ask the ARAC to convene further meetings to discuss particular issues on which the Committee's advice is sought.

Secretariat responsibilities

31. The Board Secretary will have secretariat responsibility for the Committee.

32. The Secretary must ensure Committee meeting dates are scheduled, meeting venues are booked and that Committee members are invited to attend all meetings.
33. The Secretary will liaise with the Committee Chair to create the agenda and will be responsible for collating and distributing the papers relating to the meeting. The agenda, minutes from the last meeting and the meeting papers for consideration will be distributed to the Committee one week before each meeting.
34. The Secretary will be responsible for taking minutes of meetings and recording action points. The draft minutes and action points from each meeting will be circulated as soon as possible, within one month of the meeting. Committee members will be asked to provide any comments on accuracy of the minutes by email within a time frame set by the ARAC Chair. This will ensure the key areas of discussion and action points are captured accurately.
35. The minutes will be approved by the ARAC Chair prior to being published on the HTA website. The Secretary will be responsible for ensuring that minutes are published on the website no later than two months after each meeting.
36. The Secretary will write a short summary of the issues discussed at each meeting for publication in the next staff newsletter and e-newsletter. This note will be drafted within one week of each meeting and approved by the Committee's Chair prior to being sent to the Head of Communications for publication.

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

Section 3

Audit & Risk Assurance Committee yearly work programme

Introduction

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

Audit & Risk Assurance Committee work programme

1. Winter meeting	
Regular items <ul style="list-style-type: none">• Assurance reports from Internal Audit• Audit recommendations tracker report• Strategic risk register review• Policies/procedures updates	Meeting specific <ul style="list-style-type: none">• Review and approval of the Internal Audit proposed Audit plan for the financial year• Review of the Audit & Risk Assurance Committee's performance including Members' skills and training• Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting)
2. Spring meeting	
Regular items <ul style="list-style-type: none">• Assurance reports from Internal Audit• Audit recommendations tracker report• Strategic risk register review• Policies/procedures updates	Meeting specific <ul style="list-style-type: none">• Receive Internal Audit Annual Report• 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)
3. Autumn meeting	
Regular items <ul style="list-style-type: none">• Assurance reports from Internal Audit• Audit recommendations tracker report• Strategic risk register review• Policies/procedures updates	Meeting specific <ul style="list-style-type: none">• Approval of External audit's planning report• Review of the Audit & Risk Assurance Committee's Governance including Handbook and Terms of Reference

Section 4

Role of internal audit

The role of internal audit at the Human Tissue Authority

- 1) The management of HTA is responsible for establishing and maintaining an appropriate system of internal control and for the prevention and detection of irregularities and fraud.
- 2) In fulfilling this responsibility, estimates and judgements by management are required to assess the expected benefits and related costs of control procedures.
- 3) The objectives of systems of internal control are to provide management with reasonable, but not absolute, assurance that the business is conducted in an orderly and efficient manner, that there is adherence to management policies and laws and regulation, that assets are safeguarded against loss or unauthorised use and that transactions are executed in accordance with management's authorisation and are accurately and completely recorded to permit, inter alia, the preparation of financial statements.
- 4) Internal audit is an element of the internal control framework established by management to examine, evaluate and report on accounting and other controls on operations. Internal audit assists management in the effective discharge of its responsibilities and functions by examining and evaluating controls. The objectives of internal audit include promoting effective control at reasonable cost and assisting management generally in the pursuit of value for money.
- 5) Internal Audit is an appraisal or monitoring activity established by management and directors to review and report on the adequacy and effectiveness of the system of internal control. This includes both financial and operational control and will encompass Risk Management, Governance, Accounting, Information Technology, Human Resources and Value for Money issues (VFM).
- 6) Effective internal audit requires the function to be a service to management at all levels, which identifies, evaluates and provides an opinion on the adequacy of the organisation's internal control framework with reference to achieving the organisation's objectives.

- 7) Internal Audit is a key part of the HTA's internal control system because it measures and evaluates the adequacy and effectiveness of other controls so that:
- a) the Authority and senior management can know the extent to which they can rely on the whole system; and
 - b) individual managers can know how reliable the systems are and controls for which they are responsible and any remedial action required.

Approach to internal audit

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

Statement of assurance

- 9) In order to provide the required statement of assurance, the Internal audit service will undertake a programme of work, based on risk assessment, authorised by the Authority, to achieve the following objectives:
- a) to review and appraise the soundness, adequacy and application of the whole system of control;
 - b) to ascertain the extent to which the whole system of internal control ensures compliance with established policies and procedures;
 - c) to ascertain the extent to which the assets and interests entrusted to, or funded by, the Authority are properly controlled and safeguarded from losses of all kinds;
 - d) to ascertain that management information is reliable as a basis for the production of financial and other returns;
 - e) to ascertain the integrity and reliability of information provided to management including that which is used in decision-making; and
 - f) to ascertain that systems of control are laid down and operate to achieve the most economic, efficient and effective use of resources.
- 10) In providing the annual assurance opinion, it should be noted that assurance can never be absolute. The most that the internal audit service can provide to the Accounting Officer and Audit & Risk Assurance Committee is a reasonable assurance that there are no major weaknesses in risk management, governance and control processes based on work undertaken during the year.

Reporting lines

- 11) Internal Audit is under the independent control and direction of the Audit & Risk Assurance Committee on behalf of the Authority. It is the responsibility of the Audit & Risk Assurance Committee to oversee the appointment and cost of internal audit provision, which is managed centrally by the DHSC.
- 12) The Audit & Risk Assurance Committee each year approves a rolling programme of audit work, which will be prioritised in line with an assessment of the Authority's key risks. The Director of Resources monitors progress against this programme in liaison with the Internal Auditors and they report regularly to the Audit & Risk Assurance Committee on this.
- 13) In respect of each internal audit assignment, the Internal Auditors present their findings to the Director of Resources who will, with the appropriate Director and/or Head of Service, co-ordinate a response. The Internal auditors then present their report and recommendations, together with management's response, to the next available meeting of the Audit & Risk Assurance Committee.
- 14) Management responses to internal audit findings identify responsibility for implementing recommendations and the line Director ensures that this is done within the agreed timescale. The Director of Resources reports to each meeting of the Audit & Risk Assurance Committee on progress with implementing recommendations.
- 15) Internal Audit submits an annual report to the Audit & Risk Assurance Committee that includes an overall assessment of Risk Management, Corporate Governance and the Control Environment for the year in question and a comparison of actual and planned activity for the period.

Rights of internal auditors

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

17) Staff and Authority members will co-operate openly and honestly with reviews conducted by Internal Audit.

Section 5

Role of external audit

Introduction

- a) The External Auditor for the HTA is a statutory appointment. The Comptroller and Auditor General (C&AG) is the auditor for the Human Tissue Authority under Section 16 of Schedule 2 of the Human Tissue Act 2004.
- b) The C&AG is an officer of the House of Commons appointed by the Queen to report to Parliament on the spending of central government money. The C&AG is therefore independent of Government.
- c) The C&AG is granted comprehensive audit and inspection rights and has appointed the staff of the National Audit Office (NAO) to act on his behalf.
- d) The NAO conducts financial audits of all government departments and agencies and many other public bodies, and reports to Parliament on the value for money achieved by these bodies. Its relations with Parliament are central to our work, and we work closely with other public audit bodies that have a role in other areas of public expenditure. The NAO has three main work streams – Financial Audit, VFM audits and Investigations.

Financial audit

- e) The NAO is responsible for auditing the accounts of all Government departments and agencies, and most 'arms length' public bodies including HTA known as Non-Departmental Public Bodies. The NAO is also responsible for auditing all National Loans Fund accounts and has several International clients.
- f) The C&AG is required to *form an opinion* on the accounts, as to whether they are free from material misstatement. The C&AG is also required to confirm that the transactions in the accounts have appropriate Parliamentary authority. If the NAO identifies material misstatements, the C&AG will issue a qualified audit opinion. Where there are no material misstatements or irregularities in the accounts, the C&AG may nonetheless prepare a report to Parliament on other significant matters. Such reports may be considered by the Committee of Public Accounts.

NAO timetable

- g) Each year, the NAO is committed to presenting the following to the HTA:
- h) Audit Planning Report (for the November Audit & Risk Assurance Committee) – This document outlines the risks identified during audit planning and the audit approach taken to address those risks
- i) ISA 260 report (Management Letter), for June Audit & Risk Assurance Committee - This letter contains: unexpected modifications to the C&AG's certificate and report; unadjusted misstatements (other than those deemed to be trivial); material adjusted misstatements; material weaknesses in accounting and internal control systems identified; and NAO's views about the qualitative aspects of the Authority's accounting practices and financial reporting.

Section 6

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

- a) The Chief Executive of the HTA is the Accounting Officer and is responsible for ensuring that the HTA operates:
 - a) sufficient and robust internal controls
 - b) comprehensive financial reporting systems
 - c) adequate systems for the identification and mitigation of risk
 - d) adequate governance arrangements
- b) The Accounting Officer will discharge these duties through the Director of Resources who will ensure that an adequate framework is in place so that suitable assurance and reliance can be derived. This is obtained through key documents submitted to the Committee such as financial / governance papers (e.g. accounts, policies), risk strategies / policies (e.g. risk register) and audit strategies / papers (e.g. audit plans, findings, reports), illustrated in the diagram in section 1.
- c) The Accounting Officer will undertake the following activities:

Internal audit

- a) Make recommendations to the Audit & Risk Assurance Committee to appoint the HTA's internal auditors.
- b) Review their audit plan and agree with internal audit the plan to be presented for consideration by the Audit & Risk Assurance Committee.
- c) Review the content / scope of each audit that makes up the yearly audit programme and includes an overall assessment of Risk Management, Corporate Governance and the Control Environment for the year in question and a comparison of actual and planned activity for the period. The annual audit programme will cover three areas: financial, governance and operational. These will be risk-based in nature.
- d) Review and agree the audit findings prior to submission to the Audit & Risk Assurance Committee. If audit findings are not agreed with the Accounting Officer, internal audit have a right to report independently to the Committee.
- e) Agree a response to audit findings with time frames for any actions necessary.
- f) Present regular reports (audit tracker) to the Audit & Risk Assurance Committee.

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

External audit

- a) Review external audit planning report and agree with the external auditors the plan to be presented for consideration by the Audit & Risk Assurance Committee.
- b) Review the content / scope of each audit that makes up the yearly audit programme. These will be risk-based and may include national initiatives.
- c) Review and agree the audit findings prior to submission to the Audit & Risk Assurance Committee. If audit findings are not agreed with the Accounting Officer, external audit has a right to report independently to the Committee.
- d) Agree a response to audit findings with time frames for any actions necessary.
- e) Present regular reports (audit tracker) to the Audit & Risk Assurance Committee.

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

C. Risk register

- a) Produce risk strategy for review by Audit & Risk Assurance Committee.
- b) Produce strategic risk register for review of Audit & Risk Assurance Committee.

D. Governance

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

Version history

Latest version	Date	Comments	Reviewed by	Approved by
15.0	24 February 2015	Updated to ensure factual accuracy, update membership information and add version control.	Sue Gallone / Amy Gelsthorpe-Hill	Authority Members
15.1	18 October 2016	Amendment to secretariat and updated forward plan as per May 2016 minutes	Sue Gallone / Morounke Akingbola	??
15.2	2 November 2017	Updated per November 2016 minutes	Morounke Akingbola	ARAC Members 09-11-2017
15.3	18 September 2018	Amend role to Board Secretary	Morounke Akingbola	ARAC Members 23-10-2018
15.4	6 September 2019	Plan of work amended to account for changes in meeting dates.	Morounke Akingbola	ARAC Members 22-10-2019