

Audit and Risk Assurance Committee Agenda

Date 12 June 2019
Time 10:30 – 15:00
Venue Rovos Suite, The Grosvenor Hotel, 101 Buckingham Palace Road,
Victoria, SW1W 0SJ

Private Members Session:

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

Meeting:

Main ARAC meeting (10:30 – 13:30)

Lunch:

Lunch (13:30 – 14:00)

ARAC Afternoon Session:

Training session – Risk Management and Recording for Audit Committees
(14:00 – 15:00)

Agenda

1.	Welcome and apologies	
2.	Declarations of interest	Oral
3.	Minutes of 12 February 2019	(AUD 01/19)
4.	Matters arising from 12 February 2019 and forward plan	(AUD 02/19)
5.	ARAC Chair's Update	Oral
	Internal Audit	
6.	Internal Audit update (Confidential)	(AUD 03/19)
	• Records Management	Annex A
	• Key Regulatory Processes	Annex B
	• GDPR Compliance	Annex C
	• Annual Assurance Report 2018/19	Annex D
	Audit Tracking	
7.	Audit Tracker Update	(AUD 04/19)

	Cyber Security	
8.	Information Risk Management - SIRO Report	(AUD 05/19)
	<ul style="list-style-type: none"> Records Management Policy 	Annex A
	<ul style="list-style-type: none"> Assessment of the HTAs compliance with the Security Policy Framework (2014) 	Annex B
9.	Cyber security	Oral
10.	Report from Data Protection Officer	(AUD 06/19)
	Annual Report and Accounts	
11.	Approval of the Annual Report and Accounts 2018/19	(AUD 07/19)
	<ul style="list-style-type: none"> 2018/19 Annual Report and Accounts 	Annex A
	<ul style="list-style-type: none"> External Auditor's opinion 	Annex B
	<ul style="list-style-type: none"> Letter of representation 	Annex C
	Risk Update	
12.	Risk Update	(AUD 08/19)
	<ul style="list-style-type: none"> HTA Strategic Risk Register 	Annex A
	<ul style="list-style-type: none"> HTA Operational Risk Register – Annual review 	Annex B
	<ul style="list-style-type: none"> UK exit from the European Union 	Oral
	Exploration of risk area:	
13.	DI Engagement	(AUD 09/19)
	Policy / Procedures updates	
14.	HTA Gifts and Hospitality Policy	(AUD 10/19)
	<ul style="list-style-type: none"> HTA-POL-051 HTA Gifts and Hospitality Policy 	Annex A
	Regular reporting and updates	
15.	Reports on grievances, disputes, fraud and other information	Oral
16.	Topics for future risk discussions	Discussion
17.	Topics for future ARAC training	Discussion
	Any other business	

Meeting close

Minutes of Audit and Risk Assurance Committee

Date 12 February 2019

Venue Boardrooms 1 / 2, 2nd floor, 151 Buckingham Palace Road

Protective Marking OFFICIAL

Present	
Members Amanda Gibbon (Chair) Glenn Houston Prof. Andrew (Andy) Hall Dr. Stuart Dollow William (Bill) Horne	In attendance Allan Marriott-Smith (Chief Executive) Richard Sydee (Director of Resources) Hazel Lofty (Director of Regulatory Development) Nicolette Harrison (Director of Regulatory Delivery) (by Skype) Morounke Akingbola (Head of Finance and Governance) Dr. Robert Watson (Item 11) David Thomson (Item 10) Nima Sharma (Board Secretary)
Apologies None	External Attendees Jeremy Nolan (Government Internal Audit Agency) Tony Stanley (Government Internal Audit Agency) Jill Hearne (National Audit Office) Sarah Edwards (National Audit Office)

Item 1	Welcome and apologies
	<ol style="list-style-type: none"> 1. Amanda Gibbon (the Chair) confirmed that Nicola Blackwood, Chair of the Authority, had left her post and Bill Horne had been appointed as Acting Chair until a permanent appointment is made. 2. The Chair asked the committee to confirm attendance for the June meeting as soon as possible.
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 23 October 2018 (AUD 27/18)
	<ol style="list-style-type: none"> 4. The minutes of the meeting of 23 October 2018 were agreed as an accurate record of that meeting.
Item 4	Matters arising from minutes of 23 October and forward plan (AUD 28/18)
	<ol style="list-style-type: none"> 5. The Chair noted that the actions arising from the meeting on 23 October 2018 were resolved, are noted on the forward plan or would be addressed within the relevant agenda items of the meeting. 6. Dr Hazel Loftly confirmed that the risks identified via the HA risk project were reflected in the operational risk register. 7. Dr Hazel Loftly updated Members on progress with providing improved access to email accounts and secure document storage locations. Members queried whether additional notifications were possible.

8. Richard Sydee confirmed that the actions relating to the Cyber security audit remain open and would be discussed in more detail later in the meeting with David Thomson.
9. Nicky Harrison provided the Committee with an update on the safety KPI work being undertaken. She confirmed that Rachel MacLehose, Head of Planning and Performance, is leading on this and would be looking at routinely producing data of a similar nature to that contained in the safety KPI report. Nicky Harrison reported that there were a number of challenges in extracting the data and the aim was to streamline the approach. Professor Andy Hall enquired whether this data will prove to be useful in the digital transformation project. Nicky Harrison confirmed that there is still work to be carried out to improve the way in which data is obtained and analysed.
10. The Critical Incident Response Plan had been updated following comments from ARAC members and circulated since the last meeting.
11. The Committee were notified that the closure of Corrective and Preventative Action Plans had been discussed at the Authority Meeting in February 2019.
12. The Committee were informed that the Risk assurance map will be discussed with Jeremy Nolan at the training following the next ARAC meeting. The Risk assurance map has not been updated. The Chair suggested that the assurance map should be revisited to decide whether it remains a useful way in which to capture risks.
13. The Committee were informed that mandatory training for Regulation Managers is under way.
14. The Chair requested an update on a number of issues arising from the previous meeting:
 - Recruitment - Rachel MacLehose, Head of performance and Planning, has taken up post since the last ARAC meeting.
 - 2018/19 Grant in Aid (GIA) – Richard Sydee informed the Committee that Ring Fenced Resource DEL cover for HTA's depreciation and amortisation costs has been approved and received .
 - HR Software Migration – Allan Marriott-Smith informed the Committee that Diane Galbraith plans to evaluate other HR

	<p>systems. The Committee were informed that it is unlikely that the HR migration would take place as originally scheduled as the most appropriate product still needs to be identified and procured. The security implications of any solution would also need to be addressed.</p> <ul style="list-style-type: none"> - A business case has been submitted to DHSC to apply for HTA reserves to be released to fund the transformation programme. Richard Sydee confirmed that the case had been submitted and that he hopes to have a decision in the next few weeks. - CRM upgrade- Dr Hazel Lofty informed the Committee that Martin Cranefield is currently working on the upgrade of CRM. <p>Action 1: Dr Hazel lofty to further pursue email notifications for Authority members with IT colleagues.</p>
Item 5	ARAC Chair's Update (Oral)
	<p>15. The Chair provided an oral update about the 'Brexit Preparedness and NHS Improvement' conference for DHSC ALB audit committee chairs which she had attended since the last ARAC meeting.</p> <p>16. The Chair informed the Committee that she had held her routine meeting with Clare Wend-Hansen, Freedom to speak up Champion.</p>
Item 6	NAO update (Oral)
	<p>17. Jill Hearne provided an update to the Committee following the HTA's interim audit. She thanked the finance team for providing information on time. Jill Hearne informed the Committee that there are no issues to report and that the audit is progressing well.</p> <p>18. Jill Hearne highlighted to the Committee that the NAO have changed their approach to audits following an internal audit efficiency review. Jill Hearne confirmed that the NAO's new approach for the HTA would rely on substantive testing and would involve additional sampling of transactions. The NAO believe that this change will deliver the most efficient and effective approach to the audit of an organisation of HTA's size. The Committee were content with this new approach.</p>

	<p>19. The Chair requested that the draft Annual Governance Statement be circulated to ARAC members in advance of the next ARAC meeting in order to provide NAO with comments and feedback as early as possible.</p> <p>Action 2: Richard Sydee to provide Annual Governance Statement to ARAC members ahead of the next ARAC meeting.</p>
Item 7	Internal Audit Update (AUD 29/18)
	<p>20. The Committee were provided with an update on progress against the 2018/19 Internal Audit Plan.</p> <p>21. Since the last ARAC meeting further progress against the recommendations contained within the cyber security review has been made. Six recommendations were made, of which one is still outstanding and this should be implemented in March 2019</p> <p>22. The Committee were informed that the Records Management report was still in draft form. Once it had been finalised and management's response had been agreed it would be circulated to ARAC members who could then decide whether a teleconference was needed to discuss it.</p> <p>23. The Committee noted that the GDPR Audit will be undertaken in late February. The Committee were informed that SMT has prepared for the audit, however, a few areas (including historic HR records) remain where further work is needed to achieve full compliance.</p> <p>24. The Committee were informed that staff were notified by email to ensure that HR data such as curricula vitae are not stored within email accounts.</p> <p>25. Professor Andy Hall enquired whether GDPR could be included in the induction programme for Authority Members. The Committee were informed that GDPR has now been included in new staff and Authority members' induction programmes.</p> <p>26. Dan Howard, the HTA's Data Protection Officer, provided an introduction to his role working across the HTA and HFEA. He emphasised that the role is in its infancy and there is scope to develop it further in future. The Committee noted Dan Howard's independence from the HTA as he is employed by the HFEA.</p>

Dan Howard confirmed that he would provide a report to the June ARAC meeting.

27. The Committee noted that recommendation 4 of the Cyber Security audit remains outstanding. Allan Marriott-Smith confirmed that this was a process issue managed by David Thomson. David Thomson informed the Committee that notification of changes to employment circumstances is a manual process at present. The Committee were informed that this issue should be resolved once a new HR system is in place.
28. Glenn Houston asked whether email addresses are routinely removed from the HTA's IT systems once a staff member leaves. David Thomson confirmed that email addresses are not deleted in order to prevent the HTA losing vital information contained within the email accounts.
29. Jeremy Nolan presented the GIAA's approach to audit planning for 2019/20. He had discussed his review of the key risks and issues with the SMT and they had agreed the areas for audit review for 2019/20.
30. Dr Stuart Dollow asked for some feedback on the Business Continuity plan in relation to preparedness for remote working. Dr Hazel Lofty confirmed that she would include the Business Continuity Plan as part of a wider piece of work regarding remote working.
31. Glenn Houston referred the Committee to page 4, risks 1 and 3 (key regulatory processes and stakeholder management). He suggested to the Committee that as these risks have already been covered by recent audits they need not be looked at again as part of the 2019/20 audit plan.
32. The Chair informed the Committee that the HTA has not reviewed the risks in the Post Mortem sector and it was agreed that this subject could be reviewed during a deep dive later in the year.
33. Members agreed that the audit plan for 2019/20 provided an appropriate level of assurance on key risks and priorities.

Action 3: Dan Howard to provide a report at the next ARAC meeting.

Item 8	Audit Tracker Update (AUD 30/18)
	<p>34. Morounke Akingbola presented an update to the Committee on progress made in respect of audit actions. Members were happy with the update and proposed actions.</p> <p>35. The Committee agreed that Financial controls can now be removed from the audit tracker as the actions were complete.</p> <p>36. David Thomson provided an update about Cyber security in the audit tracker. He informed the Committee that he expects the contract with BCC to be finalised by the end of February 2019.</p>
Item 9	Risk Update (31/18)
	<p>37. Richard Sydee presented an update on the strategic risks and mitigations set out within the latest iteration of the HTA Strategic Risk Register (SRR). The Committee were informed that the transformation project has now been identified as a new risk and is in addition to the five existing strategic risks which remain on the SRR.</p> <p>38. Richard Sydee confirmed that the risks associated with a change in the HTA Chair were not identified in this iteration of the register which had been agreed by SMT prior to the departure of the Chair. The February SRR will be updated to reflect this change.</p> <p>39. Richard Sydee asked for feedback from the committee about the formulation of the new risk. The Chair noted her concerns about the lack of appropriate non-executive oversight for the transformation project and highlighted the importance of recruiting an Authority Member with expertise in this area. The Chair also asked that risk six should reflect budgetary risks in taking the work forward.</p> <p>40. Richard Sydee confirmed that the HTA's lease runs out in 2021. The Committee noted that milestones relating to the project are not clearly set out at present and asked that these should be presented to the committee.</p> <p>41. Dr Stuart Dollow commented that the Committee requires further assurances in terms of the risks and resource requirements of the transformation project plan.</p>

	<p>42. Professor Andy Hall questioned whether further oversight of the project could be provided through an external advisor. The Committee agreed that an external advisor could potentially be a beneficial resource. Bill Horne suggested that it might be possible to ask for assistance from a Business School to recruit to this role.</p> <p>43. Allan Marriott-Smith suggested that it may be difficult to identify an appropriate individual to provide expert advice and that the next steps in the project will be to discuss the programme's design with the Authority. The Committee agreed that the Executive needs to work collaboratively with Members to identify someone with expertise in the digital aspects. The Committee discussed whether some funds could be spent to obtain a Programme Manager whose role is to provide support to the project.</p> <p>44. Richard Sydee informed the Committee that the HTA expects to receive a decision about whether funding will be granted. He confirmed that the detailed strategy would set out the issues facing the HTA and how the project would resolve them. The Committee agreed that the business case for the funding should clearly present the need for the transformation project.</p> <p>Action 4: Richard Sydee to add further information to risk six.</p>
Item 10	Cyber Security and IT Resourcing (Oral)
	<p>45. Allan Marriott-Smith provided an update on the current IT structure. He informed the Committee that Martin Cranefield is now supporting the HTA on a part time basis to enable David Thomson to focus on the strategic objectives and identify immediate risks.</p>
Item 11	Third Party Agreements (AUD 32/18)
	<p>46. Dr Robert Watson attended the meeting to present his paper.</p> <p>47. Dr Robert Watson confirmed that although the HTA has good oversight of third party agreements, he believes that it could be improved. He informed the Committee that during inspections there is a careful review of Third Party Agreements and this has now been prioritised as part of the inspection process.</p>

	<p>48. Dr Robert Watson emphasised the need for a risk based approach during inspections and informed the Committee that the HTA will need to ensure that areas which carry the most risk are inspected thoroughly.</p> <p>49. The Committee sought clarification with regards to paragraph 21 of the paper and asked how the HTA will assure itself that the Third Party establishment in question has addressed the identified shortfalls. Dr Robert Watson informed the Committee that the Third Party establishment has a responsibility under its agreement with the licensed establishment to address any shortfalls and he assured the Committee that the licensed establishment had been proactive to ensure that they were addressed</p> <p>50. Dr Robert Watson also informed the Committee that the HA risk project remains open and advised that this should remain on the Committee's agenda. The Chair confirmed that this should be added to the forward plan to be discussed in October 2019.</p> <p>Action 5: The HA risk project to be added to the forward plan to be discussed in October 2019.</p>
Item 12	Exploration of Risk area- Assurance associated with preparedness for the transformation programme (AUD 33/18)
	<p>51. The Committee had received a paper with responses to the question that ARAC members had posed in advance of the meeting and discussed the HTA's preparedness for the proposed digital transformation programme.</p> <p>52. The Committee asked about expenditure in relation to the Transformation Programme and emphasised the need for the Executive team to be clear about deliverables and process mapping before going out to tender.</p> <p>53. Allan Marriott-Smith informed the Committee that programme management advice would be sought once funds are confirmed. The Committee agreed that pre-tendering advice would be helpful.</p> <p>54. The Chair questioned how the HTA intends to manage the re-location to Stratford alongside managing the transformation programme. Allan Marriott-Smith and David Thomson informed ARAC members that at present it is not clear how this will be managed, and further that the resources required for the relocation project are yet to be defined.</p>

	<p>55. Dr Hazel Loftly emphasised that the HTA's systems handle complex information which includes several tissue types and as a result make the project quite complex.</p> <p>56. The Committee raised queries about migrating to the cloud. Dan Howard informed the Committee that he has experience of migrating to the cloud at the HFEA. He confirmed that at the HFEA testing has been undertaken successfully. Richard Sydee added that it is important for the HTA to consider the logistics of migrating to the cloud as this will reduce the need for physical space in the new premises.</p> <p>57. Allan Marriott-Smith informed Members that at present there is no clear process map in place of how the objectives of the digital transformation programme will be addressed. However, he agreed with the Committee's recommendation that a dedicated member of staff be recruited whose role would be to provide support to the programme. The Committee agreed that it would be beneficial to discuss progress made during May's Authority meeting</p> <p>Action 6: To discuss the progress made with the Transformation programme at the next Authority meeting.</p>
Item 13	Policy and Procedure Update (AUD 34/18)
	<p>58. Morounke Akingbola provided a summary to the Committee of policies that have been updated. She referred the Committee to the following documents:</p> <ul style="list-style-type: none"> - Annex A: Summary of changes to policies and procedures - Annex B: Anti-Fraud policy - Annex C: Whistleblowing policy <p>59. The Chair asked for comments from the Committee about these updates. Bill Horne confirmed that he will liaise with Morounke directly about comments in relation to the Anti-Fraud Policy. The Committee provided comments on the structure and layout of the Anti-Fraud Policy which were noted by Morounke Akingbola.</p> <p>60. The Committee recommended that paragraphs 4, and 5 of the Whistleblowing Policy should be removed. The Executive team confirmed that they would need to check with Diane Galbraith before deleting them. The Committee also recommended that paragraph 22 should be reviewed.</p>

	Action 7: Morounke Akingbola to make changes to the Whistleblowing Policy following the Committee's comments.
Item 14	Review of the Audit and Risk Assurance Committee's performance including Members' skills and training (Oral)
	61. It was agreed that the review would be undertaken by ARAC members by email following the afternoon's training session in order that any recommendations arising from that session could be incorporated.
Item 15	Review of Gifts and Hospitality Register (AUD 35/18)
	62. Morounke Akingbola presented the Gifts and Hospitality Register for the Committee's review. No comments or changes were made.
Item 16	Reports on grievances, disputes, complaints, fraud and other information (Oral)
	63. The Committee were notified of an ongoing complaint which has not been resolved. It was agreed that this would be brought to the June meeting to be discussed. Action 8: To discuss this complaint during the June ARAC meeting.
Item 17	Topics for future risk discussions (Discussion)
	64. The Committee discussed topics for future risk discussions and agreed to review DI training as a deep dive during the June meeting. 65. The Committee also agreed that it would be useful to review risk reporting in the PM sector and agreed that this area could be considered as a deep dive for the October meeting.
Item 18	Topics for future ARAC training (Discussion)
	66. Jeremy Nolan agreed to facilitate a training session following the June ARAC meeting at which methods of risk reporting would be discussed. It was agreed that this session would take the form

	of a workshop and it would look in particular at the adequacy of the current Strategic Risk Register as a way of recording risk.
Item 19	Any Other Business
	67. The Chair invited those present at the meeting to identify any other business that they would like to discuss. No other items of business were identified.

The next meeting will take place on Wednesday 12th June 2019.

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HTA Audit and Risk Assurance Committee

Matters arising and forward plan

Wednesday 12 June 2019

HTA Audit and Risk Committee Matters arising

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
44	2 November 2017	Action 7: The HTA SMT to ensure that the findings arising from the project undertaken to address Risks in the Human Application sector are reflected within the HTA risk registers.	Director of Regulation	February 2018	Members to receive an update under the matters arising and risk update agenda items at the ARAC Meeting on 1 February 2018. This item to remain open pending further discussion within the HTAMG on the most appropriate method of recording these risks. Ongoing	Live
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	Live
93	23 October 2018	Action 10: ANH to consider the feasibility of including some of the data from the safety KPI work into the Delivery Report	Director of Regulatory Delivery	February 2019	The members of ARAC will receive an update on this item under the matters arising item of the agenda for the 12 February 2019 ARAC meeting. Ongoing	Live
94	23 October 2018	Action 11: The Executive to consider adding a review of critical shortfalls as an agenda item at a future Authority meeting.	Director of Regulatory Delivery	February 2019	The members of ARAC will receive an update on this item under the matters arising item of the agenda for the 12 February 2019 ARAC meeting. This will be incorporated into the new structure for the Delivery Report. Ongoing.	Live
100	12 February 2019	Action 3: Dan Howard to provide a report at the next ARAC meeting.	Data Protection Officer	June 2019	Dan Howard to present a paper during item 10 at the June 2019 meeting	Live
106	12 February 2019	Action 8: To discuss this complaint during the June ARAC meeting.	Chief Executive	June 2019	This complaint will be discussed during item 15 at the June 2019 meeting	Live

Risk exploration topics

Topic	Meeting	Progress
Risks posed by sectors and the HTA's approach to protect public confidence • The HTA Inspection Rationale	February 2017	On the agenda for the February 2017 meeting. Complete.
Risks posed by sectors and the HTA's approach to protect public confidence Breadth of activity, regulatory approach and risk assessments for various aspects of the Human Application Sector – Follow-up from Authority seminar in February 2017.	May 2017	This item has been scheduled to occur as a follow up to the authority member seminar scheduled for the morning of the February Authority Meeting. Complete.
HTA interaction with DIs/DI Training and Recruitment	November 2017	Due to competing work priorities within the Regulation Directorate, The Chair of ARAC has agreed replace this topic with an item looking at the recommendations arising 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,	TBC	
Risks posed by sectors and the HTA's approach to protect public confidence.	TBC	
Post Mortem sector (due at Authority Meeting 04 May 2017)	TBC	

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.
	October 2019	TBC	
	February 2020	TBC	
	June 2020	TBC	

Forward plan

Forward Plan

Standing items	Assurance reports from Internal Audit Audit recommendations tracker report Risk update includes strategic risk register review and update on UK exit from the EU . Policies/procedures updates Cyber security (as requested by the ARAC on 19 June 2018)	
Meeting		
February 2019	Review and approval of the Internal Audit proposed Audit plan for the financial year 2019/20 Review of the Audit & Risk Assurance Committee's performance including Members' skills and training Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting) Review gifts and hospitality register Update on the review of the risk management policy and strategy	
June 2019	Approval of the Annual Report and Accounts Review of the External Auditors ISA 260 report (management letter) Consider key messages for the Audit & Risk Assurance Committee's report on its activity and performance (to the Authority) Review and approval of the Internal Audit proposed Audit plan for the financial year Internal Audit Annual statement. (Draft Note: RS to discuss the approach to this with PF, invite Information Risk management - SIRO report Annual review of the Operational Risk Register	To consider a draft update of the HTA Gifts and Hospitality Policy Incorporation of draft proposals to address the Caldicott Review within the annual review
October 2019	Review of HTA Reserves Policy Review of ARAC Handbook Review of Gifts & Hospitality Register Risk in the Human Application Sector	Update on complaints and complaints handling at the HTA Management proposals for the cross-referencing of inspection findings with compliance updates Review of ARAC Handbook 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. At the 19 June 2018 ARAC meeting, The Committee requested a follow-up review of the revised Operational Risk Register at the its meeting on 23 October 2018. 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.
February 2020	Review and approval of the Internal Audit proposed Audit plan for the financial year 2020/21 Review of the Audit & Risk Assurance Committee's performance including Members' skills and training. Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting) Review gifts and hospitality register Update on the review of the risk management policy and strategy Annual review of the Operational Risk Register	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. 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

Internal Audit Update- Confidential

Audit and Risk Assurance Committee paper

Date	12 June 2019	Paper reference	(AUD 04/19)
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. Three audits have been undertaken and completed since the February 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 Cyber Risk recommendations.

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	3	0	0	0
IA - Cyber security	2	0	2	0	0	0	0
COUNT	15	5	0	8	2	0	0

IA – Internal Audit – PwC/DH

EA – External Audit - NAO

HIGH	6	4	1	1	0
MEDIUM	7	6	0	1	0
LOW	2	0	0	2	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	<u>June 2019</u> SIRO report sets out the changes to the process for gaining assurance in response to GDPR and Records Management Audit. This will fomr the basis for the SOP that will be drafted by the end of June	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	<u>June 2019</u> As above	Richard Sydee COMPLETE
HTA to develop a comprehensive RRD policy and update retention periods on the Privacy notice and PDI accordin	Agreed. Target date – July 2019	<u>June 2019</u> Work is ongoing to finalise the records retention document, it is anticipated this will be complete by July 2019.	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		
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>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><u>June 2019</u> 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>	Nicolette Harrison ON-GOING
The HTA should provide formal training on the Human Tissue Act to ensure that all Regulation Managers are familiar with all relevant legislation.	<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><u>June 2019</u> 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>	Nicolette Harrison ON-GOING

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
<u>Records Management – Risk 1</u>	HTA's records management strategy and policy are not sufficient to ensure compliance with statutory obligations		
The Records Management policy currently in draft should be finalised and signed off by senior management as a matter of urgency. This policy will complement existing policies, with a clear focus on records management requirements, roles and responsibilities and should cover such topics as retention and disposal. This policy should be signed off by the Senior Management Team and the Audit and Risk Assurance Committee. Once agreed, this should be circulated to all HTA staff.	<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><u>June 2019</u></p> <p>Draft has been attached to Annual SIRO assessment</p>	Richard Sydee COMPLETE
<u>Records Management</u>	HTA's records management strategy and policy are not sufficient to ensure compliance with statutory obligations		
The FOI guidance should be reviewed and updated as soon as possible	Completed as part of GDPR work	N/a	COMPLETE

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		
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.	<p>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</p> <p>Target date – May 2019</p>	<p><u>June 2019</u> As per response to recommendation 1.</p>	Richard Sydee COMPLETE
<u>Records Management</u>	HTA's records management strategy and policy are not sufficient to ensure compliance with statutory obligations		
The Senior Responsible Officer (SIRO) should ensure periodic checks are carried out on the Information Asset Register, to ensure IAOs are fulfilling their responsibilities and the register is up to date	<p>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.</p> <p>Target date – May 2019</p>	<p><u>June 2019</u> Review has been undertaken at year end and IAR is now up to date</p>	Richard Sydee COMPLETE

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
<u>Records Management - Risk 3</u>	Risks and Issues are not appropriately identified and mitigated		
The revised records management guidance should include specific references to the use and updating of the Information Asset Register, linking to the roles and responsibilities in the Information Governance Policy, to ensure this is being used and updated on a consistent basis, so that reliance can be placed on the information on there.	<p>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</p> <p>Target date – May 2019</p>	<p><u>June 2019</u></p> <p>Additional objective has been drafted and will be added to the objectives of IAOs and all relevanty staff for the 2019/20 reporting year.</p>	<p>Richard Sydee</p> <p>COMPLETE</p>

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		
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	<u>June 2019</u> This is part of the agenda for the All staff away day in July	Diane Galbraith COMPLETE
A DRO should be appointed/nominated, and the roles and responsibilities of this position incorporated into the job description.	Given the size of the organisation it is not possible to simply add a further responsibility to an existing staff member without fully understanding the resource implications. Director of Regulatory Development and Head of Business Technology to discuss requirement and advise SMT of appropriate response Target date – June 2019	<u>June 2019</u> Definition for DRO and local records managers have been drafted. We would like to discuss the practicalities of implementing this with ARAC	Hazel Loftly 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		
Any individuals with specific Records Management responsibilities should have these responsibilities clearly included in their job descriptions	Agree – although would challenge urgency as links to recommendation 6. Will be completed as part of Recommendation 6, relevant IAO's will be identified and a standing IAO objective added to the PDP of those with IAO responsibilities Target date – June 2019	<u>June 2019</u> Job descriptions to be updated in line with drafted PDP objective	Richard Sydee COMPLETE

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Cyber security	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>	<u>May 2018</u> – Forensic readiness policy has been written into the HTA's contract with BCC. The next stage is to compose a plan to implement the policy. <u>October 2018</u> - Contract has been re-tendered. On award, work will begin on forensic readiness spec. <u>February 2019</u> Contract variation with BCC is to be finalised by the end of February. <u>June 2019</u> Contract variation has been agreed and signed with BCC and includes the Forensic Readiness Policy.	David Thomson COMPLETE

<u>Cyber security</u>	<p>Policy – notification of access permission changes</p> <p>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.</p> <p>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>Target date – January 2018</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</p> <p>Implementation and communication plan to be agreed in February with target launch of new process in March</p> <p>June 2019</p> <p>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 via automated workflows.</p>	<p>Diane Galbraith David Thompson</p> <p>ON-GOING</p>

Audit and Risk Assurance Committee paper

Date	12 June 2019	Paper reference	AUD (05/19)
Agenda item	8	Author	Richard Sydee, Director of Resources
Protective Marking	OFFICIAL		

Information Risk Management- SIRO Report

Purpose of paper

1. To provide an annual update to the Audit and Risk Assurance Committee (ARAC) on the annual assessment of the HTA's information risk management.

Decision-making to date

2. Reviewed by the HTA Senior Management Team (SMT) on 6 June 2019.

Action required

3. To note the SIRO's assessment of the management of information across the HTA including compliance with the Security Policy Framework 2014 as at 31 May 2019.

Background

4. The Senior Information Risk Officer's (SIRO) holds responsibility to manage the strategic information risks that may impinge on our ability to meet corporate objectives, providing oversight and assurance to the Executive and Authority of the HTA. It is a Cabinet Office (CO) requirement that Boards receive regular assurance about information risk management. This provides for good governance in its own right, ensures that the Board is involved in information assurance and informs the ARAC's consideration of the Annual Governance Statement (AGS).

5. This report is my annual report to the Accounting Officer and ARAC to inform the AGS. The SMT have also reviewed this report.
6. Her Majesty's Government (HMG) Security Policy Framework (SPF) has historically provided a suitable format for the HTA's report. ALBs are also asked to assess themselves and report against the 10 Steps to Cyber Security, the guidance issued as part of the Government's Cyber Security strategy. The HTA has made such an assessment and recorded the actions and risks as part of the operational risk register, which is reviewed monthly by the HTA Management Group.

Report

7. The HTA routinely assess the risks to information management across the organisation, through its assessment of the risk of data loss, cyber security and the inclusion of guidance on creating and managing records throughout its Standard Operating Procedures (SOPS).
8. Although the HTA has historically held, and processed, data and records effectively a recent internal audit in to Records Management highlighted a number of weaknesses relating to our documentation of processes and (RM) procedures. The report itself provided only limited assurance on our RM processes, but it must be stated that neither the audit, nor our subsequent activities, have uncovered any failure to appropriately store or retrieve records required for our operational activity.
9. On a more positive note the internal audit of our response to the introduction of GDPR provided "Moderate" assurance, with an overall positive assessment of the process undertaken to achieve compliance. As a result of both audits we have undertaken a number of additional activities to bolster our approach to information risk management. In particular:
 - We have reviewed our Information asset register, ensuring all assets have owners and linking records through to the relevant documentation on the assets purpose and use. This has provided a good level of assurance to me as SIRO that our current IAR is up to date.
 - We have circulated our draft Records Management and Retention Policy with this report (Annex A). This provides an overview of our approach to RM and specifically the roles and responsibilities of staff across the organisation as well as our approach to record retention and deletion.
 - Moving through in to the next business year information asset owners (IAOs) now have a specific objective in the personal development plans to ensure they undertake regular review of their assets to ensure compliance with our policies on retention. They will provide assurance to the SIRO that they have undertaken this

review on an annual basis. IAOs will be provided with guidance and training on their responsibilities as part of the introduction of this process.

10. We have also reviewed our process for assessing our approach to capturing and tolerance of information risk. Given the size of the HTA there is very limited resource to provide continuous oversight of this issue, as such our approach is proportionate and looks to embed the consideration of information risks within the broader assessment of organisational risks.
11. Overall we have a low tolerance of risk for information that falls within the auspices of GDPR and/or is business critical, and the focus of our resource will continue to be the secure and compliant storage of these records. We have attached the additions to the risk policy relating to records management and information governance at Appendix A in this document.
12. As in previous years I have considered the HTAs compliance with the mandatory requirements set out in the SPF, [see Security policy framework - Publications - GOV.UK](#). The requirements were last updated in July 2014 and focus on eight areas (governance, culture, risk management, information, technology, personnel, physical security, responding to incidents) with three types of consideration for each of those (information, physical and people). The requirements have been applied proportionately and matched to the HTA's organisational risks. Not all of the areas apply to the HTA. This is contained at Appendix B in this document.
13. In line with the Office of the Government SIRO handbook I have also considered a number of the factors that underpin the management of the HTA's information risks.
 - I believe the HTA have an effective Information Governance framework in place and that the HTA complies with all relevant regulatory, statutory and organisation information security policies and standards.
 - I am satisfied that the HTA has introduced further processes to ensure staff are aware of the need for information assurance and the risks affecting corporate information.
 - The HTA has appropriate and proportionate security controls in place relating to records and data and that these are regularly assessed.
14. In conclusion I believe the HTA has progressed in its approach to data, information and records management over the past year and is in a stronger position in terms of its governance in this area as a consequence. As SIRO I believe the HTA takes issues relating to information risk seriously and has appropriate processes in place to assess and minimise these risks. We will continue to maintain and improve processes over the coming year and ensure we consider how we can maximise the use of our information as a business asset.

Appendix A – Extract from Risk management policy

Managing Information Risk

The HTA places high importance on minimising information risk and safeguarding the data and records held by the organisation.

Information risk is inherent in all organisational activities and everyone working for, or on behalf of the HTA, has a responsibility to continuously manage information risk. The aim of information risk management is to provide the means to identify, prioritise and manage the risks to records and data involved in all of the organisation's activities.

The HTA will assess information risk in a number of ways, which will include the following:

- Routine review of flows of records and information in our activities, to ensure any risks identified with these flows are mitigated, including ensuring appropriate controls are in place for personal data and any data transferred outside the HTA.
- Use the risk assessment methodology (risk matrix) to assess information risks e.g. threats to information.
- Undertaking Privacy Impact Assessments and System Security Level risk assessments as methods through which information assets can be risk assessed and assured they comply with the required standards.

The organisation's risk management procedures provide clear guidance as to the way in which all risks and incidents are identified, assessed and managed across the organisation, and information risk should be assessed using the same methodology.

Appendix B - Assessment of the HTAs compliance with the Security Policy Framework 2014 (As at 31 May 2019)

	Mandatory Requirement	Compliance	Further actions required
1	Departments and Agencies must establish an appropriate security organisation (suitably staffed and trained) with clear lines of responsibility and accountability at all levels of the organisation. This must include a Board-level lead with authority to influence investment decisions and agree the organisation's overall approach to security.	Director of Resources is SIRO, Head of Business Technology has day to day responsibility of information security..	Ongoing review and refresher training as required.
2	Departments and Agencies must: * Adopt a holistic risk management approach covering all areas of protective security across their organisation. * Develop their own security policies, tailoring the standards and guidelines set out in this framework to the particular business needs, threat profile and risk appetite of their organisation and its delivery partners.	Risks identified as part of routine operational and strategic risk management as well as detailed on the information asset register Policies are in place and reviewed annually.	Ongoing review and development of the information asset register.
3	Departments and Agencies must ensure that all staff are aware of Departmental security policies and understand their personal responsibilities for safeguarding assets and the potential consequences of breaching security rules.	All staff and Authority members are informed of policies and given guidance. Annual training is undertaken by all through Civil Service Learning.	Ongoing reminders and awareness raising with staff.
4	Departments and Agencies must have robust and well tested policies, procedures and	System in place for detecting security breaches and	None.

	management arrangements in place to respond to, investigate and recover from security incidents or other disruptions to core business.	business continuity arrangements in place.	
5	Departments and Agencies must have an effective system of assurance in place to satisfy their Accounting Officer / Head of Department and Management Board that the organisation's security arrangements are fit for purpose, that information risks are appropriately managed, and that any significant control weaknesses are explicitly acknowledged and regularly reviewed.	System in place and SIRO reports annually - any weaknesses identified in Governance Statement (none). Internal audit of IT security in 2017/18 and highlighted some issues that have now been rectified. Response to GDPR and Records management audits during 2018/19 have also been reflected in HTA processes	None.
6	Departments and Agencies must have an information security policy setting out how they and any delivery partners and suppliers will protect any information assets they hold, store or process (including electronic and paper formats and online services) to prevent unauthorised access, disclosure or loss. The policies and procedures must be regularly reviewed to ensure currency.	Policies and procedures are in place and reviewed annually.	None.
7	Departments and Agencies must ensure that information assets are valued, handled, shared and protected in line with the standards and procedures set out in the Government Security Classifications Policy (including any special handling arrangements) and the associated technical guidance supporting this	The HTA's assets are all classified OFFICIAL and are appropriately controlled.	None.

	framework.		
8	All ICT systems that handle, store and process HMG classified information or business critical data, or that are interconnected to cross-government networks or services (e.g. the Public Services Network, PSN), must undergo a formal risk assessment to identify and understand relevant technical risks; and must undergo a proportionate accreditation process to ensure that the risks to the confidentiality, integrity and availability of the data, system and/or service are properly managed.	ICT systems are risk assessed as part of the overall operational risk register. IT security was reviewed by Internal Audit in 2017/18	None
9	Departments and Agencies must put in place an appropriate range of technical controls for all ICT systems, proportionate to the value, importance and sensitivity of the information held and the requirements of any interconnected systems.	Patching and firewalls in place. Assurance reports received and reviewed regularly with suppliers. Portable devices and removable media is secured.	None.
10	Departments and Agencies must implement appropriate procedural controls for all ICT (or paper-based) systems or services to prevent unauthorised access and modification, or misuse by authorised users.	Policies and staff induction in place, to clarify proper use and implications of breaches.	None.
11	Departments and Agencies must ensure that the security arrangements among their wider family of delivery partners and third party suppliers are appropriate to the information concerned and the level of risk to the parent organisation. This must include appropriate governance and management arrangements to manage risk, monitor compliance and respond	Contracts include required conditions and where appropriate third parties are given copies of the HTA's system policies. Changes to arrangements and incident monitoring	None.

	effectively to any incidents. Any site where third party suppliers manage assets at SECRET or above must be accredited to List X standards.	and results are reviewed at quarterly meetings with suppliers.	
12	Departments and Agencies must have clear policies and processes for reporting, managing and resolving Information Security Breaches and ICT security incidents.	Policies have been revised and are in place.	None.
13	Departments must ensure that personnel security risks are effectively managed by applying rigorous recruitment controls, and a proportionate and robust personnel security regime that determines what other checks (e.g. national security vetting) and ongoing personnel security controls should be applied.	Recruitment and references provide assurance. No vetting in place as very little sensitive data.	None.
14	Departments and Agencies must have in place an appropriate level of ongoing personnel security management, including formal reviews of national security vetting clearances, and arrangements for vetted staff to report changes in circumstances that might be relevant to their suitability to hold a security clearance.	N/a.	
15	Departments must make provision for an internal appeals process for existing employees wishing to challenge National Security Vetting decisions and inform Cabinet Office Government Security Secretariat should an individual initiate a legal challenge against a National Security Vetting decision.	N/a.	

16	Departments and Agencies must undertake regular security risk assessments for all sites in their estate and put in place appropriate physical security controls to prevent, detect and respond to security incidents.	Assessment and sufficient controls provided by building management.	None.
17	Departments and Agencies must implement appropriate internal security controls to ensure that critical, sensitive or classified assets are protected against both surreptitious and forced attack, and are only available to those with a genuine "need to know". Physical security measures must be proportionate to the level of threat, integrated with other protective security controls, and applied on the basis of the "defence in depth" principle.	Visitor and entry controls provided by building management. Lockable furniture provided for storage. Clear desk and clear screen requirements reinforced through training, checks and reminders.	None.
18	Departments and Agencies must put in place appropriate physical security controls to prevent unauthorised access to their estate, reduce the vulnerability of establishments to terrorism or other physical attacks, and facilitate a quick and effective response to security incidents. Selected controls must be proportionate to the level of threat, appropriate to the needs of the business and based on the "defence in depth" principle.	Sufficient controls around access and mail provided by building management.	None.
19	Departments and Agencies must ensure that all establishments in their estate put in place effective and well tested arrangements to respond to physical security incidents, including appropriate contingency plans and the ability to immediately implement additional security controls following a rise in the Government Response Level.	Building management provide the lead on incidents. HTA have contingency plans in place that are reviewed annually and incident management processes were utilised in 2018 in relation to a power outage	None.

20	<p>Departments and Agencies must be resilient in the face of physical security incidents, including terrorist attacks, applying identified security measures, and implementing incident management contingency arrangements and plans with immediate effect following a change to the Government Response Level.</p>	<p>Building managment provide the lead on incidents. HTA have contingency plans in place that are reviewed annually and incident management processes were utilised in 2018 in relation to a power outage</p>	
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HTA Policy

Reference	HTA-POL-XXX	Date approved	
Author(s)	David Thomson	Next review due	
Reviewed by		Owner	
Approved by		Distribution	All staff, Authority Members, third parties, contractors, consultants and visitors using HTA Information Systems

Protective Marking OFFICIAL

Records Management and Retention Policy

Revision history

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

Date	Version	Comments
	0.1	Initial draft

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Records and Information Management Policy

Introduction

1. Having accurate and relevant records and information 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.
3. We create and manage records and information 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 Regulatory Delivery maintains overall responsibility for the records management policy and standards, and for promoting their application throughout the HTA.

Departmental Record Officer

20. The HTA Departmental Records Officer (DRO) is responsible 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.

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

Local record managers

21. The responsibility for local records management is devolved to the relevant directorate managers. Heads of Departments, other units and business

functions within the HTA have overall responsibility for the management of records generated by their activities, i.e. for ensuring that records controlled within their area are managed in a way which meets the aims of the HTA's Records Management policies.

Responsibilities:

- know what information is being created and held
- understand the value of the information held, what it is needed for, and the technology needed to support it
- determine how long information should be kept, agree a policy for retention with the business, and ensure that information is 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 Records Management policies and with any guidance subsequently produced.

Management of records and information

23. The management of records and information falls into a number of categories, each requiring certain actions at particular times.

24. Different categories of information will be subject to different procedures and different retention or destruction timetables.

25. Certain records 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.

Creating information or records

26. 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.

27. 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 and security of records

28. Information Asset Owners (IAOs) are responsible for setting access permissions to information and records in their areas of responsibility.

29. 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.

30. 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.

31. In making records available outside of the HTA, the HTA will comply with data protection legislation and the Freedom of Information Act.

32. Refer to the HTA Information Governance and Assurance Directive [\[DN: include a link the directive once published\]](#) for further information about how to process information and data securely.

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

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

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.

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 197
- 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	12 June 2019	Paper reference	AUD (06/19)
Agenda item	10	Author	Dan Howard Chief Information Officer

Protective Marking OFFICIAL

Annual Data Protection Officer Update

Purpose of paper

1. To provide the annual DPO update, covering an assessment of the past 12 months, and a forward view for the next 12 months which includes recommendations.
2. The areas of review include governance, data protection awareness, personal data breaches, data protection impact assessments, future plans and policy development
3. This paper includes an overall assessment of compliance.

Decision-making to date

4. A verbal DPO update was provided to ARAC on 12 February 2019.
5. It was agreed that an annual report would be presented to the 12 June ARAC meeting for consideration, discussion and agreement.

Action required

6. To note the detail within the report, overall assessment and consider the recommendations.

Background

Governance

7. Our reciprocal data protection arrangements have been in place for around 12 months and I have been regularly updated on data protection issues and progress.

Data protection awareness

8. A Data Protection training course was provided to all staff in July 2018 shortly after GDPR came into force on 25 May 2018. This was delivered via British Safety Council and it was well received. Data protection awareness training is provided to all new staff as part of their induction.
9. Consideration should now be given to providing refresher training to ensure all staff continue to be aware of their obligations and to further increase awareness.

Personal Data breaches

10. There was one breach on 09 July 2018 involving an email containing referral information being sent to the wrong recipient because of a spelling error in the recipient's name. This was assessed at the time and appropriate action was taken. The ICO were consulted and confirmed it was not a notifiable incident. The DPO reporting mechanisms worked well. The incident was closed. No further breaches have been reported since.

Data Protection Impact assessments

11. A data protection impact assessment process is in place for all new projects using OneTrust. The threshold has not yet been met and so no DPIAs have taken place to date.

Future plans

12. It is planned that security and compliance controls within Office365 are used to improve data protection soon.

Policy review

13. Data protection policies exist and are reviewed annually. No changes have been identified to require a review of these policies. A further set of information governance and assurance policies will be developed shortly. Their scope will be wider than DP although they will include some elements of personal data management.

Assessment

14. The assessment of the current arrangements is that they are fit for purpose and robust. This report contains several recommendations:
- a) Consideration should be given to providing data protection refresher training to all staff;
 - b) Office365 should be used to strengthen data protection controls, if possible; and,
 - c) The development and review of the new Information Governance and Assurance policies should take place in conjunction with the DPO

Dan Howard, HTA Data Protection Officer
June 2019

Audit and Risk Assurance Committee paper

Date	12 June 2019	Paper reference	AUD (07/19)
Agenda item	11	Author	Richard Sydee, Director of Resources
Protective Marking	OFFICIAL		

Approval of the Annual Reports and Accounts 2018/19

Purpose of paper

1. To provide an overview of the HTA Annual Report and Accounts for 2018/19.

Decision-making to date

2. None.

Action required

3. Members of ARAC are required to consider the External Auditors annual statement at Annex B and ISA 260 report (management letter) at Annex C and approve the HTA Annual Report and Accounts 2018/19 for Accounting Officer sign off (Annex A).

Background

4. The content and format of the report remains consistent with that published for the 2017/18 financial year.
5. Total operating income was £4,179k (licence fees and other income) £295k higher than the previous financial year, with the majority of this change resulting from licence fees.
6. The statement of comprehensive net expenditure shows net expenditure of £808k. Grant-in-aid (GIA) was £703k. GIA is recorded as financing and as such is not shown on the face of the statement. Having taken GIA in to account we would report a net

deficit of £105k. We received non-cash funding from DHSC of £178k in the form of ring-fenced RDEL which again is not shown within the accounts. This moves us from the deficit above to a surplus of £73k.

7. Cash reserves stand at £3,448k at the end of March 2019 an increase of £36k from March 2018.

Next steps

8. After signing by the Accounting Officer, the Controller and Auditor General will sign the Annual Report and Accounts and they will be laid before Parliament. We will delay the Accounting Officer sign off until we have received a revised timeline from NAO; this ensures that the accounts are reviewed in light of any material developments prior to final sign off and before being passed to NAO. Should an update be necessary, ARAC will be informed.

Annual report and accounts 2018/19

Human Tissue Authority

Annual report and accounts 2018/19

Presented to Parliament pursuant to Schedule 2(16) of the Human Tissue Act 2004.

Ordered by the House of Commons to be printed on **DD MMM YYYY**

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Chief Executive's foreword

The past year has been the first under the three-year Strategy we launched in April 2018 which set out the HTA's aspirations over the three years through to 2021. It was developed following a comprehensive review of the extent to which we achieve our overall aim: that of protecting public and professional confidence in the use of human tissue.

Our renewed strategic focus on building agility, sustainability and resilience, when set alongside a number of political, operational and organisational challenges over the last 12 months has seen the HTA deliver significant progress against its goals within a budget and headcount that remain among the smallest of all arm's length bodies.

The number and severity of the shortfalls we find on inspection, especially in the post-mortem sector, has continued at the high levels we reported in the last business year. This places significant pressure on our organisational resources as we work with our licenced establishments to develop the appropriate actions to ensure they operate in line with our Codes of Practice. We continue to find our stakeholders to be responsive to findings and together, we have been able to ensure that organisations have clear plans to rectify issues and return to regulatory compliance.

We have worked with Department of Health and Social Care colleagues on many matters of significance to the public: the Private Members' bill on deemed consent became the Organ Donation (Deemed Consent) Act 2019, receiving royal assent on 15 March 2019. We have also been fully engaged with the Department's preparations ahead of leaving the European Union.

We have engaged closely with the public and our licence holders throughout this period. During the past year we held our first standalone conference for practitioners across all sectors and were pleased with both the attendance levels and the positive feedback the event received. We have provided training to Independent Assessors for living organ donation, and late this business year released a suite of learning materials and tests for Designated Individuals across all of our sectors to help improve knowledge and compliance. These initiatives aim to better inform and involve all parties interested in the regulatory environment and, we hope, will extend public and professional confidence in our regulated sectors.

At an organisational level, staff turnover and recruitment have continued to present management challenge, as has the introduction of updated systems and compliance procedures associated with the General Data Protection Regulation. This inevitably places a significant burden on a smaller number of core staff. However, we have been successful in recruiting a number of talented and highly qualified people to the organisation over the past year. I am, as ever, grateful for the commitment and knowledge of teams across the HTA who continue to ensure that we maintain the very highest standards and fulfil our regulatory responsibilities.

This coming year will, once again, be a busy and demanding year for the HTA. We will be working closely with professionals and stakeholders as we develop the Code of Practice to accompany the Organ Donation Act – this will reflect our interpretation of the law and provide high level advice to those carrying out activities under the scope of the new legislation. The fundamental principle of consent is central to our work, and will continue to be the guiding principle underpinning our regulatory framework.

In addition to our statutory role, we are increasingly called upon to provide guidance on areas related to our remit, but not covered by existing legislation. This is particularly important in areas

of emerging technology and cutting-edge research. In order to maintain public confidence in the system, and to ensure we remain an effective regulator, we must reflect and react to the speed of change and innovation of science and technology across the areas we regulate.

We have a strong track record of working closely with partner organisations, and the positive feedback we have received from our licence-holders is testament to our collaborative approach.

Our dedicated and expert staff will drive and implement our strategy over the coming year. They are the key to our success, and we will strengthen our management focus on recruiting and retaining high quality staff who will deliver our core regulatory business alongside a challenging programme of change.

Allan Marriott-Smith
Chief Executive

Performance

Overview

We are a Non-Departmental Public Body (NDPB) sponsored by the Department of Health and Social Care (DHSC), incorporated and domiciled in England. Our registered office is 151 Buckingham Palace Road, London, SW1W 9SZ. We were established under the Human Tissue Act (HT Act) 2004 – which covers England, Wales and Northern Ireland – to regulate activities relating to the removal, storage, use and disposal of human tissue.

What we do

Our overall goal is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent, in accordance with the provisions of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

We also have a role in maintaining professional confidence; by assuring that human material being used by professionals has been obtained with the proper consent and is managed with appropriate care.

Our role:

- We license organisations that remove, store and use human tissue for certain activities under the Human Tissue Act 2004;
- We license organisations involved in preparing tissues and cells for use in patient treatment as required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended);
- We license organisations involved in organ donation and transplantation as required by the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended);
- We monitor and inspect or audit organisations to ensure they comply with our standards;
- We use our powers to take regulatory action where we identify non-compliance;
- We assess living organ donation applications to ensure donors are protected from duress or coercion, and that no reward is offered or given;
- We provide information, advice and guidance to the public and professionals about the nature and purpose of activities within our remit;
- We monitor developments relating to activities within our remit and advise Government on related issues.

In addition to our statutory role we are increasingly called upon to provide advice on areas related to, but not specified in, our legislation. This is particularly important in areas of emerging technology and cutting-edge research not originally envisaged when the Human Tissue Act was established.

Our remit under the Human Tissue Act 2004 extends to England, Wales and Northern Ireland; however, we also carry out some activities in relation to the approval of living organ donations on behalf of the Scottish Government. Our remit as the Competent Authority for the quality and safety of tissues, cells and organs used in transplantation extends to the whole of the UK. We license approximately 860 premises across the six sectors that we regulate and publish standards and requirements that those working within the regulated fields must meet.

Whilst the HTA has an influential role in superintending compliance and promoting good practice, public confidence in the use of human tissue cannot be safeguarded by the HTA alone. Public confidence is also dependent on individuals and organisations undertaking activities within the HTA's remit to act within the standards and requirements of the legislation.

Four **guiding principles** continue to drive our work and underpin our regulatory framework. They should be followed in dealing with human bodies, tissue and organs:

- *Consent* – and the wishes of the donor (or in some cases, their nominated representatives or relatives) are the primary consideration when removing, storing and using human tissue.
- *Dignity* – is paramount in the treatment of human bodies and tissue.
- *Quality* – must underpin the management of human bodies and tissue.
- *Honesty and openness* – are the foundation of communications in matters pertaining to the use of human tissue and bodies.

The Authority – the HTA's non-executive board – is currently made up of: a chair and nine Members who are appointed by the Secretary of State for Health and Social Care; one Member appointed by the Welsh Government's Cabinet Secretary for Health, Well-Being, and Sport and; one by the Minister for Health in Northern Ireland. The professional Members of our board come from medical and scientific backgrounds linked to our work, and the lay Members bring a wide range of business, commercial and public sector experience.

The board's primary role is to ensure that the HTA discharges its statutory responsibilities effectively. It achieves this by setting the HTA's strategic direction and providing both support and challenge to our Executive team, which is responsible for the delivery of these responsibilities on a day-to-day basis.

Below are our strategic aims for 2018-2021

Strategic Aims	High level objective are to continue to:
Delivery – To deliver the right mix of operational activity to maintain public and professional confidence	<ul style="list-style-type: none"> • Deliver a right touch program 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 and the public in understanding the requirements of the legislation;

	<ul style="list-style-type: none"> • 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; • Maintain our strategic relationships with other regulators operating in the health sector.
Development – To make the right investment to continuously improve delivery and deployment	<ul style="list-style-type: none"> • Use our data and information to provide a sharper focus for our regulatory work; allowing us to target our resources effectively • Make continuous improvements to our 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; • Begin work on implementing a future operating model, which builds agility, resilience and sustainability.
Deployment – To make the most effective use of people and resources in pursuit of our goals	<ul style="list-style-type: none"> • Manage and develop our people in line with the 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 cyber security; • Plan and prioritise our resources to carefully balance activity across the organisation.

Key issues in 2018/19

This year has seen a number of challenges and achievements. In common with many other organisations, the HTA was required to be compliant with the General Data Protection Regulation that came into force in May 2018. We have achieved this but recognise there will be further work to do as we undertake changes to our systems and processes over the next two years.

The Organ Donation (Deemed Consent) Bill 2017-19 was tabled as a Private Member's Bill. This Bill was subject to [Parliamentary processes](#) and received royal assent on 15 March 2019. As a result a new system of consent for organ donation will come in to force in the spring of 2020 and adults in England will be considered potential donors unless they have chosen to opt out or are statutorily excluded.

The new Act tasks the HTA with writing a Code of Practice which will set out advice and guidance to medical practitioners to support them in acting in line with the new law. It will reflect our current interpretation of the legislation and our advice on good practice.

We are collaborating closely with DHSC, NHSBT and other key professionals on drafting of the Code, with a public consultation to be held during the summer of 2019. The work on developing the Code will affect resources available elsewhere in the business.

We increasingly encounter issues that, although strictly outside of our statutory remit, have the potential to impact on public and professional confidence. In line with our core principles we offer advice and guidance where we are able to do so, but are conscious that there are areas where the public might expect us to have regulatory tools to intervene in these areas more directly. We continue to manage this as one of our six strategic risks.

Further development work has been undertaken towards implementing the European Union Coding and Import Directives. Modifications to our licence application and variation process have been made and the associated guidance and governance documents updated.

Planning continues to ensure the necessary changes to national regulations can be made to maintain, from day one the import and export of organs, tissues and cells when the UK exits the EU.

We are a small organisation which relies on our expert workforce to deliver our objectives. While staff report that the HTA is a worthwhile and positive place to work, we have continued to experience relatively high turnover rates, mainly as a result of our small size and flat structure, which provide limited opportunities for internal career progression. In addition, and in common with other bodies in the public sector, pay constraints mean that staff must move on if they wish to significantly increase their earnings. We monitor the recruitment and retention of staff as one of our strategic risks; this year we have successfully run a large recruitment exercise to fill a number of Regulation Manager vacancies and have had significant success in attracting high calibre recruits to these roles. Moving forward we will continue to provide increased training, role enrichment and flexibility to enhance retention.

Risks as at 31 March 2019

The HTA aims to take all reasonable steps in the management of risk with the overall objective of achieving strategic and business objectives and protecting staff, stakeholders, the public and assets.

As at 31 March 2019, the HTA had six strategic risks:

Risk associated with Development	Mitigations
<ul style="list-style-type: none"> Failure to regulate in a manner that maintains public safety and confidence and is appropriate 	<ul style="list-style-type: none"> HTA Strategy clearly articulates HTA's regulatory model; Regulatory decision making framework; Annual review of Strategy; approved Business Plan which identifies a balanced programme of regulatory activity and continuous improvement; HTA People Strategy roadmap; HTA quality management system; containing decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model; Internal Audit of quality management system adequacy and adherence; Training and development of professional competence.
<ul style="list-style-type: none"> Inability to manage an incident that impacts upon the delivery of HTA strategic objectives. 	<ul style="list-style-type: none"> Critical incident response plans are regularly reviewed and communicated to staff who are trained annually; Media handling policy and guidance in place, including regular media training for key staff and Members with relevant scenarios, to supplement media releases and enquiries Standard Operating Procedures (SOPs); IT security controls and risk management in place and Business Continuity is annually reviewed and tested.
<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Log of issues with respect to the existing legislation is maintained and discussed with DHSC; Active management of issues raised by the media and public; Regular reporting to DHSC (Sponsors and Policy teams) on matters which risk public and professional confidence; Legal advice is, and will continue to be, used to clarify regulatory powers and provide guidance where appropriate.

<ul style="list-style-type: none"> • Failure to utilise people, data and business technology capabilities effectively 	<ul style="list-style-type: none"> • Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle; • Regular review of organisational structure and job descriptions; • Established annual Performance Development Planning and regular 1 – 1 meetings with all staff and mid-year reviews; • IT systems protected and assurance received from third party suppliers that protection is up to date; • Staff training in key business systems • Data relating to establishments securely stored within our Customer Relationship Management system; • HTAMG Development schedule in place.
<ul style="list-style-type: none"> • Insufficient, or ineffective management of financial resources 	<ul style="list-style-type: none"> • Budget management framework exists to control and review spend and take early action where necessary; • Financial projections, cash flow forecasting and monitoring are reviewed monthly by executive team; • Reserves policy and levels are reviewed frequently and reported to the executive team and Authority; • Internal audit and annual external audit of finance are undertaken each year; • Fee modelling which provides cost/income information for planning; • Credit control – debt recovery process in place.
<ul style="list-style-type: none"> • Failure to achieve the benefits of the organisational transformation programme 	<ul style="list-style-type: none"> • SMT expertise in organisational change, programme and project management; • Procurement and contract management experience; • Established corporate governance and financial controls.

The sixth and final risk is a new risk that has been identified and stems from a review of our three year strategy for 2018 – 2021. The review identified a number of opportunities and challenges relating to the future operating environment that will require us to adapt as an organisation. The programme of work is expected to deliver benefits to the HTA and its stakeholders from improvements to systems and processes that facilitate a more targeted, risk-based, approach to regulation.

Further information on the HTA's approach to managing risk can be found in the Annual Governance Statement.

Going concern

We consider the use of the going concern basis of accounting is appropriate because there are no material uncertainties related to events or conditions that may cast significant doubt about the ability of the organisation to continue as a going concern.

Performance analysis

Measuring performance

Each year, we agree a business plan with the Department of Health and Social Care (DHSC) that includes strategic aims, high level objectives and key performance indicators (KPIs) covering delivery of our statutory remit and public accountability.

The HTA records achievement of key performance indicators monthly and reviews achievement and action needed at the HTA Management Group (HTAMG) meeting. Our KPIs measure both financial and non-financial performance to provide a comprehensive view of our activities.

Each quarter a report is made to the Authority and DHSC providing assurance.

Analysis of performance over the year

Performance indicators 2018/19

Performance indicators	Target 2018/19	Performance 2018/19	Target 2017/18	Performance 2017/18
Delivery				
Undertake a risk-based inspection/audit program	200 site visits	222 site visits	210 site visits	240
Take appropriate action for all regulatory non-compliance ¹	100% of Corrective and Preventative Actions (CAPAs) implemented within 28 days	72%	100% of Corrective and Preventative Actions (CAPAs) implemented within 28 days	77%
Make appropriately evidenced decisions to agreed quality standard	100% of non-panel cases turned around with 5 working days	100%	100% of non-panel cases turned around with 5 working days	100%
Respond to enquiries in a timely way	95% of enquiries answered within 10 working days	95%	95% of enquiries answered within 10 working days	96%
Deployment				
Reduce attrition rates through improved selection and targeted measures to retain staff ²	Attrition rate to be no more than 18%	20%	Attrition rate to be no more than 18%	23%

¹ The change from 77% in 2017/18 to 72% this year was due to an increased number of shortfalls and the complexity of issues that rose from the shortfalls and inspections more generally.

² An improvement on the previous year. The recruitment campaign conducted earlier in the year has proved beneficial.

Financial review

We have generated the income needed to cover the cost of licensable activities and delivered within the budget set for the year. We have a comprehensive fees model that enables us to set our fees according to the regulatory workload and allocate our costs according to our activities as set out in legislation.

Summary position as at 31 March 2019

		2018/19	2017/18
	Note	£'000s	£'000s
Income			
From devolved Governments		131	130
Licence fees		3,654	3,296
Other income	(a)	394	458
Total Income¹		4,179	3,884
Expenditure			
Staff costs		2,901	2,827
General administrative and non-cash costs		2,086	1,779
Total expenditure¹		4,987	4,606
Net (expenditure)/income for the year	(b)	(808)	(722)

(a) Other income is made up of rental income from NHS Resolution and seconded staff costs.

(b) Net expenditure for the year reflects our financial position excluding the Grant-in-aid (GIA) funding received from Department of Health and Social Care. The table below reflects the revenue GIA received from DHSC, to arrive at the Net operating surplus for HTA.

Net expenditure)/income for the year	(b)	(808)	(722)
Revenue Grant in Aid	(c)	703	800
Ring-fenced RDEL	(d)	178	0
Surplus/(deficit) for the year		73	78

(c) GIA is treated as financing within statutory accounts and it is a requirement to report it this way. GIA is therefore excluded in the Statement of Comprehensive Net Expenditure (SoCNE) on page 54 within the financial statements and included in the Statement to Changes in Taxpayers Equity (SoCTE) on page 57.

¹ The total income and expenditure figures do not cast to the SoCNE on page 54 due to rounding.

(d) In addition to the cash GIA, the HTA received cover for its non-cash expenditure (depreciation and amortisation) of £178k. It is not cash and therefore not shown in the accounts. Had it been, it would move us from the deficit of £105k to an operating surplus of £73k.

Against the above surplus our operating expenditure is £4.99m. Our staff costs at £2.9m were 2.6% more than last year due to successful recruitment rounds throughout the year.

Income from contracts with customers (Licence fee income) of £3.65m is 10.86% higher than our 2017/18 fee income, and on a par with the budget.

During 2018/19 the HTA managed its income to ensure drawdowns were kept within the DHSC's cash allocation. The total available cash allocation for revenue and capital expenditure was £703,000 and £100,000 respectively, (2017/18 £800,000 and £250,000).

Supplier payments

The HTA is committed to the Better Payment Practice Code. We aim to pay suppliers within ten days of receipt of a valid invoice. No interest payments were made to suppliers under the Late Payment of Commercial Debts (Interest) Act 1998.

HTA Target	2018/19	2017/18
90% of payments made within 10 days of receipt of undisputed invoice. (Better Payment Practice Code Target is 95% in 30 days)	891 invoices received of which 887 99.6% paid within 10 days	1,123 invoices received of which 1,107 98.6% paid within 10 days

Countering fraud and corruption

Whilst the HTA have suffered no losses, it is important that we have systems in place to mitigate any fraud. The HTA has an anti-fraud and bribery policy which it reviews annually and ensures staff are aware of it. The Director of Resources is able to access the DHSC Counter Fraud unit if ever required.

Staff involvement and wellbeing

The HTA keeps all members of staff informed about organisational, management and policy issues. There is a weekly briefing for all staff and in addition all-staff meetings are held at least every three months. Directorate team meetings are also held regularly. Members of staff can raise any issues with a member of the SMT during the weekly "SMT drop-in" session.

The HTA staff survey, last undertaken in December 2017 and next planned for in 2019, had participation rates of 81%, well above the Civil Service average of 67%. The HTA is committed to engaging staff and strives to maintain and build on high staff engagement and satisfaction scores from the staff survey year on year.

The HTA has a staff forum to ensure that all staff have their say and have an opportunity to raise issues, make suggestions and give opinions. The chair of the staff forum is also the staff Freedom to Speak Up champion, to provide a secure mechanism for staff to raise any concerns. An Authority Member, the chair of the Audit and Risk Assurance Committee (ARAC), also acts as a Freedom to speak up champion and meets with the chair of the staff forum at least three times a year coinciding with ARAC meetings.

The HTA maintains an up-to-date health and safety policy and we set out our responsibilities in the Statement of Intent. The HTA has appointed first aiders and fire wardens and has online training modules and assessments to ensure staff are working in a safe environment that protects their health. No health and safety incidents were reported in the year.

Learning and development

The HTA actively promotes the development of staff by offering a wide range of corporate and specific training. Individual needs are set out in personal development plans and are met through training events, participation in projects, observing activities the HTA oversees and shadowing. This year has seen a significant investment in staff training events that has been welcomed across the organisation. Feedback is always sought from staff via evaluation forms, with most attendees indicating that the skills and knowledge gained at such events is relevant to their roles.

Our Career Investment Scheme launched over eight years ago, to assist staff members to obtain professional qualifications or undertake training to enhance their skills and knowledge to aid their career, continues to be used. In 2018/19 seven members of staff benefitted from the scheme, in addition to the 25 previous beneficiaries since the scheme began. We also have access to the Civil Service Learning portal which provides training resources for public sector staff.

Equality Act 2010 – equality and diversity and human rights

The HTA is committed to providing equal opportunities for all staff. Our aim is to ensure that all staff are aware that any form of discrimination against people, because of their race, disability, gender, gender identity, religion/belief, age, sexual orientation or any other protected characteristic is prohibited within the HTA, and to ensure that the Authority abides by the statutory regulations regarding human rights and discrimination. We periodically monitor our performance in this area with reports discussed at management meetings.

Disabled employees

We have a specific policy of inviting to interview any candidate with a disability who meets essential criteria. Support is provided for all staff who have, or develop, a disability including making any reasonable adjustments to the workplace or work processes and having advice available through the occupational health service.

An analysis of gender mix for the headcount as at 31 March 2019 is provided below. The figures exclude the Shared Director who is accounted for within the Human Fertilisation and Embryology (HFEA) and temporary staff.

Gender	Male	Female	Total 2018/19	Total 2017/18
Authority Members	7	4	11	12
Directors	1	2	3	3
Total staff (including Directors, excluding Members)	11	37	48	44

* Last year (Male 12/Female 32)

None of the HTA staff who declare report themselves as disabled. An analysis of other characteristics of all staff, as at 31 March 2019, is provided below.

Age range	2018/19	2017/18
< 34	13	17
35-44	21	16
45-54	10	8
>55	4	3

Ethnicity	2018/19	2017/18
White British	30	27
Other Ethnicity	18	17

Religion	2018/19	2017/18
Christian	10	13
Other Religions	8	3
Non-religious	27	27
Undisclosed	3	1

Social, community, sustainability and environmental issues

The HTA recognises the work-related benefits of staff joining together outside work for various events. We encourage a social committee to organise informal and more formal gatherings.

During 2018/19 HTA staff have, on their own initiative, engaged in events to raise funds for charities. The HTA has supported staff in these endeavours.

The HTA occupies space within a multi tenanted building on Buckingham Palace Road. We share this space with NHS Resolution. Our landlords, the Government Property Agency -

provide services and encourage behaviour that meets sustainability requirements. This includes recycling, energy efficiency and other facilities. HTA performance is not monitored separately.

Whilst the HTA may be exempt from formal reporting on a number of Greening Government Commitments as it has fewer than 250 FTE staff, we still consider environmental and sustainability issues when procuring goods and services. Staff are encouraged to travel on HTA business in the most sustainable and cost-effective way.

The HTA is a member of the Cycle to Work scheme, which provides tax efficient incentives for employees to use cycles to travel to work.

We are aware of the green agenda in relation to procurement and we use the Crown Commercial Service and other frameworks which have sustainability factored in.

Allan Marriott-Smith
Chief Executive
Accounting Officer

DD MMMM YYYY

Accountability

Corporate governance report

Directors' report

The Authority

Our Authority is made up of 12 Members (including the Chair) appointed through an open public process. Authority members during 2018/19 are set out below. Biographies for each can be found on our website.

Authority member	Type	Appointment start date	Appointment end date
Nicola Blackwood (Chair)	Lay	13 March 2018	12 March 2021 (resigned 9 January 2019)
William Horne (Interim Chair)	Lay	1 August 2014	31 July 2020 (re-appointed May 2017)
Professor Andy Hall	Professional	20 October 2014	19 October 2020 (re-appointed August 2017)
Hossam Abdalla	Lay	20 October 2014	19 October 2020 (re-appointed August 2017)
Amanda Gibbon	Lay	20 October 2014	19 October 2020 (re-appointed August 2017)
Professor Anthony Warrens	Professional	20 October 2014	19 October 2020 (re-appointed August 2017)
Glenn Houston	Lay	5 May 2015	4 May 2021 (re-appointed March 2018)
Dr Lorna Williamson OBE	Professional	1 April 2016	31 March 2022 (reappointed February 2019)
Professor Penney Lewis	Lay	1 April 2016	31 March 2022 (re-appointed February 2019)
Dr Stuart Dollow	Professional	1 April 2016	31 March 2022 (reappointed February 2019)
The Right Reverend Graham Usher	Lay	1 April 2016	31 March 2022 (reappointed February 2019)
Professor Dame Sally Macintyre	Lay	5 May 2016	4 May 2019 (term ended)

Member biographies are on the HTA website <https://www.hta.gov.uk/about-us/our-people>

Senior Management Team

Our Chief Executive and Directors during 2018/19 are set out below.

Senior Management	Post
Allan Marriott Smith	Chief Executive
Richard Sydee ¹	Director of Resources
Hazel Lofty (appointed 9 April 2018)	Director of Regulatory Development
Nicolette Harrison (appointed 4 June 2018)	Director of Regulatory Delivery
Christopher Birkett (interim appointment 4 December 2017 to 30 June 2018)	Director of Regulation

¹ Director of Resources is shared and seconded 2.5 days a week from the Human Fertilisation and Embryology Authority (HFEA)

Interests of Authority members and senior staff

The HTA maintains a Register of Interests. All Authority Members and staff declare any company directorships and other significant interests held by them or their close family and friends which may conflict with their HTA responsibilities. The register can be made available on request.

Members' interests are published on the HTA's website.

Pensions

Pension benefits are provided by the National Health Service (NHS) Pension Scheme. The HTA recognises the contributions payable for the year. Full details are set out in the remuneration report and note 1.11 to the accounts.

Data incidents

Arrangements for data security and any personal data-related incidents are set out in the annual governance statement.

Our auditors

The Comptroller and Auditor General is the external auditor for the HTA's accounts. The external auditor's remuneration in 2018/19 was £26,500. No fees were incurred for non-audit work.

Statement of Accounting Officer's responsibilities

Under the Human Tissue Act 2004, the HTA is required to prepare a statement of accounts in the form and basis set out in the Accounts Direction for each financial year, in conformity with The Secretary of State's direction Schedule 2 (paragraph 16), detailing the resources acquired, held or disposed of during the year and the use of resources by the HTA during the year. The Annual Accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the HTA, the income and expenditure, Statement of Financial Position and cash flows for the financial year.

In preparing the accounts, I as the Accounting Officer am required to comply with the requirements of the Government Financial Reporting Manual prepared by HM Treasury, and in particular to:

- observe the Accounts Direction issued by DHSC, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards, as set out in the Government Financial Reporting Manual, have been followed, and disclose and explain any material departures in the accounts;
- prepare the accounts on a going concern basis;
- confirm that the Annual Report and Accounts as a whole is fair, balanced and understandable and I take personal responsibility for the Annual Report and accounts and the judgements required for determining that it is fair, balanced and understandable.

The Accounting Officer of the DHSC has appointed the Chief Executive as Accounting Officer for the Human Tissue Authority with responsibility for preparing the HTA's accounts and for transmitting them to the Comptroller and Auditor General.

The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances, for which the Accounting Officer is answerable, for keeping proper records and safeguarding the HTA's assets, are set out in the Accounting Officers' Memorandum, issued by the DHSC, and in Managing Public Money published by HM Treasury. As Accounting Officer, I have taken all the steps that I ought to have taken to make myself aware of any relevant audit information and to establish that the HTA's auditors are aware of that information. So far as I am aware, there is no relevant audit information of which the auditors are unaware.

During the audit of these financial statements my staff and I have co-operated fully with the Comptroller and Auditor General. I have taken all feasible steps to ensure that I am fully aware of all information pertinent to the audit and to ensure that this information is notified and made available to the auditors. Consequently, as far as I am aware, there is no relevant information that has not been available to the National Audit Office's audit team.

Accounts direction

The Annual Accounts have been prepared and issued by the HTA, under directions given by the Secretary of State, with the approval of HM Treasury, in accordance with Schedule 2 (paragraph 16) of the HT Act. The Accounts report the resources that have been used by the HTA to deliver its objectives. These Annual Accounts have been prepared in accordance with the guidance set out in the Government Financial Reporting Manual (FReM) 2018/19.

Authority statement

The Senior Management team (SMT) of the HTA and the ARAC, on behalf of the Authority, has reviewed the Annual Report and Accounts.

Governance statement

Introduction

This statement sets out the governance and control framework at the HTA and the risks to HTA performance. It explains how I have discharged my responsibility, as Accounting Officer, to manage and control the HTA's resources in 2018/19.

During 2018/19 the Authority met its key performance indicators, with strong performance from the Board Executive, Board Committees and satisfactory outcomes from individual internal audits. There have been some changes within the SMT, which have been managed with staff playing an interim role therefore, providing continuity. This year has identified some issues in relation to records management, that were highlighted through the internal audit process and these are being addressed.

Governance framework

The Authority

The Authority (the HTA's statutory non-executive board) comprises a Chair and 11 Members who are appointed by the Secretary of State for Health and Social Care, with the exception of one Member appointed by the Welsh Government Cabinet Secretary for Health, Well-Being and Sport and one by the Minister in Northern Ireland. Members are appointed for a three-year term of office initially. At the end of 2018/19 there were 10 Members plus the Chair who come from a variety of medical, scientific, legal, administrative and ethical backgrounds. This ensures that the Authority draws on a wide range of experience relevant to the governance of the HTA. By law, at least half must be lay Members.

In January 2019 the Chair Nicola Blackwood resigned her post which has been filled on an interim basis by William Horne until a new Chair is appointed. Four Authority Members were re-appointed for a further term in February 2019:- Dr Stuart Dollow, Professor Penney Lewis, the Right Reverend Graham Usher and Dr Lorna Williamson OBE.

The Authority's primary role is to ensure that the HTA's statutory responsibilities are met. It achieves this by setting the HTA's strategic direction and providing both support and challenge to an executive that is responsible for the discharge of these responsibilities on a day-to-day basis. The Authority receives quarterly reports aligned with our strategic themes of Delivery, Development and Deployment and these include reporting on our financial priorities and an assessment of strategic risk. Reports on other matters are provided on a periodic or as required basis. The Authority questions the executive and explores aspects of work with staff (for example Cyber Security) to assure themselves that they can rely on the quality of data and information in the reports. The Authority has been satisfied with the quality and scope of the reports made. Authority Members also have an executive role in assessing applications for living organ donation for transplants.

The Authority ensures that statutory functions are delivered appropriately, in line with the Harris review. It has a clear understanding of the statutory basis of work undertaken by the HTA, ensuring there is direction or clarification from the DHSC where required.

The HTA is committed to transparency and public accountability and therefore Authority agendas, papers and minutes are published on our website, along with other policies and reports.

The Authority met 5 times during the year, with one of those meetings being open to the public. The Chief Executive and executive Directors (the SMT), attend Authority meetings. Representatives from the DHSC also attend, and other HTA staff attend as required. Member attendance at ordinary Authority meetings in 2018/19 is listed below.

Authority Member	Number of meetings attended
Nicola Blackwood	4/4
William Horne	5/5
Professor Andy Hall	4/5
Hossam Abdalla	2/5
Amanda Gibbon (ARAC Chair)	5/5
Professor Anthony Warrens	5/5
Glenn Houston	4/5
Dr Lorna Williamson OBE	5/5
Professor Penney Lewis	5/5
Dr Stuart Dollow	5/5
The Right Reverend Graham Usher	4/5
Professor Dame Sally Macintyre	5/5

Committees and groups

The Authority is supported in its work by Committees and groups involving Members. Committees review the work of the HTA and make decisions or recommend a decision to the full Authority where necessary. Groups include stakeholders and provide input to emerging strategies and approaches. The following committees and groups were in place in 2018/19.

Committees of Members:

- Audit and Risk Assurance Committee (ARAC)
- Remuneration Committee

Groups consisting of Members with external stakeholder representation:

- Transplantation Advisory Group (TAG)

- Histopathology Working Group (HWG)
- Stakeholder and Fees Group

Having external stakeholder representation on groups enables the Authority to work directly with stakeholders to review developing issues and advise the Executive. These discussions improve Member understanding of operational activity which enhances the Authority's ability to scrutinise the actions of the Executive. Groups also provide Members and stakeholders with the chance to contribute views to the early stages of significant regulatory policy development, resulting in better decision making.

TAG is a forum for the discussion of issues arising in living and deceased organ donation. In particular, the Group considers new policy issues and emerging novel areas in transplantation; identifies revisions required to current HTA or NHS Blood and Transplant (NHSBT) policies; discusses the complex ethical issues in transplantation; and reviews guidance on issues surrounding Independent Assessors (IAs), including recruitment and performance issues identified during the reaccreditation process.

HWG exists to maintain a positive and long-lasting impact on the delivery of post mortem services, working with the sector to help drive up standards. Consultation with HWG helps ensure that advice provided by the HTA remains current and in line with professional guidance. In addition, the HWG considers on an on-going basis issues facing post mortem sector establishments, in order to inform the continued development of HTA regulatory policy affecting the sector and its overlap with the research sector.

The Stakeholder and Fees Group provides a forum for regular consultation on our approach to regulatory activities, including fee-setting and an opportunity for stakeholders to make their views known to the Authority. The Stakeholder and Fees Group was established to ensure the HTA continues to improve transparency and accountability and maintain effective working relationships with establishments we license.

The ARAC met three times in 2018/19. The Chief Executive, the Director of Resources, the Head of Finance and Governance, the HTA's external and internal auditors and a representative of the Department of Health and Social Care attend meetings. Other Directors and staff are asked to attend to discuss particular risk areas that the ARAC wishes to explore, or other topics depending on the ARAC's business. The ARAC's terms of reference outline the support this body provides to the Accounting Officer (the Chief Executive) throughout the year, in particular, providing scrutiny to support the agreement of the Governance Statement. Member attendance at ARAC meetings in 2018/19 is listed below.

ARAC member attended	Number of meetings
Amanda Gibbon (Chair)	3/3
William Horne ²	2/3
Professor Andy Hall	3/3

² William Horne is currently not a member of the Committee whilst Act Chair of the Authority

Glenn Houston	3/3
Dr Stuart Dollow	3/3

In addition, the Chair of the Authority, Nicola Blackwood, attended the June meeting

Our internal auditors are the Government Internal Audit Agency who are in the second year of their appointment with the HTA. The Head of Internal Audit (HIA), Jeremy Nolan oversaw the programme of audit work which focused on Cyber Security, Key Regulatory Processes, Records Management, Stakeholder Engagement and General Data Protection Regulation.

During 2018/19, ARAC reviewed strategic risks at each meeting, approved or noted (as appropriate) updated policies on an annual cycle, took reports of audit findings from external and internal auditors and reviewed the HTA's progress in implementing audit recommendations. In February 2019, ARAC had their annual meeting in private with external and internal auditors to assure themselves there were no other matters they should be aware of.

The Remuneration Committee met twice in 2018 to agree the principles for the 2018 pay award. The Chief Executive, the Director of Resources and the Head of HR attend the Remuneration Committee as appropriate. Members and their attendance are as follows:

Member	Number of meetings attended
Nicola Blackwood (Chair)	2/2
Hossam Abdalla	1/2
Glenn Houston	2/2
Penney Lewis	2/2

Authority Members may also chair and participate in HTA conferences, events, and workshops for stakeholders; participate in working groups covering the work of the Directorates and provide advice to the executive. The Welsh Member has also liaised with the Welsh Government.

Members have attended events for non-executive directors organised by the DHSC on topics including personalised health and care, managing risk, the National Information Board (NIB) and general discussions for Chairs and NEDs.

The Chair of ARAC also attends networking meetings of audit committee chairs. There was one meeting which was hosted by National Audit Office and this was attended by Stuart Dollow (ARAC Member) on behalf of the Chair of ARAC.

Effectiveness of the Authority

The HTA complies with the *Corporate Governance Code for Central Government Departments*. Members' terms and conditions include adherence to the seven principles of public life: selflessness, integrity, objectivity, accountability, openness, honesty and leadership, and these are demonstrated in Authority meetings.

The Chair of the Authority assesses the performance of each member annually. DHSC forms a view on the effectiveness of the Authority by attending meetings and of the HTA's performance through quarterly accountability meetings. No significant issues have been raised.

ARAC makes a self-assessment of its performance annually. This was undertaken in February 2019 and *resulted in a positive evaluation* against the NAO Audit Committee checklist with some recommendations in relation to succession planning as a result of members' terms ending and a review of the timetable of meetings. Training sessions are scheduled at the end of ARAC meetings to aid understanding of current topics. The ARAC members conducted a session with HTA staff to create awareness of its role within the HTA.

Potential conflicts of interest are managed by all Authority members, and staff, declaring in a register of interests any company directorships and other significant interests held by them or their close family and friends which may conflict with their HTA responsibilities.

Members also declare their interest in any items being discussed at Authority and ARAC meetings. The Chair decides whether there is a conflict of interest and whether the Member concerned should remain involved in the discussion.

The executive

The executive implements the policy and strategic goals set by the Authority. It is led by the SMT consisting of the Chief Executive and three Directors.

The SMT meets weekly to consider a regular programme of business, ad hoc items and to exchange information. The SMT provides leadership to the staff of the HTA and makes decisions on how the strategies agreed by the Authority are to be implemented. The regular programme of business includes finance reports and reviews of the strategic risk register.

The HTA Management Group (HTAMG) consists of the SMT and the Heads of functions (the next level of management). This group meets monthly to review performance and operational risk, agree business plans and projects. Every quarter HTAMG considers operational risks alongside strategic risks.

The Accounting Officer follows the requirements of *Managing Public Money* and the delegations issued by the DHSC. To ensure compliance with the Framework Agreement agreed with DHSC the HTA ensures:

- the provision of the HTA's strategic and business plans for approval by the DHSC

- that the HTA submits quarterly performance and risk reports to the timetable outlined by the DHSC and other returns (e.g. finance and headcount) as required
- participation in quarterly accountability reviews held between the HTA's SMT and the senior department sponsor

Whistleblowing arrangements

The HTA's Whistleblowing policy sets out how any concerns can be raised by staff and what action would be taken. It aims to reassure staff that they should raise concerns openly and that there will be no repercussions for them if they raise concerns in good faith. The policy has been communicated to staff through newsletters and all staff meetings.

As well as line management and HR channels, the HTA has both a staff and Authority Member Freedom to Speak Up champion with whom staff can raise concerns. Contact details for the DHSC, National Audit Office (NAO) and the Whistleblowing Helpline are also provided.

During the year, there have been no concerns raised under the whistleblowing arrangements. The position is reported to ARAC at each meeting. Staff raise issues and make suggestions as part of day to day working in line with the culture at the HTA.

The control framework

The HTA understands the importance of risk management and internal control. All members of the Authority and the executive have responsibility for risk management.

The Authority is ultimately responsible for overseeing management of the HTA's strategic risks. The Authority is supported by the ARAC and monitors risks through reports from the executive and quarterly updates of the strategic risk register. The Chief Executive is responsible for providing leadership for management of risk within the organisation, supported by the Director of Resources, and all members of the SMT are responsible for managing the strategic risks that may impact the delivery of policies and objectives in their areas of work. Heads of functions manage the operational risks to the delivery of their areas of work, reporting to the HTAMG monthly.

There is an ongoing process designed to:

- identify and prioritise the risks to the achievement of HTA policies and aims and objectives
- evaluate the likelihood of those risks being realised, the possibility of new risks emerging and the impact should they be realised
- manage them efficiently, effectively and economically

The HTA Risk Management Strategy and Policy sets out the principles and approach to managing risk at the HTA. In the new business year the Risk Management Policy will undergo a significant review alongside the Strategic Risk Register. Training on management of risk will also be conducted to ensure existing and new Heads of function are aware of both the policy and process.

In order to ensure proper procedures are consistently followed, the control framework also includes policies and standard operating procedures that are reviewed and updated regularly. During the last quarter of the 2018/19 business year a detailed review of the governance structure around our policies commenced. There is also training and oversight by line managers.

This framework has been in place in the HTA for the year ended 31 March 2019 and up to the date of approval of the Annual Report and Accounts, and accords with HM Treasury guidance. The framework will continue to be refined and enhanced in order to ensure the HTA meets best practice for an established public body. The HTA will build on advice from our external and internal auditors as well as other professional sources to ensure it remains fit for purpose to meet the changing nature of our business.

The HTA is aware of the Macpherson report but does not use analytical models that inform government policy.

Risk assessment

The HTA has six strategic risks, five which have been present for some time and the sixth newly added in the latter part of the 2018/19 business year. The focus causes and effects and seriousness of the original five risks have varied. The sixth risk relates to benefits achieved from the impending organisational transformation programme. Two strategic risks are amber rated, the other four are yellow³.

The first amber risk is failure to manage expectations of regulation, which has been assessed at that level throughout the year. This risk arises through the potential for misperceptions of the HTA's regulatory reach and limitations in the current legislation. We also continue to communicate our remit to stakeholders and the public 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.

Failure to utilise our capabilities effectively is also an amber risk. This risk concerns how we deploy our staff and use data and business technology. During the year we have identified a lack of consistency in the way staff follow inspection process. We are mitigating against this by improving our induction procedures and providing training to all staff on report writing. There has been significant progress with delivering our People Strategy, with more activities planned in 2019/20. We will also develop plans for using our data better in 2019/20 which is incorporated into the Transformation programme. In the last quarter of the year we carried out a test of our Critical Incident Plan with lessons learnt papers tabled at the meeting of ARAC.

³ Used in risk prioritisation. Risks are scored and fall into one of four groups (Primary, Contingency, House-keeping and Negligible). The Amber risk falls into the Contingency group which means immediate action is taken and are regularly monitored. The yellow risk (house-keeping group) are monitored by management.

Previously staff turnover and capacity were a key contributory factor to several of the strategic risks, in particular our ability to carry out our statutory remit. During 2018/19 the appointment of a number of new highly qualified and experienced Regulation Managers (RMs) increased our capacity and strengthened our regulatory capability. These new recruits have completed their induction training and are now being fully deployed. In addition to the personal reasons individuals have for leaving, pay restrictions and pay levels at the HTA and the limited opportunities for progression are an ongoing cause of turnover. The HTA continues to offer other benefits and opportunities that are perceived as valuable to retain staff.

Failure to manage an incident and insufficient financial resources and the new risk of failure to achieve the benefits of the organisational transformation programme are the remaining risks and have been rated yellow at the end of this financial year.

Assurance sources are identified for all risks and these reports and feedback provide assurance to the SMT and the Authority that the controls in place are as expected and that the risks are as stated.

Pensions

As an employer with staff entitled to membership of the NHS Pension Scheme, control measures are in place to ensure all employer obligations contained within the Scheme regulations are complied with. This includes ensuring that deductions from salary, employer contributions and payments into the Scheme are in accordance with Scheme rules, and that member Pension Scheme records are accurately updated in accordance with the timescales detailed in regulations.

Data security

In accordance with our responsibilities under Schedule 2 (paragraph 16) of the HT Act and the provisions of the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the HTA has in place various robust and specific arrangements to maintain high standards of information security, including data protection. These include an information governance and cyber risk policy that applies to all staff, Members and contractors. There were no reportable personal data losses in 2018/19

A Cyber Security audit was carried out in 2018/19 by internal audit. The audit was a follow-up to the Cyber Security review conducted in November 2017. Following the 2017 review six recommendations were made (3 high level and 3 medium level). The follow-up audit sought to determine progress on implementation of the recommendations and assess whether controls and processes were strengthened. Of the six, five were successfully implemented with one high-level recommendation still outstanding. This recommendation relates to systems and processes around staff joiners and leavers.

Last year an internal audit review of GDPR preparedness was conducted with a follow-up audit undertaken in February 2019. The follow-up audit provided assurance that we have robust and effective governance and risk management arrangements in place and these demonstrates our

high level of compliance with GDPR. We received a moderate assurance rating for this audit and are actively addressing with ARAC the outstanding recommendations and associated actions.

The Director of Resources holds the role of Senior Information Risk Owner (SIRO). This is one of the requirements to strengthen controls around information security set out in the report of the Data Handling Review, which was carried out in 2008 for the Cabinet Office. The SIRO makes an annual report of compliance with the requirements for protecting information and an assessment of information risk management to the Accounting Officer and the ARAC which contributes to this Statement.

The HTA conducts an annual review of its arrangements against the Cabinet Office's mandatory requirements and reports compliance to the ARAC and DHSC using the Security Policy Framework and the 10 steps to cyber security. For the relevant requirements, there are no areas of non-compliance that put information security at risk.

Accounting Officer Responsibilities and assurance

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. My review of the effectiveness of the system of internal control is informed by the work of the internal auditors, the executive directors within the organisation who have responsibility for the development and maintenance of the internal control framework, risk management reports and comments made by the external auditors in their management letter and other reports. I have been advised on the implications of the result of the reviews of the effectiveness of the system of internal control by the Authority's ARAC and appropriate plans to address any weaknesses and ensure continuous improvement of the system are in place.

During the year, the HTA engaged its internal auditors to review the areas of GDPR compliance, Cyber Security (as mentioned above), Key Regulatory processes, Stakeholder Engagement and Records Management. There have been 3 high priority recommendations in relation to cyber security and these have been remedied. The Records Management audit provided limited assurance in this area, with 5 high level recommendations. We acknowledge the importance of these recommendations and action is already underway to ensure we resolve these issues in the early part of the 2019/20 business year.

Where high, medium or low priority recommendations have been made I am assured that appropriate action plans are in place and good progress is being made against the agreed actions. The Head of Internal Audit has concluded that they can give "moderate assurance to the Accounting Officer that the HTA has had adequate and effective systems of control, governance and risk management in place for the reporting year 2018/19".

From this, internal audit's annual opinion of moderate assurance, and the other sources stated on the risk registers (Authority reports, reviews with staff and feedback from DHSC and stakeholders), I am confident that the necessary assurances have been gained over the key areas, as set out above.

This enables me to confirm that the HTA's systems are effective and working, to ensure that we have, and continue to, fulfill our remit and our objectives.

There have been no significant internal control problems in the HTA up to 31 March 2019 and up to the date of this report.

Allan Marriott-Smith
Accounting Officer
Human Tissue Authority

Date: DD MMM YYYY

Remuneration report

This report contains details on the remuneration of members of our Authority and the Executive for the year ended 31 March 2019. It is based upon the provisions contained within the Government Financial Reporting Manual 2018/19. It also provides an analysis of staff and sickness absence data.

Audit

Specific areas of the Remuneration report are audited by NAO, the HTA's external auditors. These sections cover salary and pension data in the tables, non-cash benefits and amounts payable to third parties for services of senior staff.

Salary and benefits in kind of Authority Members

Members of the Authority receive an annual remuneration that is agreed by the Secretary of State for Health. This remuneration does not include any pension entitlements. Any increase or change to the remuneration is notified to the HTA by its sponsor department, the DHSC. Members also receive travel and subsistence expenses which are deemed a benefit in kind (see later section).

Overleaf are the payments made to Members in the financial year 2018/19 and those benefits in kind that are subject to tax and national insurance.

Trade Unions

Under the Facility Time Publication Requirements Regulations of 2017, the HTA is required to disclose the number of staff, cost and time spent on facility time by an employee who is a relevant union official if it meets certain criteria.

The HTA does not employ any staff who devote time to a trade union.

The Authority (Audited)

Authority Member		2018/19			2017/18		
Name	Role/Type	Salary range	Expenses (to nearest £100) ⁴	Total	Salary range	Expenses (to nearest £100)	Total
		£'000s	£	£'000s	£'000s	£	£'000s
Nicola Blackwood ⁵	Chair (Lay)	30-35	0	30-35	N/a	N/a	N/a
Sharmila Nebhrajani OBE	Chair (Lay)	N/a	N/a	N/a	35-40	1,900	40-45
William Horne ⁶	Lay	15-20	3,200	15-20	5-10	3,100	10-15
Amanda Gibbon	Chair of ARAC (Lay)	10-15	0	10-15	10-15	0	10-15
Hossam Abdalla	Professional	5-10	0	5-10	5-10	0	5-10
Professor Andy Hall	Professional	5-10	2,000	5-10	5-10	2,200	10-15
Professor Anthony Warrens	Professional	5-10	100	5-10	5-10	100	5-10
Glenn Houston	Lay	5-10	3,200	10-15	5-10	3,500	10-15
Dr Lorna Williamson	Professional	5-10	200	5-10	5-10	200	5-10
Professor Penney Lewis	Lay	5-10	200	5-10	5-10	100	5-10
Dr Stuart Dollow	Professional	5-10	0	5-10	5-10	0	5-10
The Right Reverend Graham Usher	Lay	5-10	700	5-10	5-10	600	5-10
Professor Dame Sally Macintyre	Lay	5-10	2,200	10-15	5-10	1,300	5-10

⁴ Members' expenses relate solely to their attendance at HTA committees, meetings and training events. Since our Authority members are located across the UK, the disparity in expenses paid to individual Authority members reflects their geographic location and the number of committees and meetings they have attended during 2018/19.

⁵ Nicola Blackwood resigned her post on 9 January 2019

⁶ William Horne is acting Chair from 10 January 2019

The Senior Management Team

Name	Position	Appointed	Until
Allan Marriott Smith	Chief Executive	6 July 2015	N/a
Richard Sydee ⁷	Director of Resources	1 November 2016	N/a
Nicolette Harrison	Director of Regulatory Delivery	4 June 2018	N/a
Christopher Birkett (seconded) ⁸	Director of Regulation	4 December 2017	30 June 2018
Hazel Lofty	Director of Regulatory Development	8 April 2018	N/a

The remuneration for SMT is agreed by the HTA Remuneration Committee and DHSC, following the very senior managers' pay framework and in-line with HM Treasury requirements.

Later sections provide details of the remuneration, pension interests and benefits in kind of SMT.

These details are shown in accordance with the Financial Reporting Manual (FReM). 'Salary' includes gross salary; performance pay or bonuses; overtime; reserved rights to London weighting or London allowances; recruitment and retention allowances; private office allowances and any other allowance to the extent that it is subject to UK taxation

Staff remuneration policy

The HTA provides for staff salaries to be uplifted annually in August. Any uplifts are in line with HM Treasury pay guidance and approved by DHSC. The HTA have made awards each year to eligible staff who are performing satisfactory that do not exceed 1% of the pay-bill.

Duration of contract, notice periods and termination payments on contracts of employment

Members of staff in Bands 1 – 2 (Assistants and Officers) are required to give the HTA six weeks' notice for termination of contract. Members of staff in Bands 3 – 4 (Managers and Heads) and Directors are required to give three months' notice. The HTA is required to give the notice period of between one and twelve weeks in line with the Employment Rights Act 1996.

Termination payments are made only in appropriate circumstances and may arise where staff are not required to work their notice period. No payments were made in 2018/19 (and none in 2017/18).

⁷ Richard Sydee is shared with the HFEA and is seconded to HTA 2.5 days per week.

⁸ Seconded to Director of Regulation post to cover period recruiting to this post

Benefits in kind

The monetary value of benefits in kind covers any benefits provided by the employer and treated by the HMRC as a taxable emolument. The HTA has agreed a PAYE Settlement Agreement (PSA) with HMRC for taxable emoluments of HTA Authority Members. This covers travel and subsistence.

Information regarding travel and subsistence claimed by Authority Members and senior management has been published on the Authority's website www.hta.gov.uk

No benefits in kind were received by senior staff members in 2018/19 or 2017/18.

Senior Management remuneration (Audited)

Senior Manager	Salary	Bonus	B-i-K	Pension Benefits ⁹	Total	Salary	Bonus	B-i-K	Pension Benefits	Total
	2018/19					2017/18				
	£000s	£000s	£	£000s	£000s	£000s	£000s	£	£000s	£000s
Allan Marriott-Smith	115-120	0-5	0	50.0-52.5	165-170	110-115 (Fte 115-120)	0	0	0	110-115 (Fte 115-120)
Sarah Bedwell ¹⁰	N/a	N/a	N/a	N/a	N/a	65-70 (Fte 90-95)	0	0	12.5-15.0	80-85 (Fte 90-95)
Nicolette Harrison	75-80 (Fte 90-95)	0	0	12.5-15.0	90-95 (Fte 90-95)	N/a	N/a	N/a	N/a	N/a
Christopher Birkett ¹¹	60-65 (Fte 90-95)	0	0	0	60-65 (Fte 90-95)	25-30 (Fte 85-90)	0	0	32.5-35	60-65 (Fte 85-90)
Richard ¹² Sydee	45-50 (Fte 90-95)	0	0	N/a	45-50 (Fte 90-95)	45-50 (Fte 90-95)	N/a	N/a	N/a	45-50 (Fte 90-95)
Hazel Lofty	90-95	0	0	65-67.5	155-160	40-45 (Fte 80-85)	0	0	27.5-30.0	65-70 (Fte 80-85)

⁹The value of pension benefits accrued during the year is calculated as (the real increase in pension multiplied by 20) plus (the real increase in any lump sum) less the contributions made by the individual.

¹⁰ Sarah Bedwell left the HTA in December 2017

¹¹ Staff were seconded into these roles part way through the year and this is reflected in the salary shown

¹² Richard Sydee is seconded to the HTA from the HFEA for 2.5 days a week and this is reflected above. His full salary and pension are accounted for by the HFEA

Victoria Marshment ¹³	N/a	N/a	N/a	N/a	N/a	40-45 (Fte 85-90)	0	0	0	40-45 (Fte 85-90)
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The factors used to calculate CETV increased on 29 October 2018. This has affected the calculation of the real increase in CETV.

Median pay and multiples (Audited)

Band of highest paid director's gross salary only	2018/19 (£'000) 115 -120 (full year equivalent)	2017/18 (£'000) 115 - 120 (full year equivalent)
Median remuneration of staff	43.0	40.9
Ratio	2.73	2.87

Under reporting requirements, public sector bodies are required to disclose the relationship between the total remuneration of the highest-paid Director in their organisation and the median remuneration of the organisation's workforce including temporary staff.

The highest paid Director for this comparison was the Chief Executive. The increase in the median remuneration of staff and subsequent reduction in the ratio is due in part to recruitment of new staff members towards the higher end of the pay-band for managers. We are a London-based small expert organisation whose work requires scientific and other professional or graduate-level skills. Consequently, median pay remains higher than that for a number of other public sector bodies.

In 2018/19, no employees received remuneration in excess of the highest paid director (2017/18, nil). Remuneration as at 31 March 2019 ranged from £23,000 to £119,000 (2017/18 £23,000 to £118,000).

Total remuneration includes salary, non-consolidated performance related pay, benefits-in-kind as well as severance payments. It does not include employer pension contributions and the cash equivalent transfer value of pensions.

¹³ Victoria Marshment left the HTA in September 2017

Staff costs (Audited)

The HTA is structured as follows: twelve Authority Members including the Chair and an Executive of 49 staff. For 2018/19, the HTA staff costs were:

	Permanently employed staff	Members	Seconded Staff	Temporary staff	Total 2018/19	Total 2017/18
	£	£	£	£	£	£
Wages and salaries	2,061,447	134,424	151,598	27,240	2,374,709	2,324,824
Social security costs	230,055	5,522	17,632	0	253,209	252,804
Pension costs	247,476	0	25,900	0	273,376	249,887
Subtotal	2,538,978	139,946	195,130	27,240	2,901,294	2,827,515
Less recoveries in respect of outward secondments	0	0	(91,403)	0	(91,403)	(61,649)
Total net costs	2,538,978	139,946	103,727	27,240	2,809,891	2,765,866

For 2018/19 all contributions were paid to the NHSPS at rates prescribed by HM Treasury. The current employer's rate for the NHSPS is 14.38 per cent of pensionable pay according to salary level.

Average number of persons employed (Audited)

The average number of whole-time equivalent (Wte) persons employed or outwardly seconded during the year was as follows.

	Permanently employed staff	Seconded Staff	Total 2018/19	Total 2017/18
SCS	3	0	3	3
Other	43	2	45	44
Total staff	46	2	48	47
Temporary staff	0	0	1	3

Staff reported in the above table are only those directly employed by the HTA. During the year, two staff were on secondment: one to the DHSC until February 2019, the other to the HFEA for approximately half of their time. As at 31 March 2019, the HTA employed 50 WTE staff (2017/18, 48).

Expenditure on consultancy

During the year we spent £159,011 on consultancy services which includes legal fees, technical consultancy and HR consultancy.

Sickness and absences

During the year ended 31 March 2019 the total number of whole time equivalent days (Wte) lost to sickness absence was 112 days (2017/18 110 days). This information is disclosed in accordance with the *Government Financial Reporting Manual* (FReM).

Off-payroll assurance statement

The HTA seeks to ensure that any engagements of more than six months in duration, for more than a daily rate of £245, include contractual provisions that allow us to seek assurance regarding the income tax and National Insurance Contribution obligations of the person engaged, and to terminate the contract if that assurance is not provided. During 2018/19 there were no engagements of this nature.

Staff pensions

Since 1 December 2009, employees have been covered by the provisions of the National Health Service (NHS) Pension Scheme.

NHS pension scheme

Past and present employees are covered by the provisions of the NHS Pension Schemes. Details of the benefits payable and rules of the Schemes can be found on the NHS Pensions website at www.nhsbsa.nhs.uk/pensions. Both are unfunded defined benefit schemes that cover NHS employers, GP practices and other bodies, allowed under the direction of the Secretary of State in England and Wales. They are not designed to be run in a way that would enable NHS bodies to identify their share of the underlying scheme assets and liabilities. Therefore, each scheme is accounted for as if it were a defined contribution scheme: the cost to the NHS body of participating in each scheme is taken as equal to the contributions payable to that scheme for the accounting period.

In 2018/19 HTA employer's contributions were £273,376 (2017/18 £249,887) at a rate of 14.38% of pensionable pay.

In order that the defined benefit obligations recognised in the financial statements do not differ materially from those that would be determined at the reporting date by a formal actuarial

valuation, the FReM requires that “the period between formal valuations shall be four years, with approximate assessments in intervening years”. An outline of these follows:

a) Accounting valuation

A valuation of scheme liability is carried out annually by the scheme actuary (currently the Government Actuary's Department) as at the end of the reporting period. This utilises an actuarial assessment for the previous accounting period in conjunction with updated membership and financial data for the current reporting period, and is accepted as providing suitably robust figures for financial reporting purposes. The valuation of the scheme liability as at 31 March 2018, is based on valuation data as 31 March 2019, updated to 31 March 2018 with summary global member and accounting data. In undertaking this actuarial assessment, the methodology prescribed in IAS 19, relevant FReM interpretations, and the discount rate prescribed by HM Treasury have also been used.

The latest assessment of the liabilities of the scheme is contained in the report of the scheme actuary, which forms part of the annual NHS Pension Scheme Accounts. These accounts can be viewed on the NHS Pensions website and are published annually. Copies can also be obtained from The Stationery Office

b) Full actuarial (funding) valuation

The purpose of this valuation is to assess the level of liability in respect of the benefits due under the schemes (taking into account recent demographic experience), and to recommend contribution rates payable by employees and employers.

The latest actuarial valuation undertaken for the NHS Pension Scheme was completed as at 31 March 2016. The results of this valuation set the employer contribution rate payable from April 2019. The Department of Health and Social Care have recently laid Scheme Regulations confirming that the employer contribution rate will increase to 20.6% of pensionable pay from this date.

The 2016 funding valuation was also expected to test the cost of the Scheme relative to the employer cost cap set following the 2012 valuation. Following a judgment from the Court of Appeal in December 2018 Government announced a pause to that part of the valuation process pending conclusion of the continuing legal process.

Pension Benefits – Senior Management Team (Audited)

Name of Officer	Real increase in pension at age 60 (a)	Real increase in pension lump sum at age 60 (b)	Pension at 31/03/2019 (c)	Lump sum at age 60 at 31 March 2019 (d)	CETV at 31/03/2019 (e)	Real increase in CETV as funded by employer 2018/19 (f)	CETV at 31/03/2018 (g)	Employers contribution to stakeholder pension
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£,000
Allan Marriott Smith	2.5-5.0	N/a	15-20	N/a	240	50	168	0
Christopher Birkett	0-2.5	-2.5-0	15-20	40-45	285	1	240	0
Nicolette Harrison	0-2.5	N/a	0-5	N/a	20	6	0	0
Hazel Lofty	2.5-5.0	N/a	10-15	N/a	139	67	58 ¹⁴	0
Richard Sydee ¹⁵	N/a	N/a	N/a	N/a	N/a	N/a	N/a	0

The factors used to calculate a CETV increased on 29 October 2018. This affects the calculation of the real increase in CETV but does not affect the real increase in pension benefits.

Cash equivalent transfer value (CETV)

Column (f) reflects the increase in cash equivalent transfer value effectively funded by the employer. It takes account of the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

A cash equivalent transfer value is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the staff member's accrued benefits and any contingent spouse's pension payable from the scheme. A cash equivalent transfer value is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the pension scheme, not just their service in a senior capacity, to which disclosure applies. The cash equivalent transfer value figures, and from 2003/04 the other pension details, include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the National Health Service Pension Scheme /Principal Civil Service Pension Scheme arrangements and for which, the Civil Superannuation Vote has received a transfer payment commensurate to the additional pension liabilities being assumed.

¹⁴ Figures re-stated due to updated information

¹⁵ Richard Sydee is a member of the Civil Service Pension Scheme and is accounted for with the financial statements of the HFEA

They also include any additional pension benefit accrued to the member as a result of their purchasing additional years of pension service in the scheme at their own cost.

Cash equivalent transfer values are calculated within the guidelines and framework prescribed by the Institute and Faculty of Actuaries, as advised by the actuary to the Principal Civil Service Pension Scheme.

The real increase in the value of the CETV

This takes account of the increase in accrued pension due to inflation and contributions paid by the officer and are calculated using common market valuation factors for the start and end of the period.

Allan Marriott-Smith
Accounting Officer
Human Tissue Authority

Date: DDMMYYYY

Parliamentary accountability and audit report

Accountability (the details below are subject to audit)

Fees charging and cost allocation

Our licence fees are set to recover the full cost incurred in the granting of licences and regulation. The table below shows the income from each sector, other income for licensing activities and the costs of licensing activities. The income shown is that which relates to licensable activities and therefore excludes an element of rent and income from secondments.

We confirm that we have complied with the cost allocation and charging requirements as set out in HM Treasury's guidance.

SECTOR	31 March 2019	31 March 2018
	£	£
Applications	64,610	45,553
Anatomy	93,000	88,675
Post Mortem	1,151,567	1,052,721
Public Display	20,175	18,742
Research	639,820	589,267
Human Application	1,394,968	1,254,586
Organ Donation/ Transplantation	290,270	246,700
Other income for licensing activities ¹⁶	347,325	392,149
Total Income from contracts with Customers¹⁷	4,001,735	3,688,393
Costs allocated to licensing activities	(3,934,911)	(3,592,689)
Surplus/(Deficit) on activities	66,824	95,704

In addition, there are elements of our work that do not relate directly to the cost of regulating the sectors above. The DHSC accordingly contributes to the funding of these activities through the provision of Grant-in-aid.

Losses and special payments

Losses and special payments are items that Parliament would not have contemplated when it agreed funds for the health service or passed legislation. By their nature they are items that ideally should not arise. They are therefore subject to special control procedures compared with the generality of payments. They are divided into different categories, which govern the way that individual cases are handled.

There were no losses or special payments of £300,000, either individually or in aggregate, made in 2018/19.

Remote contingent liabilities

There were no remote contingent liabilities in 2018/19.

¹⁶ Figure includes income from Devolved Governments, staff secondments and rental of excess office space.

¹⁷ This is the total income allocated to licensable activities and therefore differs from that on page 17.

THE CERTIFICATE AND REPORT OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSES OF PARLIAMENT

Opinion on financial statements

I certify that I have audited the financial statements of the Human Tissue Authority (“the Authority”) for the year ended 31 March 2018 under the Human Tissue Act 2004. The financial statements comprise: the Statements of Comprehensive Net Expenditure, Financial Position, Cash Flows, Changes in Taxpayers’ Equity; and the related notes, including the significant accounting policies. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Accountability Report that is described in that report as having been audited.

In my opinion:

- the financial statements give a true and fair view of the state of the Authority’s affairs as at 31 March 2018 and of its net expenditure for the year then ended; and
- the financial statements have been properly prepared in accordance with the Human Tissue Act 2004 and Secretary of State directions issued thereunder.

Opinion on regularity

In my opinion, in all material respects the income and expenditure recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Basis of opinions

I conducted my audit in accordance with International Standards on Auditing (ISAs) (UK) and Practice Note 10 ‘Audit of Financial Statements of Public Sector Entities in the United Kingdom’. My responsibilities under those standards are further described in the Auditor’s responsibilities for the audit of the financial statements section of my certificate. Those standards require me and my staff to comply with the Financial Reporting Council’s Revised Ethical Standard 2016. I am independent of the Authority in accordance with the ethical requirements that are relevant to my audit and the financial statements in the UK. My staff and I have fulfilled our other ethical responsibilities in accordance with these requirements. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Responsibilities of the Accounting Officer for the financial statements

As explained more fully in the Statement of Accounting Officer’s Responsibilities, the Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Auditor's responsibilities for the audit of the financial statements

My responsibility is to audit, certify and report on the financial statements in accordance with the Human Tissue Act 2004.

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (UK), I exercise professional judgment and maintain professional scepticism throughout the audit. I also:

- identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Authority's internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may cause the entity to cease to continue as a going concern.
- evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

In addition, I am required to obtain evidence sufficient to give reasonable assurance that the income and expenditure reported in the financial statements have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

Other Information

The Accounting Officer is responsible for the other information. The other information comprises information included in the annual report, other than the parts of the Accountability Report described in that report as having been audited, the financial statements and my auditor's report thereon. My opinion on the financial statements does not cover the other information and I do not express any form of assurance conclusion thereon. In connection with my audit of the financial statements, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or my knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work I have performed, I conclude that there is a material misstatement of this other information, I am required to report that fact. I have nothing to report in this regard.

Opinion on other matters

In my opinion:

- the parts of the Accountability Report to be audited have been properly prepared in accordance with Secretary of State directions made under the Human Tissue Act 2004;
- in the light of the knowledge and understanding of the Authority and its environment obtained in the course of the audit, I have not identified any material misstatements in the Performance Report or the Accountability Report; and
- the information given in the Performance Report and the Accountability Report for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the parts of the Accountability Report to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.

Report

I have no observations to make on these financial statements.

Sir Amyas C E Morse **Date 21 June 2018**
Comptroller and Auditor General

National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

Financial statements

Human Tissue Authority
Annual Report and Accounts 2018/19

Statement of Comprehensive Net Expenditure for the year ended 31 March 2019

	Note	<u>31-Mar-19</u> £	<u>31-Mar-18</u> £
Income from sale of goods and services			
Revenue from contracts with customers	4	3,654,410	3,296,244
Other Operating Income	4	525,559	588,114
Total operating income		<u>4,179,969</u>	<u>3,884,358</u>
Expenditure			
Purchase of goods and services	3	893,144	626,379
Staff costs	3	2,901,294	2,827,515
Depreciation, amortisation and impairment charges	3	187,231	177,003
(Gain)/Loss on disposal of fixed assets	3	(1,350)	9,095
Reversal of accrued income	3	86,254	
Other operating expenditure	3	921,065	966,284
Total operating expenditure		<u>4,987,638</u>	<u>4,606,276</u>
Net (Income)/Expenditure		<u>807,669</u>	<u>721,918</u>

There are no items of expenditure that should be shown as Other Comprehensive Expenditure.

Notes 1 to 14 form part of these financial statements

Human Tissue Authority
Annual Report and Accounts 2018/19

**Statement of Financial Position as at
31 March 2019**

		<u>31-Mar-19</u>	<u>31-Mar-18</u>
	Note	<u>£</u>	<u>£</u>
Non-current assets:			
Property, plant and equipment	5	319,848	436,561
Intangible assets	6	145,378	173,585
Total non-current assets		<u>465,226</u>	<u>610,146</u>
Current assets:			
Trade and other receivables	8	480,944	183,542
Cash and cash equivalents	9	3,448,075	3,411,837
Total current assets		<u>3,929,019</u>	<u>3,595,379</u>
Total assets		<u>4,394,245</u>	<u>4,205,525</u>
Current liabilities			
Trade and other payables	10	634,206	340,817
Total current liabilities		<u>634,206</u>	<u>340,817</u>
Total assets less current liabilities		3,760,039	3,864,708
Total assets less total liabilities		<u>3,760,039</u>	<u>3,864,708</u>
Taxpayers' Equity			
I&E Reserve		3,760,039	3,864,708
Total equity		<u>3,760,039</u>	<u>3,864,708</u>
		-	

The notes on pages 58 to 70 form part of the accounts

The financial statements on pages 55 to 71 were signed on behalf of the Human Tissue Authority by:

(Signed)
Allan Marriott-Smith

(Accounting Officer)

DD-MMM-YYYY

Human Tissue Authority
Annual Report and Accounts 2018/19

**Statement of Cash Flows for the year ended
31 March 2019**

		31-Mar-19	31-Mar-18
		Total	Total
Note		£	£
Cash flows from operating activities			
		(807,669)	(721,918)
	3	175,841	177,003
		3,102	0
	3	(1,350)	9,095
	8	(297,402)	49,195
	10	293,389	39,097
		<u>(634,089)</u>	<u>(447,528)</u>
Cash flows from investing activities			
	5	(30,063)	(110,301)
	6	(3,960)	(71,940)
		1,350	0
		<u>(32,673)</u>	<u>(182,241)</u>
Cash flows from financing activities			
		703,000	1,050,000
		<u>703,000</u>	<u>1,050,000</u>
Net increase/(decrease) in cash and cash equivalents in the period			
		<u>36,238</u>	<u>420,231</u>
Cash and cash equivalents at the beginning of the period			
	9	3,411,837	2,991,606
Cash and cash equivalents at the end of the period			
		<u>3,448,075</u>	<u>3,411,837</u>

The notes on pages 58 to 70 form part of the accounts

Human Tissue Authority Annual Report and Accounts 2018/19

Statement of Changes in Taxpayers' Equity For the year ended 31 March 2019

		I & E Reserve
	Note	£
Balance at 1 April 2017		3,536,626
Changes in taxpayers' equity for 2017/18		
Retained surplus/(Deficit)		(721,918)
Total recognised Income and expense for 2017/18		(721,918)
Grant from sponsor department		1,050,000
Balance at 31 March 2018		3,864,708
Changes in taxpayers' equity for 2018/19		
Retained surplus/(Deficit)		(807,669)
Total recognised Income and expense for 2018/19		(807,669)
Grant from sponsor department	1.8	703,000
Balance at 31 March 2019		3,760,039

The notes on pages 58 to 70 form part of the accounts

Human Tissue Authority Annual Report and Accounts 2018/19

Notes to the accounts

These notes form an integral part of and should be read in conjunction with the accompanying financial statements.

1. Statement of accounting policies

These financial statements have been prepared pursuant to the Human Tissue Act 2004, Schedule 2 (paragraph 16) and in accordance with the 2018-19 Government Financial Reporting Manual (FReM) issued by HM Treasury. The accounting policies contained in the FReM apply International Financial Reporting Standards (IFRS) as adapted or interpreted for the public sector context. Where the FReM permits a choice of accounting policy, the accounting policy which is judged to be most appropriate to the particular circumstances of the Human Tissue Authority (HTA) for the purposes of giving a true and fair view has been selected. The particular policies adopted by the HTA for the year ended 31 March 2019 are described below. They have been applied consistently in dealing with items that are considered material to the accounts.

1.1 Accounting Convention

The accounts have been prepared on the going concern basis under the historical cost convention.

1.2 Accounting Policies and estimates

There are changes to accounting policies arising from IFRS 9 and 15. The effect of introduction of the standards have a minimal impact on these financial statements.

There are no voluntary changes to accounting policies that have had an impact in these accounts.

The following Accounting policies have been applied to the accounts for 2018/19.

1.3 Non-current assets

Non current assets are property, plant and equipment and intangible assets including the costs of acquiring or developing computer systems and software. Only items or groups of related items costing £5,000 or more are capitalised. Items costing less are treated as revenue expenditure in the year of acquisition.

All property, plant and equipment and intangible assets held by the HTA at 31 March 2019 are carried in the Statement of Financial Position at depreciated (property, plant and equipment) or amortised (intangible assets) historical cost. The depreciated or amortised historical cost is used as a proxy for fair value, for the classes of assets listed below, since the useful life over which the asset class is depreciated or amortised is considered to be a realistic reflection of the consumption of that asset class. Depreciation and amortisation are provided on a monthly basis from the date of deemed economic benefit, at rates calculated to write off the costs of each asset evenly over its expected useful life.

Plant and Equipment

Information Technology	4 years
Furniture and fittings	3 or 5 years
Refurbishment Costs	5 or 10 years

Intangible assets

Information Technology	5 years
Websites	3 years

1.4 Assets under Construction (Development expenditure)

These are the costs related to the upgrade of HTA systems whether that be the hardware or applications that are yet to be deployed. These assets are not depreciated.

1.5 Impairments

IFRS 9 requires the recognition of impairments on a forward looking expected credit loss model. HMT has interpreted the provisions in the standard for calculating the expected credit loss to mandate the use of the simplified approach. This means that loss allowance at initial recognition is equal to the lifetime expected credit loss.

An assessment of all of the HTA's financial assets has resulted in movement in the value of the impairment of receivables. In carrying out the assessment of licence fee debtors, account is taken of the sector, economic climate (past and future) and previous losses. A default rating (weighted) is applied to debts aged over period of 28, 42 and 56 days. An impairment for expected credit loss of £11,390 was charged to the SoCNE.

1.6 Critical accounting judgements and key sources of estimation uncertainty

In the application of the HTA accounting policies, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered relevant. Actual results may differ from those estimates. The estimates and underlying assumptions are reviewed annually. Revisions to accounting estimates are recognised in the period of the revision and future periods if the revision affects both current and future period.

Due to an ongoing dispute between the tenants of our office accommodation at 151 Buckingham Palace Road and the leaseholders (recently transferred to Government Property Agency) we have reviewed the accrued income due to us through a sub-lease arrangement we hold with another tenant. The dispute is based around the addition of a VAT element which tenants had believed was already contained within the agreed charge.

The sub lease arrangement assumes a direct pass through of all costs based on the proportion of the space provided to the tenant. Recent correspondence has highlighted that our tenant is unlikely to agree to meet the VAT element of our sub lease arrangement, which has led to us impairing the existing income accrual. The sum of £147k has been debited to the Statement of Net Expenditure.

1.7 Government Grants and Grant-in-aid

Grant-in-aid (GIA) received is used to finance activities and expenditure which support the statutory and other objectives of the HTA. Grant-in-aid is treated as financing and credited to the income and expenditure reserve, because it is regarded as contributions from a controlling party.

1.8 Leases

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the income and expenditure account on a straight line basis over the period of the lease. Rents for those leasehold properties which are held under operating leases are charged to expenditure.

Rental income from operating leases is recognised on a straight-line basis over the term of the lease. Initial direct costs incurred in negotiating and arranging an operating lease are added to the carrying amount of the leased asset and recognised on a straight-line basis over the lease term.

1.9 Income

IFRS 15 - Revenue from contracts with customers came into force for accounting periods beginning on or after 1 January 2018. It supersedes IAS 18 - Revenue. The standard is prescriptive as to what constitutes a contract. Assessment of the impact of IFRS 15 was carried out and was found to have very little impact on how we recognise income.

Our main source of income takes the form of fees for licences from establishments which have human tissue on their premises and fixed fees from devolved administrations, for work on policies and transplants.

There is a contractual arrangement between the HTA and its establishments as per IFRS 15 and the 5-step model. Performance obligation between the HTA and Establishments is where the establishments are obligated to comply with certain standard conditions and the HTA will grant them a licence. A transaction price (licence fee) is chargeable which is different for each type of licence. Licences fees are charged for the financial year April through March reflecting regulatory activity being carried out. We recognise this income in the financial year it is invoiced. Other income may be recognised on an accruals basis when the goods or services are delivered or represent charges for staff seconded out. There has been no adjustment to the accounts for the cumulative effect of applying IFRS 15.

1.10 Employee benefits

Salaries, wages and employment-related payments are recognised in the period in which the service is received from employees. The cost of leave earned but not taken by employees at the end of the period is recognised in the financial statements to the extent that employees are permitted to carry forward leave into the following period.

1.11 Pensions

Past and present employees are covered by the provisions of the NHS Pensions Scheme (NHSPS). Details of the benefits payable under these provisions can be found on the NHS Pensions website at www.nhsbsa.nhs.uk/pensions. The Scheme is an unfunded, defined benefit scheme that covers NHS employers, General Practices and other bodies, allowed under the direction of the Secretary of State, in England and Wales. The Scheme is not designed to be run in a way that would enable NHS bodies to identify their share of the underlying Scheme's assets and liabilities. Therefore, the Scheme is accounted for as if it were a defined contribution scheme: the cost to the HTA of participating in the Scheme is taken as equal to the contributions payable to the Scheme for the accounting period.

1.12 Receivables

Receivables are non-derivative financial assets with fixed or determinable payments which are not quoted in an active market. They are included in current assets. The HTA's receivables comprise of cash at bank and in hand, NHS Receivables, prepayments and accrued income.

In addition to the above, recognition of impairments on an expected loss basis for financial assets is required. We are mandated to use the simplified approach which means recognition of lifetime expected credit losses are charged to the SoCNE.

1.13 Financial Instruments

The HTA's financial assets liabilities which arise from contracts for the sale or purchase of non-financial items (such as goods and services), which are entered into in accordance with the HTA's normal purchase, sale or usage requirements, are recognised when, and to the extent which, performance occurs i.e. when receipt or delivery of the goods or services are made. The HTA has simple financial assets/liabilities in the form of contract receivables and contract payables.

Under IFRS 9 a new approach to classification and measurement of financial assets and liabilities was introduced. Under the new classification, our receivables are classified according to how they are subsequently measured in this case at amortised cost using the 'business model test'.

1.14 Cash

Cash is cash in hand and deposits with any financial institution repayable without penalty on notice of not more than 24 hours. Cash equivalents would be investments that mature in 3 months or less from the date of acquisition and that are readily convertible to known amounts of cash with insignificant risk of change in value.

1.15 IFRS issued but not yet effective

The Treasury FReM does not require the following Standards and Interpretations to be applied in 2018/19. The application of the Standards as revised would not have a material impact on the accounts in 2017/18, were they applied in that year.

IFRS 16 Leases replaces IAS 17 and is effective for the public sector from 1 January 2020. The new standard amends the accounting for lessees, removing the distinction between recognising an operating lease (off balance sheet) and a finance lease (on balance sheet). The new standard requires recognition of most leases which last more than 12 months to be recognised on balance sheet. The know effect of applying IFRS 16 has not been applied as it is unlikely to have an effect as our lease term ends when IFRS 16 comes into force for FReM bodies.

2. Analysis of Net Expenditure by Segment

Under the definition of IFRS 8 the HTA is a single operating segment whose objectives are the licensing and inspection of premises involved in the storage and use of human tissue for purposes such as research, patient treatment, post-mortem examination, teaching and public exhibitions.

The HTA also gives approval for organ and bone marrow donations from living people.

The HTA charges fees for its licensing activities which, along with Grant-in-aid from the DH, its sponsoring body, are applied in pursuit of these objectives.

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3. Other Expenditure

	Notes	31-Mar-19 £	31-Mar-18 £
Staff Costs	3.1	2,901,294	2,827,515
Purchase of goods and services			
Computer running costs		304,315	228,459
Staff recruitment, training and welfare		134,965	60,636
Consultancy		50,199	21,172
Office and administration costs	(a)	40,806	23,136
Maintenance Contracts		50,973	43,519
Travel subsistence and hospitality		144,568	131,625
Conferences & Events		30,359	23,858
Stationery and publications		25,285	14,202
Auditors Remuneration	(b)	46,068	57,065
Provision for bad debts	(c)	(3,654)	(15,704)
Legal and professional fees		69,260	38,411
		<u>893,144</u>	<u>626,379</u>
Other operating costs			
Accommodation	(d)	823,272	884,484
Project Costs		68,077	56,165
Telecommunications		29,716	25,635
		<u>921,065</u>	<u>966,284</u>
Non-cash items			
Depreciation and amortisation		175,841	177,003
Impairments		11,390	0
(Gain)/Loss on disposal of non-current assets		(1,350)	9,095
Non-cash expense	(e)	86,254	-
		<u>272,135</u>	<u>186,098</u>
Total		<u>4,987,638</u>	<u>4,606,276</u>

Notes

(a) The Office and administration costs are higher this year due to the inclusion bad debts written off totalling £30,280.

(b) Audit fees	Internal	19,568	30,565
	External	26,500	26,500
		<u>46,068</u>	<u>57,065</u>

The External audit fee for 2018/19 is £26,500 (2017/18 £26,500).

(c) Provision has been released as no longer needed.

(d) Accommodation costs are the rent payments for 151 Buckingham Palace Road and in addition an accrual for potential value added tax (VAT) on the charges.

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3.1 Staff numbers and related costs

Staff costs comprise:

	Permanently Employed Staff 31-Mar-19 £	Seconded Staff 31-Mar-19 £	Temporary Staff 31-Mar-19 £	Total 31-Mar-19 £	Total 31-Mar-18 £
Wages and salaries	2,195,871	151,598	27,240	2,374,709	2,324,824
Social security costs	235,577	17,632	0	253,209	252,804
Pension costs	247,476	25,900	0	273,376	249,887
Sub Total	2,678,924	195,130	27,240	2,901,294	2,827,515
Less recoveries in respect of outward secondments	0	91,403	0	91,403	61,649
Total net costs	2,678,924	103,727	27,240	2,809,891	2,765,866
Of which Members emoluments	139,946	0	0	139,946	136,608

Details of remuneration paid to Members and the Senior Management team are given in the Remuneration Report.

For 2018/19 contributions of £273,376 (2017/18, £249,887) were paid to the NHS Pensions (NHSPS) at rates prescribed by the Treasury. The current rate for the NHSPS is 14.38 per cent of pensionable pay according to salary level.

Average number of persons employed

The average number of whole-time equivalent (Wte) persons employed or seconded during the year was as follows.

Number	Permanently Employed Staff	Seconded Staff	31-Mar-19 Total	31-Mar-18 Total
Directly Employed	46	2	48	47
Subtotal	46	2	48	47
Temporary staff			1	3
Total			49	50

All staff are directly employed by HTA. During the year, two staff were on secondment for part of their time; one to the HFEA for two and a half days per week and one to the DHSC full-time. As at 31 March 2019 the HTA employed 49 Wte staff (2017/18, 44).

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4. Income

	31-Mar-19	31-Mar-18
	£	£
Revenue from contracts:		
Licence Fee Income	3,654,410	3,296,244
Income from devolved administrations	131,081	129,964
	3,785,491	3,426,208
Other Income	394,478	458,150
	4,179,969	3,884,358

The HTA's remit is to regulate the removal, storage, use and disposal of human organs and tissue from the living and deceased. In accordance with section 16, schedule 3, paragraph 2 (4) (f) and paragraph 13 of the Human Tissue Act 2004, the HTA may grant licences to other organisations and charge fees for those licences.

4.1 Other Operating Income

	31-Mar-19	31-Mar-17
	£	£
Other Income - Rent	303,075	396,501
Other Income - Outward secondees	91,403	61,649
	394,478	458,150

Other income - outward secondees relates to two members of staff who worked for other organisations full and part-time.

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5. Property, Plant and Equipment

	Information Technology Hardware £	Furniture & Fittings £	Assets Under Construction £	Refurbishment Costs £	Total £
Cost or valuation					
At 1 April 2018	262,879	147,732	82,864	1,093,661	1,587,136
Additions	5,135	0	24,928	0	30,063
Disposals	(40,978)	0	0	0	(40,978)
Reclassifications and transfers	79,762	0	(82,864)	0	(3,102)
At 31 March 2019	306,798	147,732	24,928	1,093,661	1,573,119
Depreciation					
At 1 April 2018	241,935	120,156	0	788,484	1,150,575
Charge for the year	20,899	9,455	0	113,320	143,674
Disposals	(40,978)	0	0	0	(40,978)
Reclassifications and transfers	0	0	0	0	0
At 31 March 2019	221,856	129,611	0	901,804	1,253,271
Net book value at 31 March 2019	84,942	18,121	24,928	191,857	319,848
Net book value at 1 April 2018	20,944	27,576	82,864	305,177	436,561
Asset financing:					
Owned	84,942	18,121	24,928	191,857	319,848
At 31 March 2019	84,942	18,121	24,928	191,857	319,848
Cost or valuation					
At 1 April 2017	239,439	147,732	0	1,093,661	1,480,832
Additions	27,437	0	82,864	0	110,301
Disposals	(3,997)	0	0	0	(3,997)
At 31 March 2018	262,879	147,732	82,864	1,093,661	1,587,136
Depreciation					
At 1 April 2017	234,605	110,701	0	675,164	1,020,470
Charge for the year	9,662	9,455	0	113,320	132,437
Disposals	(2,332)	0	0	0	(2,332)
At 31 March 2018	241,935	120,156	0	788,484	1,150,575
Net book value at 31 March 2018	20,944	27,576	82,864	305,177	436,561
Net book value at 1 April 2017	4,834	37,031	0	418,497	460,362
Asset financing:					
Owned	20,944	27,576	82,864	305,177	436,561
Net book value at 31 March 2018	20,944	27,576	82,864	305,177	436,561

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6. Intangible Assets

	Information Technology	Websites	Assets Under Construction	Total
	£	£	£	£
Cost or valuation				
At 1 April 2018	1,080,255	58,350	71,940	1,210,545
Additions	0	0	3,960	3,960
Adjustments/Transfers	75,900	0	(75,900)	0
At 31 March 2019	1,156,155	58,350	0	1,214,505
Amortisation				
At 1 April 2018	981,535	55,425	0	1,036,960
Charged in year	30,117	2,050	0	32,167
At 31 March 2019	1,011,652	57,475	0	1,069,127
Net book value at 31 March 2019	144,503	875	0	145,378
At 1 April 2018	98,720	2,925	71,940	173,585
Asset financing:				
Owned	144,503	875	0	145,378
At 31 March 2019	144,503	875	0	145,378
Cost or valuation				
At 1 April 2017	1,091,263	58,350	0	1,149,613
Additions	0	0	71,940	71,940
Disposals	(11,008)	0	0	(11,008)
At 31 March 2018	1,080,255	58,350	71,940	1,210,545
Amortisation				
At 1 April 2016	957,105	38,867	0	995,972
Charged in year	28,008	16,558	0	44,566
Disposals	(3,578)	0	0	(3,578)
At 31 March 2018	981,535	55,425	0	1,036,960
Net book value at 31 March 2018	98,720	2,925	71,940	173,585
Net book value at 1 April 2017	134,158	19,483	0	153,641
Asset financing:				
Owned	98,720	2,925	71,940	173,585
Net book value at 31 March 2018	98,720	2,925	71,940	173,585

The gross cost of our Customer Relationship Management(CRM) system is £1,118k and it's Net book value is £137k. The CRM is an internally generated asset.

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7. Financial instruments

IFRS 7 Financial Instruments Disclosure requires disclosure of the role that financial instruments have had during the period in creating or changing the risks an entity faces in undertaking its activities. Financial instruments play a much more limited role in creating or changing risk at the HTA than would be typical of the listed companies to which IFRS 7 mainly applies. Financial assets and liabilities are generated by day-to-day operational activities rather than being held to change the risks facing the HTA in undertaking activities.

Liquidity risk

The HTA receives the majority of its income from annual licence fees payable by establishments mainly in the public sector. Other revenue resource requirements are financed by a grant from the DHSC. These, together with a robust debt recovery and payment process, ensure that the HTA is not exposed to significant liquidity risk.

Market and interest rate risk

At 31 March 2019 the HTA's financial liabilities carried nil rates of interest. The HTA's financial assets relate to receivables and cash balances held at 31 March 2019 within the Royal Bank of Scotland bank account and Barclays commercial current account, which are not interest bearing. Interest on cash balances are set by the banks. The HTA is therefore not exposed to significant interest-rate risk.

Credit risk

The HTA receives most of its income from licence fees from within both the NHS and non-NHS market. It has in place and operates a fit for purpose credit control policy and, where applicable, provides for the risk of debts not being discharged by those establishments it licenses. The HTA is therefore not exposed to significant credit risk.

The aged debtor report for NHS and non-NHS receivables at the 31 March 2019 was:

	£'000s
Not past due	0
Past due 0-28 days	71
Past due 29 days	179

Foreign currency risk

There were no foreign currency transactions conducted by the HTA during the period ended 31 March 2019. There was therefore no significant foreign currency risk during the year.

Financial assets

By category	Receivables and other financial assets
	31-Mar-19
Assets per Statement of Financial Position	£
Trade receivables (net of provisions)	238,330
Other receivables	242,614
Cash at bank and in hand	3,448,075
Total at 31 March 2019	3,929,019
Trade receivables (net of provisions)	1,666
Other receivables	181,876
Cash at bank and in hand	3,411,837
Total at 31 March 2018	3,595,379

The cash balances as at 31 March 2019 carried a floating rate.

Financial liabilities

By category	Other financial liabilities
	31-Mar-19
Liabilities per Statement of Financial Position	£
Trade payables	48,242
Other payables	11,239
Accruals	574,725
Total at 31 March 2019	634,206
Trade payables	7,134
Other payables	11,635
Accruals	322,048
Total at 31 March 2018	340,817

As at 31 March none of the HTA's liabilities carried a floating rate of interest.

Fair values

The fair value of the financial assets and liabilities was equal to book value.

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8. Trade receivables and other current assets

	31-Mar-19 £	31-Mar-18 £
Amounts falling due within one year:		
Trade receivables (contracts with customers)	249,720	5,320
Impairments for credit losses	(11,390)	(3,654)
Other Receivables	9,941	22,936
Prepayments and accrued Income	232,673	158,940
	480,944	183,542

Amounts falling due after more than one year:

There are no debtors falling due after more than one year.

9. Cash and cash equivalents

	£
Balance at 31 March 2017	2,991,606
Net change in cash and cash equivalent balances	420,231
Balance at 31 March 2018	3,411,837
Net change in cash and cash equivalent balances	36,238
Balance at 31 March 2019	3,448,075

	31-Mar-19 £	31-Mar-18 £
The following balances were held at:		
Commercial banks	3,082,227	2,774,238
Government Banking Services	365,848	637,599
	3,448,075	3,411,837

10. Trade payables and other current liabilities

	31/03/19 £	31-Mar-18 £
Amounts falling due within one year		
Trade payables	48,242	7,134
Other payables	11,239	11,635
Accruals	574,725	322,048
	634,206	340,817

The cash balances as at 31 March 2019 carried a floating rate.

There are no creditors falling due after one year.

**Human Tissue Authority
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11. Commitments under leases

Operating leases

11.1 Operating Lease Payments

Commitments under operating leases to pay rentals during the year following the year of these accounts are given below, analysed according to the period in which the lease expires.

A Memorandum of Terms of Occupation (MOTO) exists between the HTA and the Government Property Agency (GPA) for rental of space at 151 Buckingham Palace Road. The lease runs till March 2021.

Total future minimum lease payments	Buildings	Other	31-Mar-19	31-Mar-18
	£	£	Total	Total
			£	£
Payable:				
Not later than one year	458,338	2,367	460,705	460,606
Later than one year not later than five years				
	458,338	2,238	460,576	917,469
Total	916,676	4,605	921,281	1,378,075

Total payments made under leases in 2018/19 were £860,780 (2017/18, £849,094)

11.2 Sub-lease receipts recognised as revenue

Total future minimum lease receivables	31-Mar-19	31-Mar-18
	£	£
Receivable:		
Not later than one year	303,174	310,138
Later than one year not later than five years		
	303,174	620,276
Total rental revenue	606,348	930,414

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12. Contingent liabilities

There are no contingent liabilities.

13. Related party transactions

The DHSC is regarded as a related party and had various transactions totalling £771,270 with the HTA during the year. This mainly related to grant-in-aid of £803,000 (of which £703,000 was drawn down), £46,627 for a member of staff seconded to DHSC and £19,568 for the provision of Internal Audit Services. At 31 March 2019 the HTA owed the DHSC £4,512 for internal audit services and the DHSC owed the HTA £8,693 relating to secondment.

The HTA has also had material transactions with other entities for which the DHSC is regarded as the parent

NHSBT – transactions totalled £216,685 (2017/18 £206,639) and were fees for the provision of licences in the human application and post mortem sectors and invoices for the provision of assisted functions to the HTA. The balance outstanding as at 31 March 2019 was £850 (2017/18 £Nil for licence fees paid) and HTA has accrued £53,640 due to NHSBT.

The NHS Resolution occupies part of our office space and had transactions totalling £303,174 (2017/18 £396,491).

HFEA - transactions totalled £107,682 (2017/18 £99,497) and were mainly for fees charged for shared resources and seconded staff during this financial year.

The HTA has also had material transactions with the Department for Business, Energy & Industrial Strategy (BEIS) throughout the year.

During 2018/19 no Authority Member or senior manager or other related parties undertook any material transactions with the HTA.

14. Events after the reporting period

In accordance with the requirements of International Accounting Standard 10, reports after the accounting period are considered up to the date the accounts are authorised for issue. This is interpreted as the date of the Certificate and Report of the Comptroller and Auditor General.

CCSXXXXXXXXXX

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National Audit Office

Human Tissue Authority
Audit completion report and
management letter on the 2018-19
**FINANCIAL STATEMENT
AUDIT**

Report to those charged with governance
12th June 2019

This report presents our findings from the audit of 2018-19 financial statements

We anticipate recommending to the Comptroller and Auditor General (C&AG) that he should certify the 2018-19 financial statements with an unqualified audit opinion, without modification. The draft audit certificate is presented in Appendix 2 – Audit Certificate.

At the date of this report our audit of the financial statements is substantially finalised subject to completion of our internal review process.

The total audit fee charged for the year is in line with that set out in our Audit Planning Report, £26,500. There are no contingent fees in respect of the Human Tissue Authority.

At the date of issuing this report our audit of the financial statements is substantially complete subject to completion of our full internal review processes. Please note that other queries may emerge as this work progresses.

Actions for the Audit Committee

The Audit Committee is invited to:

- Review the findings set out in this report, including the draft letter of representation and audit certificate at Appendix 1 and 2 respectively.
- Note that there are no unadjusted errors to report which were above our clearly trivial threshold. Adjusted misstatements are included on page 8.

We would like to thank the Director of Finance and his staff for their assistance during the audit process.

George Smiles

Engagement Director

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

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Audit risks (pages 4 to 7)

Significant Audit Risks

Management Override of Controls:

Under International Standards on Auditing, there is a presumed risk of material misstatement due to fraud arising from management override of controls.

Conclusion: no indicators of management override were identified.

Revenue Recognition

As the HTA's main income stream is licence fees from customers, there is a risk that not all organisations are invoiced or organisations are invoiced incorrectly.

Conclusion: no indicators of management override were identified.

Areas of Audit Focus

Upgrade of CRM System:

During the year the HTA have completed the upgrade of their Customer Relationship Management (CRM) system.

Conclusion: No issues have been noted in respect of this upgrade

Exiting the European Union:

There is still uncertainty around exiting the EU. As part of our audit enquiries we have reviewed management consideration of the impact of Brexit.

Conclusion: There are no further matters arising as a result.

Materiality

£96,000

We have reported all misstatements above £2,000

Audit adjustments (page 8)

£172k

The net effect of adjustments on the accounts is £172k.

Unadjusted misstatements

£0k

There were no unadjusted misstatements above our trivial threshold.

Findings from our work on significant risks

The risks previously communicated in our Audit Planning Report are presented below

1. Management Override of Controls:

Details and audit response

Management is in a unique position to perpetrate fraud because of its ability to manipulate accounting records and prepare fraudulent financial statements by using its position to override controls that otherwise appear to be operating effectively. Under International Standards on Auditing, there is a presumed risk of material misstatement due to fraud arising from management override of controls. The standard requires that auditors perform audit procedures to address this risk, focusing on three key areas: journal entries, bias in management estimates and significant or unusual transactions.

We have reviewed the design and implementation of controls over journal entries, accounting estimates and significant or unusual transactions. This has been supplemented by the substantive testing of the above areas.

Audit findings and conclusion

Our interim and final audit work has considered the following: the appropriateness of journal entries and other adjustments processed in preparing the financial statements, a sample test of journals based on a risk criteria, any accounting estimates presented in the financial statements for evidence of management bias and any significant transactions outside HTA's normal course of business or that otherwise appear to be unusual.

No issues were identified from the above work. All journals tested had appropriate supporting evidence and did not indicate management override of controls.

We have also reviewed all adjustments made in finalising the financial statements. One significant adjustment made related to the reversal of the accrued income due from NHS Resolution (relating to VAT on the sub-lease of office space). The full amount due in respect of VAT has been written off, totalling £146,988. We have reviewed the supporting evidence provided by HTA and consider this an appropriate adjustment based on the available evidence; appropriate disclosures have been included in the accounts to support the adjustment.

In conclusion, we have not found any indication of management override of controls.

Findings from our work on significant risks

The risks previously communicated in our Audit Planning Report are presented below.

2. Revenue Recognition

Details and audit response

Under International Standards on Auditing, the Auditor's there is a presumed risk of fraud in revenue recognition, albeit rebuttable in all entities. As HTA's main income stream is licence fees from customers, there is a risk that not all organisations are invoiced or organisations are invoiced incorrectly. This significant risk relates only to the fraud element of revenue recognition, for instance erroneous application of the cut-off. Other elements of revenue recognition are not considered a significant risk.

We have reviewed controls in place over HTA's income streams and performed substantive testing of income.

Audit findings and conclusion

As part of our audit work we have performed a substantive analytical review using HTA licence data based on the information stored in the CRM database. We have also considered new income streams for 18/19 financial year and tested the reconciliations of licence holder income, performed by HTA.

We stated in our Audit Planning Report that we would rely on review of management accounts as part of this work. However, as reported to you at the February 2019 ARAC, we made the decision to change the audit approach to one more substantive –focused, in order to improve our audit efficiency. This was not as a result of any deficiencies in the management account process.

We reviewed the CRM to Great Plains reconciliation control and obtained assurance over the accuracy and completeness of licence fee revenue. No issues were identified. We have also formed a prediction for licence fee revenue based on information derived from the CRM licence system and confirmed that the revenue recognised was consistent with this prediction.

Sufficient assurance has been obtained that there is no material misstatement in the accounts in respect of income recognition and we have found no evidence of fraud in revenue recognition.

Key audit findings

Other areas of audit focus

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

Title	Audit response	Audit findings and conclusion
Upgrade of the CRM System	The HTA have completed the upgrade of their Customer Relationship Management (CRM) system this year. The HTA will need to ensure that any expenditure relating to this upgrade is capitalised correctly.	Our audit has not identified any expenditure on the CRM upgrade that had been incorrectly capitalised. We have tested all additions to intangible assets as part of our audit work.
Exiting the European Union	The process of exiting the EU is continuing. As part of our audit enquires we have reviewed managements consideration of the impact of Brexit and any disclosures that may be required in the accounts; for example, the impact on the HTA's role in respect of EU regulations.	We have considered managements response to Brexit and concluded that no additional disclosures were required in the HTA's accounts, outside of those which have already been made in the draft accounts.

Adjusted misstatements

Misstatements that have been identified by either ourselves or HTA, have been adjusted and are above our clearly trivial threshold of £2,000. The net effect of these adjustments on the financial statements is £147k.

Adjusted misstatements								
Title	Error type	Description	Account Line	Unit	SOCNE		SOFP	
					DR	CR	DR	CR
Non current Assets: Classification Error	Known	Computer monitors were incorrectly capitalised as intangible assets.	Property Plant and Equipment	£'k			25	
			Intangible Assets	£'k				25
Write-off of VAT amounts relating to lease on 151 BPR	Known	Following further assessment by HTA of the likelihood of recovery of sub-lease income relating to VAT, HTA have removed amounts relating to: a) Income accrued in prior years (£86k) b) Income accrued during 2018/19 (£61k) Current year amounts have been derecognised against 2018/19 income; with prior year amounts recognised as expenditure in line with accounting standards.	Income	£'k	61			
			Accrued Income	£'k				147
			Expenditure	£'k	86			
		Cumulative misstatements:	Debits and credits		147		25	172
			Net impact on financial statements		147			147

There were no unadjusted misstatements to report which were above our clearly trivial threshold.

Financial statement disclosures

We have challenged management over the adequacy of disclosures in the financial statements in the following areas:

- Income (relating to the new accounting standard, IFRS15)
- Financial assets (relating to the new accounting standard, IFRS9)

We have made a number of suggestions to improve narrative disclosures in respect of these items and to ensure completeness of the disclosures required under the FReM and other relevant guidance.

We are content with the overall neutrality, consistency and clarity of the disclosures in the financial statements as well as judgments made in formulating particularly sensitive financial statement disclosures.

Accounting policies and financial reporting

We have performed the following procedures with regards to the appropriateness of the judgements made by the entity on accounting policies, particularly new or changed policies:

- We have reviewed management judgement used in determining the application of IFRS15 and 9.

We have performed the following procedures on the appropriateness of the judgements made by the entity on the required accounting estimates:

- Reviewed the expected credit loss model applied by management
- Reviewed the useful life and valuation of intangible assets

We are content that the accounting policies are complete, accurate and compliant with the relevant standards and have been appropriately applied.

Regularity, propriety and losses

We found no issues of irregularity or impropriety during our audit.

Internal control issues

Internal control

During the course of our audit we identified one control observation that we would like to report to you as those charged with governance.

Classification		Low Risk
Finding As reported in the adjusted error schedule we found evidence that items had been incorrectly classified as intangible assets. Although this had no net impact on the statement of financial position the note in the accounts was incorrect in the first version of accounts provided to us.	Our recommendation We appreciate the tight timetable for the production of HTA's accounts, which limits time available for detailed management review. However HTA should consider whether they are applying sufficient checks of non-current asset balances prior to finalisation of the accounts as part of their high level review.	Management response Agreed. The error was not in the source (i.e. Great Plains) but in the note that is provided in excel. The assumption was that the additions related to CRM (intangibles).

High risk: major issues for the attention of senior management which may have the potential to result in a significant deficiency in internal control

Medium risk: important issues to be addressed by management in their areas of responsibility.

Low risk: problems of a more minor nature which provide scope for improvement

Follow up to recommendations made in the previous year

In 2017-18 we made the below recommendations to the Human Tissue Authority and throughout this year's audit we have followed up with management on progress in implementing the accepted recommendations. Below is an update on the status of these recommendations.

Capitalisation		Medium Risk
Finding We identified two instances where items had been capitalised erroneously, one had been included in the incorrect category and the second should not have been capitalised.	Our recommendation Management should review the capitalisation process and consider whether it is sufficient to ensure that firstly, only items that meet the criteria are capitalised, and secondly, that they are categorised correctly.	Management response "Partially agree. We will ensure in that our QA process is robust to ensure correct categorisation in the Annual Accounts." NAO assessment: Raised again in 2018-19. See page 10.
Grant in aid		Low risk
Finding Management correctly reported the grant-in-aid drawn down from DHSC. However, when we reviewed the allocation from the Department we noted that it included an additional £273k to cover depreciation. When this was raised with the finance team they were unaware of this element which had not been requested.	Our recommendation This oversight did not cause any problems as the grant available was more than HTA was expecting or used. However, management should ensure that they are fully aware of the allocation from the Department.	Management response "Agreed. We will ensure that the final allocation letter is shared on receipt from DHSC." NAO assessment: Closed. We have not identified a repeat of this issue in 2018-19.

We have completed our audit of the 2018-19 financial statements in accordance with International Standards on Auditing (UK) issued by the Financial Reporting Council and with the Audit Planning Report presented to the Audit Committee in November 2018.

We have also read the content of the draft annual report and the governance statement to confirm that:

- the parts of the Accountability Report and Remuneration Report to be audited have been properly prepared in accordance with HM Treasury directions and the Government Financial Reporting Manual made under the Government Resources and Accounts Act 2000 and Human Tissue Act 2004;
- in the light of the knowledge and understanding of the Human Tissue Authority and its environment obtained in the course of the audit, we have not identified any material misstatements in the Performance Report or the Accountability Report;
- the information given in the Performance and Accountability Reports for 2018-19 is consistent with the financial statements of the same year; and
- that the governance statement has been prepared in accordance with HM Treasury guidance.

As part of our audit, we assessed:

- whether the accounting policies are appropriate to the Human Tissue Authority's circumstances and have been adequately disclosed;
- the reasonableness of significant accounting estimates made by the Accounting Officer; and
- the overall presentation of the financial statements.

We are also required to obtain sufficient evidence to give reasonable assurance that the expenditure and income recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Independence

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

Information on NAO quality standards and independence can be found on the NAO website:

<https://www.nao.org.uk/about-us/our-work/governance-of-the-nao/transparency/>.

International standards on Auditing (UK)

We consider that there are no additional matters in respect of items requiring communication to you, per International Standards on Auditing (UK), that have not been raised elsewhere in this report or our audit planning report. Items requiring communication cover:

- Fraud
- Going concern
- Human Tissue Authority's compliance with laws and regulations
- Significant difficulties completing the audit
- Disagreements or other significant matters discussed with management

Cooperation with other auditors

Internal Audit

Discussion with Internal Audit at the planning stage informed our risk assessment. In addition we have read the reports of Internal Audit during the 2018-19 year, and although we have not placed direct reliance on the results of any of their work, it has informed our consideration of the adequacy of disclosures in the Governance Statement.

Management of personal data

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

The General Data Protection Regulations (GDPR) came into force in May 2018. These regulations make no difference to the C&AG's access rights.

The Data Protection Act provides the C&AG with an exemption from the individual rights provisions where to apply the provisions would be likely to prejudice the proper discharge of the C&AG functions. For example this would mean that we would not need to inform an individual about processing nor could an individual object to processing of their information for audit purposes where that would disrupt an efficient audit.

We take our obligations under GDPR seriously. We have appointed a Data Protection Officer and all our staff are required to comply with formal data protection policies, guidelines and procedures designed to keep third party data secure and support privacy by design. We will destroy, return, or store personal data as necessary on completion of our work.

We confirm that we have discharged those responsibilities communicated to you in the NAO's Statement on Management of Personal Data.

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

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

Communication with the NAO

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

We share this through our [e:newsletter](#), [Round-up for Audit Committees](#) and email notifications about our work on particular sectors or topics. If you would like to receive any of these, please sign up at: <http://bit.ly/NAOoptin>. You will always have the option to amend your preferences or unsubscribe from these emails at any time.

Appendices

The Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
LONDON
SW1W 9SP

LETTER OF REPRESENTATION: HUMAN TISSUE AUTHORITY, 2018-19

I acknowledge as Accounting Officer of the Human Tissue Authority my responsibility for preparing accounts that give a true and fair view of the state of affairs, net expenditure deficit, changes in tax payers equity and cash flows of the Human Tissue Authority for the year ended 31st March 2019.

In preparing the accounts, I was required to:

- observe the accounts direction issued by the Secretary of State with the approval of HM Treasury, including the relevant accounting and disclosure requirements and apply appropriate accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards have been followed and disclosed and explain any material departures in the accounts; and
- make an assessment that the Human Tissue Authority is a going concern and will continue to be in operation throughout the next year; and ensure that this has been appropriately disclosed in the financial statements.

I confirm that for the financial year ended 31 March 2019:

- neither I nor my staff authorised a course of action, the financial impact of which is that transactions infringe the requirements of regularity as set out in Managing Public Money;
- having considered and enquired as to the Human Tissue Authority's compliance with laws and regulations, I am not aware of any actual or potential non-compliance that could have a material effect on the ability of the Human Tissue Authority to conduct its business or on the results and financial position disclosed in the accounts;
- all accounting records have been provided to you for the purpose of your audit and all transactions undertaken by the Human Tissue Authority have been properly reflected and recorded in the accounting records. All other records and related information, including minutes of all management meetings which you have requested have been supplied to you; and
- the information provided regarding the identification of related parties is complete; and the related party disclosures in the financial statements are adequate.

All material accounting policies as adopted are detailed in Note 1 to the accounts.

INTERNAL CONTROL

I acknowledge as Accounting Officer my responsibility for the design and implementation of internal controls to prevent and detect error and I have disclosed to you the results of my assessment of the risk that the financial statements could be materially misstated.

I confirm that I have reviewed the effectiveness of the system of internal control and that the disclosures I have made are in accordance with HM Treasury guidance on the Governance Statement.

FRAUD

I acknowledge as Accounting Officer my responsibility for the design and implementation of internal controls to prevent and detect fraud and I have disclosed to you the results of my assessment of the risk that the financial statements could be materially misstated as a result of fraud.

I am not aware of any fraud or suspected fraud affecting the Human Tissue Authority and no allegations of fraud or suspected fraud affecting the financial statements has been communicated to me by employees, former employees, analysts, regulators or others.

ASSETS

General

All assets included in the statement of financial position were in existence at the reporting date and owned by the Human Tissue Authority, and free from any lien, encumbrance or charge, except as disclosed in the accounts. The statement of financial position includes all tangible assets owned by the Human Tissue Authority.

Non-Current Assets

All assets over £5,000 are capitalised. They are valued at historic cost. Depreciation is calculated to reduce the net book amount of each asset to its estimated residual value by the end of its estimated useful life in the Human Tissue Authority's operations.

Other Current Assets

On realisation in the ordinary course of the Human Tissue Authority's operations the other current assets in the statement of financial position are expected to produce at least the amounts at which they are stated. Adequate provision has been made against all amounts owing to the Human Tissue Authority which are known, or may be expected, to be irrecoverable.

LIABILITIES

General

All liabilities have been recorded in the statement of financial position. There were no significant losses in the year and no provisions for losses were required at the year-end.

Provisions

There were no provisions in the financial statements as at 31 March 2019.

Contingent Liabilities

I am not aware of any pending litigation which may result in significant loss to the Human Tissue Authority, and I am not aware of any action which is or may be brought against the Human Tissue Authority under the Insolvency Act 1986.

OTHER DISCLOSURES

Results

Except as disclosed in the accounts, the results for the year were not materially affected by transactions of a sort not usually undertaken by the Human Tissue Authority, or circumstances of an exceptional or non-recurring nature.

Unadjusted Errors

There were no unadjusted errors brought to my attention.

Events after the Reporting Period

Except as disclosed in the accounts, there have been no material changes since the reporting date affecting assets, liabilities and commitments, and no events or transactions have occurred which, though properly excluded from the accounts, are of such importance that they should have been brought to notice.

Management of Personal Data

Except as disclosed in the relevant sections of the Annual Report, there have been no personal data related incidents in the accounting period subject to audit which are required to be reported.

Allan Marriott-Smith
Accounting Officer

Date:

THE CERTIFICATE AND REPORT OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSES OF PARLIAMENT

Opinion on financial statements

I certify that I have audited the financial statements of the Human Tissue Authority (“the Authority”) for the year ended 31 March 2019 under the Human Tissue Act 2004. The financial statements comprise: The Statements of Comprehensive Net Expenditure, Financial Position, Cash Flows, Changes in Taxpayers’ Equity; and the related notes, including the significant accounting policies. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Accountability Report that is described in that report as having been audited.

In my opinion:

- the financial statements give a true and fair view of the state of the Authority’s affairs as at 31 March 2019 and of net expenditure for the year then ended; and
- the financial statements have been properly prepared in accordance with the Human Tissue Act 2004 and Secretary of State directions issued thereunder.

Opinion on regularity

In my opinion, in all material respects the income and expenditure recorded in the financial statements have been applied to the purposes intended by Parliament and the financial transactions recorded in the financial statements conform to the authorities which govern them.

Basis of opinions

I conducted my audit in accordance with International Standards on Auditing (ISAs) (UK) and Practice Note 10 ‘Audit of Financial Statements of Public Sector Entities in the United Kingdom. My responsibilities under those standards are further described in the Auditor’s responsibilities for the audit of the financial statements section of my certificate. Those standards require me and my staff to comply with the Financial Reporting Council’s Revised Ethical Standard 2016. I am independent of the Authority in accordance with the ethical requirements that are relevant to my audit and the financial statements in the UK. My staff and I have fulfilled our other ethical responsibilities in accordance with these requirements. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Conclusions relating to going concern

We are required to conclude on the appropriateness of management’s use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority’s ability to continue as a going concern for a period of at least twelve months from the date of approval of the financial statements. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor’s report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my auditor’s report. However, future events or conditions may cause the entity to cease to continue as a going concern. I have nothing to report in these respects.

Responsibilities of the Accounting Officer for the financial statements

As explained more fully in the Statement of Accounting Officer’s Responsibilities, the Accounting Officer is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Auditor’s responsibilities for the audit of the financial statements

My responsibility is to audit, certify and report on the financial statements in accordance with the Human Tissue Act 2004.

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (UK), I exercise professional judgment and maintain professional scepticism throughout the audit. I also:

- identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Authority's internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

In addition, I am required to obtain evidence sufficient to give reasonable assurance that the income and expenditure reported in the financial statements have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them

Other Information

The Accounting Officer is responsible for the other information. The other information comprises information included in the annual report, other than the parts of the Accountability Report described in that report as having been audited, the financial statements and my auditor's report thereon. My opinion on the financial statements does not cover the other information and I do not express any form of assurance conclusion thereon. In connection with my audit of the financial statements, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or my knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work I have performed, I conclude that there is a material misstatement of this other information, I am required to report that fact. I have nothing to report in this regard.

Opinion on other matters

In my opinion:

- the parts of the Accountability Report to be audited have been properly prepared in accordance with Secretary of State directions made under the Human Tissue Act 2004;
- in the light of the knowledge and understanding of the Human Tissue Act 2004 and its environment obtained in the course of the audit, I have not identified any material misstatements in the Performance Report or the Accountability Report; and
- the information given in the Performance Report and Accountability Report for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which I report by exception

I have nothing to report in respect of the following matters which I report to you if, in my opinion:

- adequate accounting records have not been kept or returns adequate for my audit have not been received from branches not visited by my staff; or
- the financial statements and the parts of the Accountability Report to be audited are not in agreement with the accounting records and returns; or
- I have not received all of the information and explanations I require for my audit; or
- the Governance Statement does not reflect compliance with HM Treasury's guidance.

Report

I have no observations to make on these financial statements.

Gareth Davies
Comptroller and Auditor General

Date

National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

Accounting standard	Detail	Future direction for HTA
<p>IFRS 16: Leases</p> <p>Effective from 2019-20 for bodies that follow pure IFRS and specific bodies agreed by HM Treasury. For all other public sector bodies, effective from 2020-21</p> <p>HM Treasury have consulted on the public sector interpretation of this Standard for FReM bodies. It is expected that it will issue guidance in March 2019 which will allow time for public sector bodies to work through the impact of the standard on their budgets and forecasts.</p>	<p>IFRS 16 eliminates the operating/finance lease distinction for leases and imposes a single model geared towards the recognition of all but low-value or short term (<12m) leases. The proposals arise partly from the IASB's view that:</p> <ul style="list-style-type: none"> disclosures around operating lease commitments have lacked prominence and tended towards understatement; and even in leases where the underlying asset is not acquired for its whole useful life, the lessee nevertheless acquires an economic right to its use, along with obligations to make good on minimum lease payments. <p>These will now be recognised on the Balance Sheet as a 'right of use' asset and lease liability reflecting the obligation to make lease payments. The lease liability will be measured at initial recognition as the value of future lease payments, with the asset additionally including any initial direct costs incurred by the lessee, plus an estimate of any dismantling/restoration costs. Subsequent measurement of both asset and liability will need to respond to any changes in lease terms.</p> <p>Successful transition will depend on organisations pro-actively capturing additional information about leases – new and existing – which they expect to remain in place at the date of adoption of IFRS 16, especially regarding future minimum lease payments. Organisations should also ensure systems for capturing cost information are fit for purpose, can respond to changes in lease terms and the presence of any variable (e.g. RPI-based) lease terms where forecasts will need to be updated annually based on prevailing indices.</p> <p>There are no changes to the accounting requirements where you are acting as a lessor but disclosure requirements around risk exposure are required</p>	<p>We have had initial discussions with HTA management, and they are awaiting confirmation of the adoption of the standard as well as any adaptations for public sector from HM Treasury.</p> <p>Management should ensure they have the information necessary to meet the disclosures required by IAS 8 in the 2019-20 financial statements.</p>

**Protective OFFICIAL
Marking**



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Victoria
LONDON
SW1W 9SP

Human Tissue Authority
151 Buckingham Palace Road
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Tel 020 7269 1900
Email enquiries@hta.gov.uk
Web www.hta.gov.uk

Date 12 June 2019

LETTER OF REPRESENTATION: HUMAN TISSUE AUTHORITY, 2018-19

I acknowledge as Accounting Officer of the Human Tissue Authority my responsibility for preparing accounts that give a true and fair view of the state of affairs, net expenditure deficit, changes in taxpayers' equity and cash flows of the Human Tissue Authority for the year ended 31st March 2019.

In preparing the accounts, I was required to:

- observe the accounts direction issued by the Secretary of State with the approval of HM Treasury, including the relevant accounting and disclosure requirements and apply appropriate accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards have been followed and disclosed and explain any material departures in the accounts; and
- make an assessment that the Human Tissue Authority is a going concern and will continue to be in operation throughout the next year; and ensure that this has been appropriately disclosed in the financial statements.
- I confirm that for the financial year ended 31 March 2019:
- neither I nor my staff authorised a course of action, the financial impact of which is that transactions infringe the requirements of regularity as set out in Managing Public Money;
- having considered and enquired as to the Human Tissue Authority's compliance with laws and regulations, I am not aware of any actual or potential non-compliance that could have a material effect on the ability of the Human Tissue Authority to conduct its business or on the results and financial position disclosed in the accounts;
- all accounting records have been provided to you for the purpose of your audit and all transactions undertaken by the Human Tissue Authority have been properly reflected and recorded in the accounting records. All other records and related information, including minutes of all

management meetings which you have requested have been supplied to you; and

- the information provided regarding the identification of related parties is complete; and the related party disclosures in the financial statements are adequate.

All material accounting policies as adopted are detailed in Note 1 to the accounts.

INTERNAL CONTROL

I acknowledge as Accounting Officer my responsibility for the design and implementation of internal controls to prevent and detect error and I have disclosed to you the results of my assessment of the risk that the financial statements could be materially misstated.

I confirm that I have reviewed the effectiveness of the system of internal control and that the disclosures I have made are in accordance with HM Treasury guidance on the Governance Statement.

FRAUD

I acknowledge as Accounting Officer my responsibility for the design and implementation of internal controls to prevent and detect fraud and I have disclosed to you the results of my assessment of the risk that the financial statements could be materially misstated as a result of fraud.

I am not aware of any fraud or suspected fraud affecting the Human Tissue Authority and no allegations of fraud or suspected fraud affecting the financial statements has been communicated to me by employees, former employees, analysts, regulators or others.

ASSETS

General

All assets included in the statement of financial position were in existence at the reporting date and owned by the Human Tissue Authority, and free from any lien, encumbrance or charge, except as disclosed in the accounts. The statement of financial position includes all tangible assets owned by the Human Tissue Authority.

Non-Current Assets

All assets over £5,000 are capitalised. They are valued at historic cost. Depreciation is calculated to reduce the net book amount of each asset to its estimated residual value by the end of its estimated useful life in the Human Tissue Authority's operations.

Other Current Assets

On realisation in the ordinary course of the Human Tissue Authority's operations the other current assets in the statement of financial position are expected to produce at least the amounts at which they are stated. Adequate provision has been made against all amounts owing to the Human Tissue Authority which are known, or may be expected, to be irrecoverable.

LIABILITIES

General

All liabilities have been recorded in the statement of financial position. There were no significant losses in the year and no provisions for losses were required at the year-end.

Provisions

There were no provisions in the financial statements as at 31 March 2019.

Contingent Liabilities

I am not aware of any pending litigation which may result in significant loss to the Human Tissue Authority, and I am not aware of any action which is or may be brought against the Human Tissue Authority under the Insolvency Act 1986.

OTHER DISCLOSURES

Results

Except as disclosed in the accounts, the results for the year were not materially affected by transactions of a sort not usually undertaken by the Human Tissue Authority, or circumstances of an exceptional or non-recurring nature.

Unadjusted Errors

There were no unadjusted errors brought to my attention.

Events after the Reporting Period

Except as disclosed in the accounts, there have been no material changes since the reporting date affecting assets, liabilities and commitments, and no events or transactions have occurred which, though properly excluded from the accounts, are of such importance that they should have been brought to notice.

Management of Personal Data

Except as disclosed in the relevant sections of the Annual Report, there have been no personal data related incidents in the accounting period subject to audit which are required to be reported.

Allan Marriott-Smith
Accounting Officer

Date:

Audit and Risk Assurance Committee paper

Date	12 June 2019	Paper reference	AUD (08/19)
Agenda item	12	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 June 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 SMT monthly and the register updated. The strategic risk register that was updated at the beginning of May is at Annex A.
5. In February, we reported that two risks were amber rated: failure to manage regulatory expectations (risk three); and failure to utilise our capabilities (risk four). In May, a third risk was assessed as amber rated risk; 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, however over the March and April 2019 period, it was felt that the

risk had heightened slightly. Over this period we continued to monitor and manage perimeter issues for the HTA such as taphonomy as well as managing an increase in activity in preparation for EU Exit. Overall, this remains an area of increased activity for the HTA with an associated increase in delivery risks. At this point SMT does not feel that the overall risk has increased even with the ongoing uncertainty relating to EU Exit. We will continue to monitor this and the potential impact on regulatory expectations.

7. Risk 4, failure to utilise capabilities effectively, saw an increase from February to May 2019. The results of our Stress Survey reflects the increased pressure staff are under and where the funding for the Transformation Programme business case was not approved, SMT feel will have an impact on staff who may be required to pick up pieces of work as part of the programme. The residual risk has reduced slightly as a result of a fundamental annual assessment. SMT considered that the residual risk had previously been overstated.
8. The newly formulated risk, failure to achieve the benefits of the organisational transformation programme (risk six), has increased from quarter four. The submitted business case was not approved. SMT recognises the impact that this will have on work priorities and its associated impact on risk 4. The mitigations for this risk centre around phased delivery and use of internal expertise.
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
May 2019

Overview: Risks reflect the strategy for **2019 - 2022**. Our highest 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 which is currently affected by recent staff changes. A number of more recently recruited Regulation Managers are now signed off to support and lead. This will increasingly have a mitigating impact on risks 1 and 4. Recruitment for Regulation Managers has been successful with only one RM post vacant at the start of April.

Other notable risks: Uncertainty posed by EU Exit, which is largely dependent on outcomes of the ongoing negotiations and resource dedicated to 'no-deal' planning which impacts on other work. The recently created Head of Planning and Performance role is once again vacant, which will impact on our resource and business planning (R6). We are also recruiting for a permanent replacement for our Head of HR. During recent recruitment rounds we have experienced high levels of drop out for candidates invited to interview as well as poor quality applications. Progress on development activity has been slower than hoped due to staff redeployment to carry out work relating to EU exit and the opt-out consent Code. DHSC spending controls are likely to place continuing pressures on ALBs to make savings.

Funding for transformation programme has not been approved for the current business year. Whilst BAU will be managed within current envelope, we recognise that pressures across the business will increase as we try to bring about essential change in 2019/20 with the same resources. This could more directly affect R1, R2, R3, R4 and R6 as the year progresses.

Risk	Feb 2019	Mar 2019	Apr 2019	May 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 and continuous improvement is planned. It is important to identify changes and remain agile to adapt to these. A number of new Regulation Managers have increased the organisation's capacity and strengthened our regulatory capability. Recent recruitment has resulted in all but one Regulation Manager posts being filled. Recruitment for other vacancies is ongoing and despite seeing high levels of candidate drop out at interview stage, we have been successful in our recent recruit rounds so that, for example, our new Transplant Officer will take up post shortly before the departing Transplant Officer leaves. The development of a revised induction programme for RMs is progressing well but a review of Standard Operating Procedures is required in order to achieve consistency with consistent training in up to date practice. A training session with RMs on CAPA management and procedures to facilitate consistency have recently taken place. We recognise that there has been an issue with the speed at which new RMs are being inducted which is related to the pressure on existing staff who not only maintain BAU but are involved in other projects. We are actively working to address this and have maintained the risk level. Recent churn amongst the Authority, including the Chair, leaves potential gaps in oversight and support on upcoming regulatory and transformation issues.
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 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 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. Media and FOI interest has stepped up and media are running stories for longer (or running multiple articles) than would usually be the case. 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 continue to be in a position to use the skills of our newer recruits more fully. Recruitment to RM posts has been successful, but not without salary pressure. Other roles have been harder to fill as a result of salary and T&C differences with other organisations. Workload and pressure continue to be monitored closely by the management team and the actions agreed as a result of the staff survey have now been completed. We achieved our planned position relating to GDPR by the end of March 2019 and have received moderate assurance from internal audit. The additional funding available at the end of 2018/19 was used effectively. Good progress has been made on improving our induction procedures and this will be supported by the appointment of two RMs with responsibility for induction, learning and development. DHSC has introduced spending controls which could impact on future delivery. Related to R1, the challenge of employing the right people for the right jobs suggest that this risk has risen slightly. The recently conducted stress survey results and feedback reflect the pressure staff are under. An increase in workloads is a key factor. The response to this is being led by the CEO. Hard decisions around resourcing for the Transformation Programme will need to be made if funding is not approved by DHSC. Funding for Transformation Programme not approved. The result of this means that staff will need to be redeployed to carry out work on the programme which will impact on BAU in terms of quality and pace
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 will continue to be tight however as inflationary pressures and the non-funded portion of Employers' Pension contributions offset these gains. This pressure will become more acute if the business case to release reserves is not approved. Funding for Transformation programme not approved in the current business year. This does not impact on BAU activities as we will manage within the agreed budget. We do however, recognise that there will be pressures elsewhere in the business as staff are asked to take on unfunded work for the above programme.
6 - Failure to achieve the benefits of the organisational transformation programme (Development objectives a-d)	→	→	→	↑	This is a new risk for which we have begun to look at the outcomes and deliverables. The risk has been scored as high impact and low likelihood due to the proximity of the programme. The impact of 'high' recognises that aspects of the programme in particular IT related could have significant impact on the business should things go wrong. No change. DHSC have not agreed funding for this programme in the current business year, this will require a re-prioritisation of work to increase our capacity to take on necessary change associated with the Programme in 2019/20.

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
	4. High	4	8	12	16	20
	3. Medium	3	6	9	12	15
	2. Low	2	4	6	8	10
	1. Very Low	1	2	3	4	5
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>(Risk to Delivery objectives a-d & f Development objectives a-d)</p> <p>Risk Owner:</p> <p>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	Regulatory model	5	1		1	2	3			
						HTA Strategy 2018 to 2021 clearly articulates the HTA's regulatory model					X		Preventative	Authority developed and approved the HTA Strategy	HTA Strategy published in May 2019
						Regulatory decision making framework			X				Preventative	Reports to Authority of key decisions in Delivery Report	Satisfactory report made in May 2019
						Annual scheduled review of Strategy			X	X			Preventative	Outputs from annual strategy review translate into revised annual Strategy	Annual strategic planning away day completed in September 2018
						Approved HTA Business Plan 2018/19 identifies a balanced programme of regulatory activity and continuous improvement			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
						Well established processes support our core regulatory business.						X	Detective	Internal audit conducted on Key Regulatory Processes, receiving substantial assurance and noting good areas of best practice	Final report received April 2019
						Quality management systems									
						HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model			X				Preventative/Monitoring	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
						People									
						Adherence to the HTA People Strategy which has been substantially amended and approved by the Authority			X				Preventative	Management information and assessment presented to the Authority quarterly as part of the Deployment report	Quarterly report made at May 2019 Authority meeting
						Training and development of professional competence			X				Preventative	Annual PDPs, RM proposals to SMT	Regulation training plan agreed by SMT in June. Training records added onto Simply Personnel and monthly HR updates presented at SMT. End of year PDP process has commence and due to complete by end May 2019.
						Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas			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
						EU Exit									
						Close liaison with DHSC and contingency planning for a range of outcomes including no-deal									
						Use of existing regulatory model to manage the outcomes of 'no-deal'									
						Board									
						Experienced Authority Member appointed as interim Chair Future appointments pending - have requested that the Department expedite recruitment for Chair and additional members									
									Regulatory model						
						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 (HL)			X				Preventative		
						Consideration of Import licenced establishment in HA inspection planning. Establishments assessed in order of existing risk profile and level of activity			X				Preventative		
						Other									
						Strengthening horizon scanning arrangements			X				Preventative		
						Embed Better Regulation initiatives in the regulatory model			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:</p> <p>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	Filled identified business-critical roles	3	2		X			Preventative	Monthly reports to HTAMG	Monthly 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.
						Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff				X	X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Reviewed by ARAC October 2018
						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				X			Preventative	Policy reviewed annually, training specifications	Media policy to be reviewed.
						Accessible lines to take and key messages for likely scenarios				X			Preventative	Documented, incidents reported to Chair and in Delivery Report	Delivery report to Authority meeting May 2019
						Availability of legal advice				X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy				X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Policy reviewed by Authority July 2018
						Onward delegation scheme and decision making framework agreed by the Authority				X	X		Preventative	Standing Orders and Authority minutes	SO reviewed and agreed in 4 May 2017 (next review May 2019)
						Regulatory decision making framework				X			Preventative	Reports to Authority of key decisions in Delivery Report	RDMs summarised in Delivery Report to Authority Meeting in May 2019.
						IT security controls and information risk management				X	X		All	SIRO annual review and report Internal audit reports	Cyber security review - standing agenda item at ARAC June 2018
						Critical incident response plan regularly reviewed and tested				X	X		Preventative	Critical Incident Response Plan and notes of test, reported to SMT	CIP was used to manage a power outage during March 2018 and a regulatory incident arising in April
						Evaluate test exercise of incident and feedback to all staff.				X			Preventative		Process has been utilised twice in 2018, lessons learned papers to be presented to ARAC June 2018
						Plan to develop and strengthen the relationship with DIs				X			Preventative	Blog and DI training	Project on business plan
						EU exit plans in place								Paper on EU Exit plans to be reviewed by SMT in January, and considered by Authority at February meeting	EU Exit planning is a standing item on the weekly Senior Management Team Meeting and was covered in detail at both the February and May Authority Meetings.

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	Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach (Risk to Delivery objective e, and Development c) Risk Owner: Hazel Lofty	<u>Cause</u> External factors <ul style="list-style-type: none"> No scheduled review of Human Tissue Act and associated regulations, <i>or Quality and Safety Regulations (other than for EU Exit)</i> 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 <i>Introduction of deemed consent for Organ donation in England</i> <i>Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario</i> Matters which certain stakeholder groups believe require review <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 Matters which stakeholders/public may expect to be inside regulatory scope <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 <i>Clinical waste</i> Other Inadequate stakeholder management <u>Effect</u> <ul style="list-style-type: none"> Diminished professional confidence in the adequacy of the legislation Reduced public confidence in regulation of matters relating to human tissue 	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 March 2019
						Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope					X		Monitoring		
						Active management of issues raised by the media – including the development of the HTA position on issues				X			Preventative/ Detective	Stakeholder Group meeting minutes Authority minutes (including Public Authority Meeting) <i>TAG and HWG meetings</i>	Last stakeholder group meeting in October 2018 <i>Public Authority Meeting in May 2019 ; Histopathology Working Group January 2019; Transplant Advisory Group May 2019</i>
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence				X			Preventative/ Detective	Quarterly reports to Authority on communication (including media) activities	Last report to Public Authority Meeting in May 2019
						Action where we believe it will support public confidence (e.g. publication of pregnancy remains guidance)					X		Monitoring	Quarterly Accountability meetings with DH	<i>Full year accountability meeting in May 2019</i>
						Clear view of use of s.15 duty to report issues directly to Ministers				X			Preventative	Published guidance for particular issues (e.g. pregnancy remains, and cord blood)	<i>Pregnancy remains guidance published March 2015</i> Cord blood guidance issued in March 2016 <i>Guidance is still current.</i> <i>Conservation information for public</i>
						Legal advice now gives a clearer view of our Schedule 2, s. 20 powers				X			Preventative	Duty and its uses understood by SMT and Chair	Letter to Minister re. import and consent requirements for public
						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	Legal advice to be followed	Legal advice September 2016. No change to position.
						Partial implementation of triennial review recommendations March 2017				X			Preventative and remedial	Codes published on website	<i>Supplementary guidance on PM standard on traceability issued Feb 2019</i>
						Public research - gaining a better understanding of public confidence and the factors which impact it - complete Q2 2017/18				X			Preventative	Recommendations form part of business plan	Good progress, most complete with only benchmarking to be finalised
						Proactive horizon scanning and development of policy in emerging/complex areas Project complete Q3 2017, now business as usual							Preventative		Authority undertook review of headline messages at strategic awayday October 2017. Public forum and review of public guides
										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
									Deliver programme of work to improve relationships with licensed establishments	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
									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		x		Preventative	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	On track, but uncertainty remains Guidance to sector published Feb19 ORC assessment of preparedness as green <i>Extension period agreed to 31 October 2019; frequency of meetings reduced pending outcome of further Govt negotiations</i>

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>(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)</p> <p>Risk Owner:</p> <p>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	4	4		People	4	3		1	2	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. Monthly 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	Insufficient, or ineffective management of, financial resources (Risk to Deployment objective b Risk Owner: Richard Sydee	<u>Cause</u> <ul style="list-style-type: none">Fee payers unable to pay licence feesThe number of licenced establishments changes, leading to reduced fee incomeManagement fail to set licence fees at a level that recover sufficient income to meet resource requirementsFailure to estimate resource required to meet our regulatory activityPoor budget and/or cash-flow managementUnexpected increases in regulatory responsibilitiesUnforeseeable price increases / reductions in GIA	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 November 2018		
		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 April 2018		
		Prioritisation when work requirements change				X					Preventative	Agreed business plan, monthly HTAMG and SMT reports	Last HTAMG report December 2018		
		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 2018 - 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 April 2019		
		Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) Ongoing				X			X		Detective	Quarterly Finance Directors and Accountability meetings	Last FDs meeting Nov 2017. DoF wider network January 2019		

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	Failure to achieve the benefits of the organisational transformation programme (Development objectives a-d)	Causes	5	4			4	4		1	2	3			
		<ul style="list-style-type: none">• Uncertainty of funding				SMT experience of organisational change, programme and project management				X			Preventative		
		<ul style="list-style-type: none">• Programme and project benefits poorly defined and understood				HTA approach to the management of change projects (underpinned by PRINCE2)				X			Preventative		
		<ul style="list-style-type: none">• Inadequate programme and project governance arrangements				A number of trained project managers among HTA staff				X			Preventative		
		<ul style="list-style-type: none">• Poorly specified programme and projects				Experience of procurement and contract management				X			Preventative		
		<ul style="list-style-type: none">• Insufficient programme, project and change management skills				Existing mechanisms for engaging staff				X			Preventative		
		<ul style="list-style-type: none">• Inadequate leadership of change				Well established corporate governance arrangements and financial controls					X		Monitoring		
		<ul style="list-style-type: none">• Inability to access the necessary skills required at a affordable cost				Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding				X			Preventative		
		<ul style="list-style-type: none">• Lack of staff buy-in to change				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	
		<ul style="list-style-type: none">• Management and Head stretch of delivering transformation alongside business as usual and other development activity							Embed Benefits Realisation Management methodology within programme	X			Preventative		
		<ul style="list-style-type: none">• Insufficient agility in (re)deploying people to change projects							Introduce a Programme Management Office	X			Preventative		
		<ul style="list-style-type: none">• Poorly specified procurement and inadequate contract management							Authority approval to proceed at key Gateway decision points		X		Monitoring		
		<ul style="list-style-type: none">• Realisation of single points of failure for DDAT and People Strategy							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	
		Effects							Training plan to encompass project and change management and HTA approach	X			Preventative		
		<ul style="list-style-type: none">• Wasted public money							Development of procurement plan to deliver the DDAT Strategy	X			Preventative		
		<ul style="list-style-type: none">• Failure to achieve the central strategic intent of the Authority							SROs identified for Programme and individual projects	X			Preventative		
		<ul style="list-style-type: none">• Distracts senior management from operations at a time when demands have increased							Schedule a regular programme of staff engagement events	X			Preventative		
		<ul style="list-style-type: none">• Reputational damage							Establish an external stakeholder communications and engagement plan	X			Preventative		
		<ul style="list-style-type: none">• Unaffordable cost over run							Recruitment of new Authority Member(s) with digital and organisational change experience		X		Monitoring		
		<ul style="list-style-type: none">• Staff demotivation							Programme to become a focus for appropriate internal audit			X	Monitoring/ Detective		
		<ul style="list-style-type: none">• Data remains under-utilised							Appointment of external critical friend to counter potential optimism bias			X	Preventative		
		<ul style="list-style-type: none">• Technology inadequate to meet future needs (cost, functionality)													
		<ul style="list-style-type: none">• Limited ability to achieve improvements in efficiency and effectiveness													
		<ul style="list-style-type: none">• Pace of change is inadequate and impacts negatively on other work													



				Likelihood		
		1	2	3	4	5
Impact		Rare	Unlikely	Possible	Likely	Almost Certain
5	Very high	5 Medium	10 Medium	15 High	20 Very High	20 Very High
4	High	4 Low	8 Medium	12 High	16 High	20 Very High
3	Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2	Low	2 Very low	4 Low	6 Medium	8 Medium	10 Medium
1	Very low	1 Very low	2 Very low	3 Low	4 Low	5 Medium

			Inherent Risk Priority		>>	Residual Risk Priority		
Ref	Risk	Risk Owner	Impact	Likelihood	Proximity	Impact	Likelihood	Comments
1	Failure to provide accurate advice or to make evidence-based regulatory decisions, when assessing new licence applications, varying licences, undertaking inspections or considering living organ donation cases, leading to known or inadvertent breaches of statutory and regulatory requirements (Delivery a-c)	Heads of Regulation (JP lead)	4	4	Ongoing, with heightened risk with newer staff	4	3	<p>Update for April HTAMG: Further RM interviews scheduled to account for loss in experienced staff. No change to risk status.</p> <p>Update for May HTAMG: Further RM interviews scheduled to account for loss in experienced staff. No change to risk status.</p> <p>Update for June HTAMG: Further RM interviews scheduled to account for loss in experienced staff. HoR / DoR have made some amends to risk one to ensure current risk / priorities are reflected. No change to risk status.</p> <p>Update for July HTAMG: RM recruitment progressing well. No change to risk status.</p> <p>Update for August: Successful RM recruitment. Heads have discussed with Nicky the operational risk register and the desire to work on this further. No change to risk status.</p> <p>Update for September: RO post vacant which increases pressure on the regulatory operations team. Successful RM recruitment. No change to risk status.</p> <p>Update for October: RO post remains vacant which increases pressure on the regulatory operations team - interviews scheduled. A number of RMs in probation period at the moment. No change to risk status.</p> <p>Update for November HTAMG: Successful recruitment of Regulation Officer (starting 3 December 2018). Successful recruitment of RMs, with several in probationary periods. No change to risk status</p> <p>Update for February HTAMG: Full complement of Regulation Managers in post. Transplant Manager due to start maternity leave in April, intention at this stage is to have this key role covered by mid-March. No change to risk status at the current time.</p> <p>Update for March HTAMG: No Transplant Manager in post since February. This has placed a great deal of pressure on the Head and LDAT team. Interviews on 27 March.</p> <p>Update for April HTAMG: Transplant Manager appointed. Two Regulation Manager - Training posts are being advertised and one Regulation Manager. No change to risk status.</p>
2	Inadequate management of stakeholder relationships (Delivery d-e)	Head of Communications (MS)	4	4	Ongoing with potential peaks depending on the external and internal environment	3	3	<p>Update for March HTAMG: No change to risk status.</p> <p>Update for April HTAMG: no change to risk status, though recent media interest and other high profile factors continue to cause the wider external environment to be potentially fractious and complex. Update for May HTAMG: no change.</p> <p>Update for June HTAMG: no change.</p> <p>Update for July: no material change, but external environment feels increasingly febrile.</p> <p>Update for September: no change</p> <p>Update for October: no change</p> <p>Update for November: as we continue to have uncertainty on whether a deal will be reached regarding EU Exit, the risk that establishments will lose confidence and the media will take more of an interest in practical implications of this increases, with the knock on effect on the HTA's reputation and public confidence in key areas such as organ donation and transplantation.</p> <p>Update for December: No change</p> <p>Update for January: with the planned EU Exit date nearing and a closing of relationship with, and oversight from, colleagues at DHSC/DexEU and beyond resulting in protracted timescales for external communications referencing EU Exit preparedness, the knock on affects to stakeholder relationships from delayed and/or inadequate messaging out to potentially affected stakeholders has increased. We are working with our key partners to mitigate against this, but cognizant we are one relatively small strand of a much larger tapestry across not just the health and social care environment, but central government.</p> <p>February - similar to last month's update, but heightened somewhat as we creep closer to a potential EU Exit, further complicated by the uncertainty around date and manner of exit. We continue to mitigate against this potential confusing working with other partners in the system on providing and signposting to advice and guidance to establishments.</p> <p>May: not change in the risk, though it is fair to say that the coming and going of the March date for the UK's exit from the EU has removed some stress and tension from across the shoulders of the system, though we are still currently operating under uncertainty as to what will eventually happen.</p>

HTA Operational Risk Register 2017-2018

Ref	Risk	Risk Owner	Inherent Risk Priority		>> Proximity	Residual Risk Priority		Comments
			Impact	Likelihood		Impact	Likelihood	
3	Failure to deliver development and change activities (Development a-d)	Head of Development (AT)	5	4	Ongoing with peaks	4	4	Update for October: As per September. RM resource allocated to some development work. No change for risk scoring as ability to deliver change is dependent on training of new staff and potential for external factors such as EU Exit to divert resource allocation. November update: No change for risk scoring as ability to deliver change is dependent on training of new staff and potential for external factors such as EU Exit to divert resource allocation December update: No change to risk scoring because of uncertainty regarding the allocation of resource to EU exit January update: as per December update Update for February: No change to risk status as delivery of development and change activities has to be balanced against post inspection workloads, and increased demands placed on staff through EU exit work. Update for March: A need for greater organisational capability in policy and development work is a key limiting factor and competing priorities continue to be a factor. No change to risk status. Update for April: No change to risk status Update for May: No change to risk status
4	Failure to manage staff turnover and workforce capability (Deployment a)	Head of HR (DG)	5	4	Ongoing	4	4	Update for April HTAMG: Stress survey results to be discussed at HTAMG. Two posts being actively recruited for at present with a further two posts to be recruited shortly. Have completed workshop re: induction with ongoing work required on this.
5	Inadequate management of finances (Deployment b)	Head of Finance and Governance (MA)	5	4	End of 2019/20 business year.	3	2	Update: May - Ended the year on a surplus. As of April there are no immediate issues.
6	Inadequate management and utilisation of data and business technology (Deployment c)	Head of Business Technology (DT)	5	5	Ongoing	5	5	Update for April HTAMG: No change from previous month Update for March HTAMG: risk increased following a penetration test which highlighted a number of issues. A remediation plan has been produced to resolve highest rated vulnerabilities immediately followed by lower risk vulnerabilities. Update for February HTAMG: Need to consider whether the impact and likelihood should be increased in light of recent audits. Update for January HTAMG: Need to consider whether the impact and likelihood should be increased in light of recent audits. Update for December HTAMG: No change to risk status.
7	Inadequate business planning (Governance)	Director of Regulatory Development	4	4	Ongoing	3	3	Update for December HTAMG: No change to risk score, Head of Planning and Performance role has been recruited to and will start in January. Update for January: Risk score has been reduced to reflect overall assessment of risk Update for February: No change to risk score, work continues under listed actions Update for March: No change to risk score

Reference		Comments:
1	<p>Failure to provide accurate advice or to make evidence-based regulatory decisions, when assessing new licence applications, varying licences, undertaking inspections or considering living organ donation cases, leading to known or inadvertent breaches of statutory and regulatory requirements</p> <p>Linked to Strategic Risk 1 & 2</p>	<p>Update for April HTAMG: Further RM interviews scheduled to account for loss in experienced staff. No change to risk status.</p> <p>Update for May HTAMG: Further RM interviews scheduled to account for loss in experienced staff. No change to risk status.</p> <p>Update for June HTAMG: Further RM interviews scheduled to account for loss in experienced staff. HoR / DoR have made some amends to risk one to ensure current risk / priorities are reflected. No change to risk status.</p> <p>Update for July HTAMG: RM recruitment progressing well. No change to risk status.</p> <p>Update for August: Successful RM recruitment. Heads have discussed with Nicky the operational risk register and the desire to work on this further. No change to risk status.</p> <p>Update for September: RO post vacant which increases pressure on the regulatory operations team. Successful RM recruitment. No change to risk status.</p> <p>Update for October: RO post remains vacant which increases pressure on the regulatory operations team - interviews scheduled. A number of RMs in probation period at the moment. No change to risk status.</p> <p>Update for November HTAMG: Successful recruitment of Regulation Officer (starting 3 December 2018). Successful recruitment of RMs, with several in probationary periods. No change to risk status</p> <p>Update for February HTAMG: Full complement of Regulation Managers in post. Transplant Manager due to start maternity leave in April, intention at this stage is to have this key role covered by mid-March. No change to risk status at the current time.</p> <p>Update for March HTAMG: No Transplant Manager in post since February. This has placed a great deal of pressure on the Head and LDAT team. Interviews on 27 March.</p> <p>Update for April HTAMG: Transplant Manager appointed.Two Regulation Manager - Training posts are being advertised and one Regulation Manager. No change to risk status.</p>
Risk owner	Heads of Regulation (JP lead)	
Proximity	Ongoing, with heightened risk with newer staff	

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

Risk Analysis						
Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance	Assured Position
Inexperience of regulatory decision makers including those making decisions on living donation cases	<p>Failure to identify or follow up a shortfall against HTA standards</p> <p>Incorrect interpretations by staff of statutory and regulatory requirements</p> <p>Failure to follow up with an Independent Assessor or Living Donor Coordinator leading to an incorrect decision being made and / or inconsistent decision making across the team</p>	<p>Guidance on inspections, SOPs and templates for staff</p> <p>Induction and ongoing training programme for RMs to include codes of practice/standards and core elements of inspection and HTA regulation. This includes QA checks of enquiries by line manager</p> <p>Inspection evidence workbooks across all sectors</p> <p>Process for escalating regulatory decisions (RDM process).</p> <p>Audit of percentage of CAPA plans as part of organisational QA process.</p>	<p>PS&C project to develop organisational QA processes to include inspection- related activities</p> <p>e.g. proposal to review a percentage of draft inspection reports reviewed against evidence contained in inspection workbooks on an ongoing basis, as part of organisational QA process.</p> <p>Review and development of formalised RM induction. Project on 18/19 business plan</p> <p>Training for RMs on developing CAPAs and assessing evidence submitted to demonstrate that actions have been met</p>	<p>QA project to be scoped in 2018/19</p> <p>To be completed during 2018/19 business year - in progress</p> <p>To be completed during 2018/19 business year - in progress</p>	<p>Records of quality assurance of inspection reports and the evidence used to support judgements / decision making.</p> <p>Minimal representations & appeals rate</p> <p>Quarterly quality assurance checks of a 10% sample of living donation cases by each decision maker</p>	Minimal representations and appeals rate

Inadequate training for regulatory decision makers	<p>Inconsistent regulatory decision making</p> <p>Inconsistent application of enforcement processes</p> <p>Inaccurate or poor quality advice and guidance given, leading to inadvertent regulatory or statutory breaches by licensed establishments</p> <p>Establishments fail to comply with Codes, directions, licensing standards and conditions</p> <p>Increased risk of SAEARs and HTARIs</p> <p>Loss of public and/or professional stakeholder confidence</p>	<p>Induction and ongoing training programme training on core elements and training on HTARIs and SAEARs</p> <p>Decision-making framework</p> <p>Sector-specific publications provide a learning resource for RMs and establishments</p> <p>Before end of probation, all RMs observed by HoR on their first inspection as support RM and their first lead inspection. In addition, RMs are observed for their first lead inspection in each sector</p>	New RMs are assigned a "buddy" when they start at HTA	To be completed in 2018/19 business year	<p>Records of quality assurance of inspection reports and the evidence used to support judgements</p> <p>Minimal representations & appeals rate</p> <p>Quarterly quality assurance checks of a 10% sample of living donation cases by each decision maker</p>	Minimal representations and appeals rate
Heads' time focussed on developing new team members so less capacity to support other team members	Inadequate supervision and oversight of regulatory decision making	<p>Regular 1:1s with staff and annual PDP process</p> <p>Directorate meetings</p> <p>'Open door' approach adopted by HoRs</p> <p>Each new licence application is discussed with relevant HoR</p>	Proposal to introduce new Senior RM roles across the organisation	To be completed by Q3 2018/19		
Loss of knowledge and experience through staff attrition	<p>Heavy reliance on remaining RMs and HoR for sector-specific knowledge</p> <p>Insufficient trained staff to undertake inspections and specialised project work</p> <p>Reprioritisation of business plan activities such as projects and inspections</p>	<p>Handover of current work to ensure work is not lost</p> <p>Sector specific induction and training</p> <p>Use of inspection workbooks to capture inspection findings</p> <p>Ongoing sector update sessions and opportunities for RMs to share learning</p> <p>Regular RM meetings to discuss current issues e.g. findings on inspection</p> <p>Management of data / inspection findings captured on CRM</p>	Contingency arrangements for staffing on key programmes and projects (Directors)	We have an information management system but this needs further improvement.		

<p>Inadequate systems (including quality management systems) and processes to support effective, risk-based, regulatory decision making</p>	<p>Poor clarity and transparency of regulatory processes</p> <p>Inadequate risk evaluation resulting in inspection schedule that may not reflect risk</p> <p>Site visit inspections which do not provide for adequate scrutiny of licensed activities (e.g. at satellite premises or during themed inspections)</p> <p>Emphasis on self assessment at licence compliance updates, which informs risk profiles of licensed establishments</p> <p>Decline in professional and public confidence in the work of the HTA</p> <p>Quality Management processes not clearly codified</p> <p>Poor quality documents made public/shared with the Authority</p> <p>Regulatory practices not consistent with Regulators' Code</p> <p>Increased scrutiny by DH/Select Committees</p>	<p>Suite of standard operating procedures underpin regulatory processes</p> <p>2-yearly compliance updates with more focused and risk-based questions across all sectors; 2 yearly inspections in the HA sector and annual activity data</p> <p>Decision-making framework and tools, including escalation procedures for 'significant' regulatory action</p> <p>Quarterly audit of evidence submitted to satisfy completion of agreed CAPAs</p> <p>Review of risk areas in human application as part of HA risk project, including risk based approach to inspection and oversight of TPAs</p>	<p>Compliance updates inform inspection scheduling</p> <p>Making better use of data / information available and focusing on prevention of serious incidents</p> <p>Decision-making framework update</p> <p>Information sharing with CQC and other organisations to inform risk profiles</p> <p>Internal audit assurance / quality assurance of processes and outputs by appointed auditors (PS&C)</p> <p>Internal quality management system, to include audit of compliance with procedures and inspection evidence gathering (PS&C)</p> <p>Improved process for review of policies and procedures (PS&C)</p> <p>Regular review and revision of position statements and governance documentation.</p> <p>Improvements to oversight of TPAs in response to HA Risk project.</p>	<p>Project to look at safety KPI to explore how we capture and use our data 18/19</p> <p>MOU with CQC to be reviewed 18/19 and MOU with HRA to be published 18/19</p> <p>QA project to be implemented in 18/19.</p>	<p>Records of quality assurance of inspection reports and the evidence used to support judgements</p> <p>Minimal representations & appeals rate</p> <p>Quarterly quality assurance checks of a 10% sample of living donation cases by each decision maker</p>	<p>Minimal representations and appeals rate</p>
<p>Lack of sufficient relevant expertise within the PPDWG to support decision making and lack of access to relevant scientific publications</p> <p>Limitation of current systems and processes in relation to PPDs as set out in HA risk findings</p>	<p>Failure to identify, adequately resolve and follow up issues with submitted validation data</p> <p>Poor/inappropriate decisions reached regarding PPD authorisation</p> <p>Inefficient use of resources</p>	<p>PPDWG made up of people with a range of scientific backgrounds including those with direct experience relevant to HA sub-sectors</p>	<p>HTA to explore and, if appropriate, implement a system for accessing external, independent expertise if the need arises. A procedure for when to seek such advice to be developed in parallel.</p> <p>Identification of possible experts and development of support procedures (e.g. agreements, conflict of interest statements, etc.)</p> <p>HTA to explore improved access to scientific journals</p> <p>HTA participation in the EU GAPP project regarding authorisation of preparation processes</p> <p>Improvements to PPD process as part of HA risk implementation</p>	<p>To be completed in 2018/19 business year - scheduled for Q3.</p> <p>GAPP project to be completed by 2020</p>		

Reference		Comments:
2	Inadequate management of stakeholder relationships Linked to Strategic Risks 1 & 3	Update for March HTAMG: No change to risk status. Update for April HTAMG: no change to risk status, though recent media interest and other high profile factors continue to cause the wider external environment to be potentially fractious and complex. Update for May HTAMG: no change. Update for June HTAMG: no change. Update for July: no material change, but external environment feels increasingly febrile. Update for September: no change Update for October: no change Update for November: as we continue to have uncertainty on whether a deal will be reached regarding EU Exit, the risk that establishments will lose confidence and the media will take more of an interest in practical implications of this increases, with the knock on effect on the HTA's reputation and public confidence in key areas such as organ donation and transplantation. Update for December: No change Update for January: with the planned EU Exit date nearing and a closing of relationship with, and oversight from, colleagues at DHSC/DexEU and beyond resulting in protracted timescales for external communications referencing EU Exit preparedness, the knock on affects to stakeholder relationships from delayed and/or inadequate messaging out to potentially affected stakeholders has increased. We are working with our key partners to mitigate against this, but cognizant we are one relatively small strand of a much larger tapestry across not just the health and social care environment, but central government. February - similar to last month's update, but heightened somewhat as we creep closer to a potential EU Exit, further complicated by the uncertainty around date and manner of exit. We continue to mitigate against this potential confusing working with other partners in the system on providing and signposting to advice and guidance to establishments. May: not change in the risk, though it is fair to say that the coming and going of the March date for the UK's exit from the EU has removed some stress and tension from across the shoulders of the system, though we are still currently operating under uncertainty as to what will eventually happen.
Risk owner	Head of Communications (MS)	
Proximity	Ongoing with potential peaks depending on the external and internal environment	

Inherent Risk >>		>> Residual Risk		FALSE		
Impact	Likelihood	Impact	Likelihood			
4	4	3	3			
Risk Analysis						
Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance	Assured Position
Ineffective relationships/communication with sponsor branch	Reputational damage and reduced confidence in our work	*Framework agreement *Good communications channels with sponsor team and press office *Communications attends various ALB communications meetings *DH sit on the HTA's stakeholder group and Authority as observers *Regular business and accountability meetings with DH *Informal communications as required	*Work with the DH to ensure that information is passed on in the most effective way *Work to ensure that the HTA is not overburdened with information requests	17/18	Positive feedback from DH at accountability meetings Feedback from DHSC accountability meetings	
Ineffective relationships /communications with the interested public	Reputational damage and reduced confidence in our work	*Public engagement plan agreed *Effective communications routes (website, social media, newsletter) along with SOPs *Public representation on Stakeholder Group (and other groups) *Bi-monthly public e-newsletters *Annual review publication and event *Key meetings organised with partners, comms team offered briefs *Regular surveys *Monitoring of enquiries and monthly reporting: 95% of enquiries answered in 10 days *Plan for regular website review updating - improved search,/navigation, updated content etc... *Review of public facing information and creation of cord blood pack etc. *Internal staff group to look at public engagement	*Enquiries project (from Q3 2017/18) to address process, quality, systems etc... *Implementation of style guide, key messages, templates training for staff *Refresh Stakeholder Group membership *Improve look and feel of website content (Web Survey and Content review in 17/18) *Guidance for people attending external events *Public Evaluation in 2017 (outcomes to influence the public engagement plans) *Website developments *New public information review group and online forums *Work to disseminate public communications via partner organisations *Investigate online panel solution (i.e. online community for public engagement)	17/18	Evaluation forms part of the communications – quarterly report to the Authority Results from surveys of public via the public panel, website and other channels including general enquiries, media coverage and commentary and via social media etc...	

Ineffective relationships /communications with stakeholders, including DIs, IAs and AAs	Reputational damage and reduced confidence in our work	<ul style="list-style-type: none"> *Public patient engagement plan agreed *Effective communications routes (website, social media, newsletter) along with SOPs *Effective Stakeholder Group *Two monthly professional and public e-newsletters *Annual review publication and event *Key meeting organised with partners, comms team offered briefs *Regular surveys: feedback sought after inspections, events, training and other ad hoc work *Monitoring of enquiries and monthly reporting: 95% of enquiries answered in 10 days *New website and regular website updating 	<ul style="list-style-type: none"> *Better relationships with establishments project (formerly known as the DI relationship project and DI e-learning project) *Enquiries database and survey *Triennial review action plan published *Implementation of style guide, key messages, templates training for staff *Refresh Stakeholder Group membership *Review critical incident plan *Improve look and feel of website content *Guidance for people attending external events and toolkit *2016 stakeholder survey 	17/18	<p>Evaluation forms part of the communications – quarterly report to the Authority</p> <p>Results from surveys of professionals, feedback and insight from the LEEP group</p>	
Ineffective relationships /communications with media	Reputational damage and reduced confidence in our work	<ul style="list-style-type: none"> *General media approach agreed - why is this litigation? *Lines up to date, weekly news digest, list of media mentions, list of journalist contacts *Subscription to Meltwater *Media handling SOPs *E-newsletter *Key meeting organised with partners, comms team offered briefs *Media guidance for AMs *Media training *Out of hours rota *Contact with other press offices 	<ul style="list-style-type: none"> *SOPS *Filming guidelines *FOI and enquiries target *Continued publication of data (transparency) *Review critical incident plan *Update media handling SOP *Continue to work on projects related to HTA regulation to build our profile 	17/18	<p>Evaluation forms part of the communications – quarterly report to the Authority</p> <p>Evaluated quarterly through Authority reporting (Delivery report) and kept under review on an ongoing basis.</p>	
Inaccurate stakeholder analysis	Lack of understanding in the HTA about our key audiences and their concerns	*Yearly stakeholder analysis takes place	*Review contacts in CRM and Mail chimp	17/18	<p>Evaluation forms part of the communications – quarterly report to the Authority</p> <p>Need to think about how we are assured that we are accurate; Stakeholder mapping?</p>	
Inadequate communications tools (website, social media, newsletter, events etc.)	Inability to communicate with key audiences	<ul style="list-style-type: none"> *New website developed *Social media presence maintained *e-newsletters maintained *Internal branding and design support 	<ul style="list-style-type: none"> *Review of website content assign web pages to owners *Digital survey *Website developments ongoing *DI e-learning *Increased use of webinars and webchats 	17/18	<p>Evaluation forms part of the communications – quarterly report to the Authority</p> <p>Survey results from web pop up, and other channels, to measure user experience and effectiveness of engagement and comms channels</p>	
Inadequate communications input into HTA work and projects (Codes and Standards, Import and Coding, Fees etc.)	Poor stakeholder understanding about HTA's work and lack of input from our audiences	*Comms team involvement in projects including Standards and Codes roll out, fees and Coding and Import	<ul style="list-style-type: none"> *Develop media plans *Develop publication schedule 	17/18	<p>Evaluation forms part of the communications – quarterly report to the Authority</p> <p>Each project or programme has a comms representative</p>	
Inadequate understanding about changes in the external environment (legislation, burden reduction etc.)	Poor at influencing the external environment and lack of HTA understanding of important policy changes	<ul style="list-style-type: none"> *SK and the upcoming media/publications plan *SK on the DH media call and feeding back *Weekly news digest *Events in the staff newsletter *Regular meetings with stakeholders <p><i>Is SK a person if so not a mitigation</i></p>	<ul style="list-style-type: none"> *Establish appropriate knowledge management and horizon scanning functions for the HTA *Communications timetable regularly at SMT *Develop horizon scanning function 	17/18	<p>Evaluation forms part of the communications – quarterly report to the Authority</p> <p>Establishment of a Horizon Scanning function across all areas of the HTA</p>	
Inadequate staffing and knowledge management of the communications team	Communications team unable to operate properly	*Cross team knowledge developed about different aspects of our work *Appropriate professional development courses and membership identified	*Head of Communications handover effective	17/18	<p>Evaluation forms part of the communications – quarterly report to the Authority</p> <p>Proactive approach to recruitment, retention, and training/development.</p>	

Reference		Comments:
3	Failure to deliver development and change activities	Update for October: As per September. RM resource allocated to some development work. No change for risk scoring as ability to deliver change is dependent on training of new staff and potential for external factors such as EU Exit to divert resource allocation.
	Linked to Strategic Risks 1 and 4	November update: No change for risk scoring as ability to deliver change is dependent on training of new staff and potential for external factors such as EU Exit to divert resource allocation December update: No change to risk scoring because of uncertainty regarding the allocation of resource to EU ex it
Risk owner	Head of Development (AT)	January update: as per December update Update for February: No change to risk status as delivery of development and change activities has to be balanced against post inspection workloads, and increased demands placed on staff through EU exit work.
Proximity	Ongoing with peaks	Update for March: A need for greater organisational capability in policy and development work is a key limiting factor and competing priorities continue to be a factor. No change to risk status. Update for April: No change to risk status Update for May: No change to risk status

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

Risk Analysis						
Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance	Assured Position
Identification of change						
Inadequate horizon scanning and stakeholder engagement to inform development	Failure to identify areas for improvement	Horizon scanning lead by Heads of function with expertise and links to key stakeholders Advisory groups	Project to strengthen horizon scanning arrangements	Ongoing	Horizon scanning map; Minutes of stakeholder meetings.	
Inadequate use of internal data sources to inform horizon scanning	Failure to identify areas for developments	RMs included in policy and development team to bring current insights	Safety KPI report will consolidate and provide analysis of a number of internal data sources for the management team and Authority		Figures published in annual review document; Sector specific publications based on data analysis. Provides assurance that we are using internal data sources to inform our work	
Inadequate horizon scanning and stakeholder engagement to inform priorities	Failure to effectively prioritise work to meet stakeholder (internal and external) expectations and meet externally imposed outcomes or deadlines	Central policy team who co-ordinate and oversee development activities; Discussion of priorities at HTAMG	Strengthen systems and processes for policy and development work (policy framework)	Q1 2018/19	HTAMG minutes	
Planning and Management						
Risk of not delivering change poorly understood	Poor resource allocation between core operational business and development projects.	Continuous business planning includes consideration of project and development work and how to balance competing work priorities - discussions via HTAMG and at SMT	Improvements to continuous business planning process to include greater emphasis on resource allocation	Ongoing		
Projects are not added to the business plan	Poor resource and skills allocation Project objectives not in line with business priorities	Oversight of business plan by Heads and Directors	Cultural change to encourage Heads to discuss items at HTAMG and add to the business plan Build on continuous business planning process to be clear about what is added to corporate and team plans	Ongoing	Business plan and pipeline updated monthly; HTAMG minutes.	
Lack of management support	Project team does not have authority to achieve project objectives	Projects discussed by HTAMG and approved by SMT; SRO at Head or Director level. Key projects have Authority Member on project board.			SMT minutes (Projects standing agenda item)	
Poorly defined project outcomes and measures of success	Outcomes which do not meet stakeholder (internal and external) expectations or project objectives	Outcomes included in project templates reviewed by HTAMG	When reviewing milestone log, consider whether the milestone is still the right one		Project documentation in IMPACT; HTAMG papers and minutes.	
Scope is poorly defined	Scope creeps with uncontrolled changes and is no longer in line with business plan objectives Project becomes undeliverable	Project scope included in planning templates Governance arrangements (SRO/project board) for individual programmes and projects in place	Formalise 'issue logs' as part of the project planning and feed into horizon scanning	Q1 2018/19	Project documentation in IMPACT; HTAMG papers and minutes.	
Required activities and tasks are missing from project plan	Project requires further resource or extension to timelines to deliver Quality of project is compromised	Project plans approved by HTAMG	Greater scrutiny of project plans by HTAMG	Ongoing	Project documentation in IMPACT; HTAMG papers and minutes.	

Required activities and tasks are not completed as part of project plan	Poor quality outcomes which leave the organisation exposed to risk	Project milestones reviewed at HTAMG Progress tracked on BP monitor Key projects reported to Authority in Development report			HTAMG minutes Business plan monitor spreadsheet Development report to Authority (quarterly) Authority minutes	
Inaccurate estimates of resource during project planning	Resource requires diverting from delivering other objectives or project takes longer to deliver Poor use of resources	Project plans approved by HTAMG			Project documentation in IMPACT; HTAMG papers and minutes.	
Frequent changes to scope	Schedule and/or budget are continually extended leading to perception that project has failed	Changes to scope approved by HTAMG			Project documentation in IMPACT; HTAMG papers and minutes.	
Poorly defined project/change process	Inconsistency in decision making		Further embed continuous business planning process and make improvements to documentation to make process accessible and more efficient	Ongoing	Completed project documentation in Programme Office area of IMPACT; HTAMG minutes.	
Insufficient resource (budget, staff) allocated or available to deliver change projects.	Delays to delivery of projects or poor quality outcomes Staff perception of change and morale affected		Greater scrutiny of resources required by HTAMG prior to project approval	Ongoing	Project documentation in IMPACT; HTAMG papers and minutes.	
Poor governance and oversight of project delivery	Delays to delivery of projects or poor project outcomes	Progress on projects reviewed at HTAMG monthly Key projects include Authority Members on project board			Project board meeting notes HTAMG papers and minutes	
Skills/resource						
Insufficient programme and project management training and/or experience	Delays to delivery of projects or poor quality outcomes	Central location for project information in IMPACT	Experienced staff to share learning to develop a wider set of HTA project managers All Officers trained in project support	Ongoing	Key members of staff hold project management qualifications or have relevant experience	
Specific programme and project knowledge concentrated in the hands of small number of people (vulnerable to staff loss).	Delays to delivery of projects or poor quality outcomes		Experienced staff to share learning to develop a wider set of HTA project managers All Officers trained in project support	Ongoing		
Delivery of change						
Failure to communicate change effectively (internal and external stakeholders)	Reputational impact Inconsistency in application of change Change not fully embedded within organisation	Member of Comms team should input into all projects			Internal and external newsletters Monday briefings Sector specific communications (Mail Chimp) HTA Website	
Failure to train those affected by change (internal and external stakeholders)	Reputational impact Inconsistency in application of change Change not fully embedded within organisation				RM meeting agendas Published HTA Guidance and information	
Failure to ensure change is appropriately documented in policies, SOPs, guidance etc.	Reputational impact Inconsistency in application of change Change not fully embedded within organisation					
Dependencies on external partners outside the HTA's control	Poor quality outcomes which leave the organisation exposed to risk	Clear lines of communication with key project partners, with escalation routes identified if required Ongoing relationship management with key partner organisations			Contracts with third party providers specify agreed service level provision	

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

Risk		Comments:
4	Failure to manage staff turnover and workforce capability Linked to Strategic Risk 4	Update for April HTAMG: Stress survey results to be discussed at HTAMG. Two posts being actively recruited for at present with a further two posts to be recruited shortly. Have completed workshop re: induction with ongoing work required on this.
Risk owner	Head of HR (DG)	
Proximity	Ongoing	

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

Risk Analysis						
Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance	Assured Position
Workforce skills and behaviours not aligned with the needs of the business	Weakened ability to deliver the HTA's statutory remit	* People Strategy and road map for 2017/18 * Comprehensive suite of HR policies * Clearly articulated organisational values	* Fundamental review of People Strategy for 2018/19 * Regular review of HR policies * Investigate introduction of HTA Competence Framework	* Jan 2018 * Ongoing * August 2017	Staff Survey and staff forum feedback	
Ineffective recruitment practices	* Insufficient staff capacity * Recruits with the wrong skills * Recruits who are not a good fit for the HTA	* Well developed recruitment processes including to business critical posts * Use of testing for Head roles and above			Quarterly HR reports to SMT to provide an overall picture of vacancies and recruitment	
Ineffective induction	* Lack of knowledge about what is expected of objectives or behaviours leading to poor performance	* Induction workbook and new starter process * Structured feedback sought on the induction process for new starters at six month anniversary	* Continuous improvement the induction process and pack * Review of the induction process for RMs	* Ongoing * Summer 2017	Feedback from new starters (as part of the revised induction process)	
Inadequate leadership and management	* Lack of understanding and buy-in to the HTA Strategy * Poor understanding of business objectives and priorities * Poor motivation	* Standard management leadership objective for Heads and Directors to be measured against, including holding regular 121 meetings. * Development plan introduced for HTAMG	* Introduction to line management training * Advanced line management training	* TBC * Oct/Nov 2017	* Staff Survey and staff forum feedback * Annual Exit Interview reporting	
Inadequate utilisation of the skills, knowledge and experience of individuals	* Individual demotivation * Failure to capitalise on opportunities	* Well established PDP process * Revised PDP forms and support for 2017/18 to focus on development * Skills matrix made available via the Wiki			Staff forum chair meeting regularly with ARAC chair	
Poor management of workloads	* Uneven or unfair distribution of activities * Stress on individuals	* Regular discussion between staff and line managers at 121s	* Increased scrutiny by HTAMG	* Monthly	HTAMG Assessment	
Inadequate involvement and communication	* Poor understanding of objectives, priorities and decisions * Belief that an individual's voice or concerns are not heard	Variety of mechanisms for two-way communication * Newsletter * Monday briefing and regular staff meetings * SMT drop in * Quarterly business away day * Staff survey * Staff forum			Staff Survey and staff forum feedback	

Inadequate learning and development	* Insufficient skills and knowledge to deliver business objectives * Poor personal and professional development leading to poor motivation	* Learning and development framework * Learning and development plans for each member of staff	Introduction of team learning and development plans	Summer 2017	Quarterly and annual reporting of learning quality through bespoke evaluation forms	
Incorrect salary payments	*Job satisfaction *Stress on individuals *Loss of confidence in HTA systems	*Employing specialist payroll contractor * Payroll change/variation forms	*Management of specialist payroll contractor		Reported payroll errors - ????	

Reference		Comments:
5	Inadequate management of finances Linked to Strategic Risk 5	Update: May - Ended the year on a surplus. As of April there are no immediate issues.
Risk owner	Head of Finance and Governance (MA)	
Proximity	End of 2019/20 business year.	

Inherent Risk >>		>> Residual Risk				
Impact	Likelihood	Impact	Likelihood			
5	4	3	2			
Risk Analysis						
Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance	Assured Position
Unsophisticated budget setting process.	Breaching mandatory obligations and running out of cash	Budgetary control framework and budget holders manual.	Budget Holder training – attach to meetings	In line with policy review dates	Quarterly finance meetings, noted back to directorates. Monthly reports submitted to Directorates.	Finance Reports and quarterly review highlighted the trending increase in underspend.
Inadequate budget management skills across the HTA.	Where overspend exists, inability to respond to demanding changes (lack of flexibility).	Monthly/Quarterly finance meetings attended by heads of directorates and directors.		Quarterly throughout business year		
Ineffective reporting system for managers to compare performance against budget.		Monthly management accounts with accompanying transaction listings. Quarterly review meetings		5 days after end of each month, so ongoing		
Failure to disseminate the budget and delegated authorities.	Consumption of finance resource unplanned. If significant affects cash flow	Budget training and meetings to be held.	Delegation letters issued annually confirming financial responsibilities - Completed Q1			
Reduction in license fee collection (unable to increase price again).	Failure to deliver statutory remit and operational plans.	Credit control system and supporting SOPs in place.	Detailed quarterly reviews carried out enabling us to re-forecast	July, October, December of each financial year	ALB Monitoring returns to DH quarterly	Positive Cash reserves

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

Reference		Comments:
6	Inadequate management and utilisation of data and business technology Linked to Strategic Risk 4	Update for April HTAMG: No change from previous month Update for March HTAMG: risk increased following a penetration test which highlighted a number of issues. A remediation plan has been produced to resolve highest rated vulnerabilities immediately followed by lower risk vulnerabilities. Update for February HTAMG: Need to consider whether the impact and likelihood should be increased in light of recent audits. Update for January HTAMG: Need to consider whether the impact and likelihood should be increased in light of recent audits. Update for December HTAMG: No change to risk status.
Risk owner	Head of Business Technology (DT)	
Proximity	Ongoing	

Inherent Risk >>		>> Residual Risk					
Impact	Likelihood	Impact	Likelihood				
5	5	5	5				
Risk Analysis							
Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance	Assured Position	SPF
No knowledge transfer	Lack of operational resilience due to reliance on knowledge of single individual.	Information captured in IT systems in a way that is retrievable and searchable including HTA wiki, IMPACT and CRM. See also: Risk 1 - Capability & Capacity Risk 9 - Governance SOPs, training and guidance on HTA systems.	Consolidate guidance into wiki. Encourage use of wiki to capture more informal knowledge. Review list of systems and related guidance Remove out of date guidance from all systems.	Year end	Systems guidance and SOPs Wiki	The HTA still relies on informal knowledge transfer but, along with regularly reviewed SOPs, the wiki has the potential to make existing guidance more accessible and to capture more informal organisational knowledge.	1
No information maintenance	Not compliant with -Data Protection Act/GDPR -FOI Act -Public Records Act Inefficient use of resources Inefficient HTA operations	Information asset register defines retention periods. Staff clear out of personal data complete.	Review actions against information assets and continue to add new information assts. Consider retention periods and housekeeping with IAOs.	Year end	Information Asset Register on the wiki	The information asset register goes some way to defining what should happen to assets, and when. At present this is done on an ad-hoc, when needed basis. The HTA has undertaken an exercise with all staff to clear out personal data no longer needed. The IQ project will continue to address this.	1
No information strategy	Inconsistent development of information systems and processes leading to no control or oversight of information assets. Information not stored in most efficient or reusable way leading to duplication and poor analysis of buried/hidden data which in turn can lead to poor decision making.	IT Strategy updated annually. BCC IT, CRM and LAN support, contracts. Webcurl support contract.	Develop an 'information strategy' with an overarching view and road map of how to store and make best use of information. Strategy to include -Information architecture -Information capture/consolidation -Information processing -Information analysis		IT strategies and HTAMG papers. Quarterly meetings with BCC Quarterly meetings with Webcurl	The HTA has a good idea of where it is going from an ICT point of view but needs to remain flexible and open to new developments.	1
Information Risk Management Regime							

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

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

No user security Policy No staff Induction Process Users not aware of threats No formal assessment of IA Skills	Unacceptable use Use of personal removable media and devices may lead to security incidents. (e.g. malware) HTA subject to legal and/or regulatory sanction. Increased impact of incidents. Misuse of system may lead to compromise. User becomes means of external attack. User becomes source of attack.	IT systems policy (covering acceptable use) Social Media policy Information Governance policy covering information assurance, data protection, forensic readiness, incident response and records retention (actual periods listed in information asset register). Disciplinary policy. Induction process and documents. CSL courses for Information assurance. BSC data protection course. Ad-hoc newsletter updates. Ad-hoc all staff meeting updates. System guidance. Internal audit survey. Policy acknowledgements now being received by email.	<i>Promote formal IA qualifications and courses.</i> <i>Promote awareness of Information asset register.</i>	<i>Quarter two</i> <i>Throughout the year.</i>	IT Systems Policy Information Governance Policy Social Media Policy. Disciplinary Policy. Guidance on HTalk. CSL records. BSC records. Newsletters and all staff meeting minutes. CRM Incident cases.	Staff are generally aware of cyber risks but it would be good to get additional assurances that the message is getting out to all staff and that they remain aware. HTA staff and suppliers are required to annually acknowledge the IG and Cyber risk policy by email.	2, 3
Incident Management							
No senior management approval and support No incident response and DR capability No specialist training	Major and/or continual disruption of business operations. Non-compliance with legal and regulatory reporting requirements.	SMT approval of Information Governance Policy which covers incident response and forensic readiness. Business continuity plan with defined roles and responsibilities. Business continuity plan updated yearly in line with business plan. Incidents captured and tracked in CRM. Server and data backups to BCC DR site. Lessons learned following major incidents. New CIRP now in place aligning critical incidents and business plans and training in place.			Ad-hoc DR test report emails from BCC Fortnightly backup report emails from Martin. CRM incidents. Full business continuity tests including DR site.	Information is backed up and replicated to an offsite DR site. The DR site was tested fully in October 2014 with a good awareness of DR procedures shown by all staff. We now have a new critical incident response plan which covers business continuity, DR and critical incidents. This has clear links from day to day SOPs and clear responsibilities for handling and escalating incidents.	4
Removable media controls & Malware Prevention							
No removable media corporate policy No limits on use of removable media No scanning of removable media for malware No corporate malware policies No anti-malware defences No scans for malware	Loss/leakage of information through theft, loss or neglect. Introduction of malware via: -Email -Web browsing and social media -Removable media and personal devices. Reputational damage. Financial loss or fines.	IT Systems policy covers use of removable media and personal devices. Websense scans email and webtraffic before it enters the HTA network. Websense blacklists websites. (The firewall can blacklist IP addresses.) Microsoft Forefront protects laptops from malware. Laptop baseline build HTA encrypted USB keys available for staff. USB devices are blocked by default on HTA laptops.	<i>Consider CESG end user device configuration guidance (covers all points above)</i>	<i>Quarter 3</i>	Websense logs. Quarantined emails. Forefront logs.	The HTA is comprehensively covered across the internal network and the risk of malware is small. The PWC tests recommended that malware scanning should take place on the portal server itself. The HTA has mitigated the risks of malware entering the network via the portal and does not consider this necessary. CESG provide detailed guidance around the configuration of end user guidance which will be considered. The greatest risk in this area is users so awareness is important.	1
Home and mobile working							

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

Reference		Comments:
7	Inadequate business planning	Update for December HTAMG: No change to risk score, Head of Planning and Performance role has been recruited to and will start in January. Update for January: Risk score has been reduced to reflect overall assessment of risk Update for February: No change to risk score, work continues under listed actions Update for March: No change to risk score
	Linked to Strategic Risk 4	
Risk owner	Director of Regulatory Development	
Proximity	Ongoing	

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

Risk Analysis						
Potential Causes	Potential Effects	Existing Controls/Mitigations	Actions to improve mitigation	Date	Sources of Assurance	Assured Position
Planning						
Lack of clarity on/buy-in to business planning process	New items not added on to the plan Plan does not capture all current and planned activity, leading to confusion and poor use of resource	Updated ToR for HTAMG Standard agenda for monthly team planning meetings	Improvements to the process for continual business planning and project planning	Q4 2018/19	Minutes of HTAMG minutes Documented business plan pipeline, discussed and reviewed by HTAMG monthly	
Insufficient time dedicated to business planning process.	New items not added on to the plan Too little focus on the future leading to poor use of resource and risk of not meeting strategic aims	Central and Directorate resource dedicated to business planning and monitoring.	Review of planning process (Q4) Development of guidelines and sign off for Projects and clarity of how these link to BP.	Q4 2018/19	KPIs signed off by Authority annually, PIs signed off by HTAMG annually	
Over-optimism regarding what can be delivered with HTA capability and capacity.	Elements of plan are not delivered, or quality is affected	Resourcing will need to be carefully considered at HTAMG	Better use of dashboards and data to inform resource planning. Development of dashboard data using new CRM system to aid monitoring of resources and activities. Aim to have this in place at the end of Q1 of 19/20 Business year.	Q1 2019/20	HTAMG meetings and minutes. Revision to inspection and audit schedule as required.	
		Annual all-Head Operational Risk Register session to benchmark all risks.			Strategic plan scrutinised by Authority (annually)	
Monitoring						
Failure to adapt the plan in light of change in circumstances.	Business objectives and targets are not met. Lack of revaluation / reprioritisation of business plan (review and adapt).	Monthly reviews at team meetings HTAMG meetings Continual business planning element of HTAMG	Increased focus on resource planning and management Clear process for agreeing what activities should be prioritised/stopped if resources become stretched Inclusion of priority ranking of activities in BP		HTAMG scrutiny of missed KPIs and Pis HTAMG minutes	
Insufficient time to monitor the business plan.	Poor organisational performance.	Monthly reviews at HTAMG	Dedicated time at HTAMG/SMT for areas showing slippage on delivery/failure to meet KPIs		Authority scrutiny of KPIs (monthly)	
Lack of focus on the business plan.	Over and under burden on staff.	Monthly reviews at team meetings HTAMG meetings All staff away days	Proactive engagement with colleagues to ensure business plan development is focused. Streamline business planning process	Ongoing		

IT problems prevent easy access to the business plan.	New and changing demands are not met.		Review and consider improvements to tracker to make it straight forward to use.			
SMT and/or Heads of function fail to act critically and challenge assumptions.	Reputational damage caused by not delivering the published plans.	Monthly review at HTAMG	Risk based approach to monitoring plans			
Deterioration of relationship with DHSC	Business plan is poorly understood by DHSC	The Department holds quarterly accountability meetings with the HTA. The HTA is well prepared to account for risks and performance.	Any actions related from the Accountability meetings that will/potentially affect are reported to HTAMG for action as soon as possible		Minutes of Quarterly Accountability meeting (also circulated to Members)	
Lack of organisational awareness of strategic priorities	Failure to deliver strategic objectives.	New strategic objectives agreed for 2018 - 2021 Strategic objectives translated into business plan for 2018/19 Resources made available to support PDP process linking personal objectives to business plan	Information shared through team meetings and then incorporated into PDPs			
Stakeholder issues not addressed or recognised in business plan	Damage to stakeholder relationships.	Stakeholders are frequently consulted.	Issues identified in Stakeholder Survey or Inspection feedback visits are considered for inclusion in the 19/20 Business Plan		Minutes of Stakeholder and Fees Group, Histopathology Working Group and Transplantation Advisory Group	
Resources						
Lack of resources, primarily staff.	Under-utilisation of staff skills and capacity.	SMT oversight of staffing and skills profile.	Improved assessment of resource planning, with more formal tools.			
Lack of knowledge and/or skills of Heads of function to carry out the monitoring.	Failure to address the performance issues highlighted by performance information.		Ongoing support from DoRD on monitors and measures			
High turnover of Heads of function.						
Staff responsible for updating the business plan are not available when required.	Incomplete performance information	QaCGM responsible for commissioning and collating all updates	The business plan can be accessed by all colleagues.			

Audit and Risk Assurance Committee paper

Date	12 June 2019	Paper reference	AUD (09/19)
Agenda item	13	Author	Nicolette Harrison, Director of Regulatory Delivery
Protective Marking	OFFICIAL		

Designated Individual Engagement

Purpose of paper

1. To provide a written summary of Regulation Directorate responses to the questions outlined by ARAC to aid their deep dive review of Designated Individual (DI) engagement.

Decision-making to date

2. ARAC's questions have been shared by the Director of Regulatory Delivery with all Heads of Regulation and discussed with them and the Director of Regulatory Development in formulating responses to ARAC's questions.

Action required

3. For consideration by ARAC.

Background

4. DIs have a key role to play in implementing the legislative requirements under which they are licensed. They are the person under whose supervision the licensed activity is authorised to be carried out.
5. For establishments licensed under the HT Act, DIs have the primary legal responsibility under Section 18 of the HT Act to secure:
 - that suitable practices are used in undertaking the licensed activity;
 - that other persons working under the licence are suitable, and;

- that the conditions of the licence are complied with.
6. For establishments licensed in the Human Application (HA) sector, the DI has further responsibilities. DIs in the HA sector have the primary legal responsibility under Regulation 12 of the (Q&S Regulations) to ensure:
 - the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activities;
 - suitable practices are used in the course of carrying out the licensed activities;
 - the conditions of the licence are complied with;
 - that licensable activities carried out by third parties are subject to suitable practices and are carried out by suitable persons; and
 - the requirements of Regulation 13(1) relating to information and confidentiality are complied with.
 7. Information on the roles and responsibilities of DIs is provided on our website for the [HT Act sectors](#) and [HA sector](#).
 8. Further information for DIs in the HA sector is provided in the [Guide to Quality and Safety Assurance of Human Tissues and Cells for Patient Treatment](#) (pages 13-14).
 9. There are no DIs for licences in the Organ Donation and Transplant (ODT) sector. Instead there are named contacts against each licence but they do not have the same legal responsibilities as DIs in other sectors. This is because in the ODT sector we license organisations, not individuals or premises.

ARAC Questions

10. The deep dive questions received from ARAC are set out below along with responses (*in italics*) from the Regulation Directorate.

10.1 Appointment

10.1.1 How are DIs appointed?

Applications to become DI are made by submitting a DI application form to the HTA. The form is included as part of the application for a new licence and as a standalone form to vary the DI on an existing licence.

The DI application is assessed by a Regulation Manager (RM). Guidance for RMs assessing the suitability of DI applications is provided in the standard operating procedure.

Assessment of DI applications in the HA sector includes consideration that the individual meets the minimum requirements for qualifications/experience stipulated in the Q&S Regulations.

10.1.2 What information does the HTA have regarding the qualifications and positions of the existing group of DIs?

At the point of application to be DI, we ask for details such as:

- *educational and/or professional qualifications;*
- *any other relevant experience, including managerial experience and training;*
- *job title;*
- *lines of responsibility between the DI and any persons working under the licence;*
- *involvement in governance and quality management activities within the establishment; and*
- *any practical experience in the fields of medicine, biological science, managerial experience and training.*

10.1.3 What control does the HTA have over who can be a DI?

All proposed DIs must be assessed for suitability by an RM. If a proposed DI is deemed to be unsuitable, we will reject the application and the Corporate Licence Holder (CLH) must apply for a new proposed DI.

In the HA sector, the Q&S Regulations include some minimal requirements (experience, qualifications, etc.) that must be met. Arguably, this gives us some further control over who becomes the DI.

10.1.4 How does the HTA assure itself that the DI to be appointed has the appropriate qualifications, training, job description, influence and capability to oversee quality standards and effect change in the organisation where required?

We assess this as part of the DI application process by assessment of the answers in the DI application form. The application form includes information such as:

- *educational and/or professional qualifications;*
- *any other relevant experience, including managerial experience and training;*
- *job title;*
- *lines of responsibility between the DI and any persons working under the licence;*
- *involvement in governance and quality management activities within the establishment; and*

- *any practical experience in the fields of medicine, biological science, managerial experience and training.*

For HA sector licences, the Q&S Regulations require that the DI must have either:

- *a diploma, certificate or other evidence of formal qualification in the fields of medical or biological sciences, or*
- *be otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications and practical experience, and*
- *have at least two years' practical experience which is directly relevant to the activity to be authorised by the licence.*

10.1.5 Can the HTA reject or object to a DI? If so on what grounds?

Yes, a DI can be rejected if any of the prerequisite requirements are not fulfilled by the proposed applicant. Our procedures require that the DI must be advised of the reason for not accepting him/her, and the Licence Holder is asked to nominate another candidate for the role.

10.1.6 How are DI vacancies monitored? What steps are taken to ensure replacements are appointed before the vacancy arises?

If we are advised by an establishment that a change of DI is required in the future we log this for follow up at the appropriate time. We also advise stakeholders, via the e-newsletter and on our website, of the lawful requirement for an HTA approved DI to be in post and for any variation requests to be submitted prior to the date of change (to allow time for assessment).

Inspections include a 1:1 interview with the DI and planned organisational changes are discussed.

10.1.7 What action is taken when licence holders fail to fill a vacancy prior to the departure of outgoing DI?

This is handled on a case-by-case basis and the action taken reflects this. A priority is to establish the level of activity under the licence at that time/going forward and what interim measures are in place to ensure appropriate oversight of licensable activities. If needed, a Regulatory Decision Meeting (RDM) will be scheduled to discuss the need for regulatory action.

10.1.8 How often has this occurred and how often has this resulted in formal action by the HTA?

We do not keep a log of this information, so cannot provide numbers. However, it is not unheard of and formal action has been taken in some instances (e.g. an inspection brought forward).

10.1.9 How are the delegated powers of the Person Designate managed and assured?

This is primarily achieved through the inspection process.

10.2 Oversight

10.2.1 How does the HTA assure itself of the ongoing suitability and performance of DIs?

This is principally achieved through inspections, although other factors also contribute to our assessment of a DI, such as SAEARs reporting/follow-up, submission of Preparation Process Dossier (PPD) data, Annual Activity (AA) returns, etc. In general terms, any information that informs the HTA about what is going on at an establishment, and the DIs level of oversight, is used to assess the DIs ongoing suitability for the role.

10.2.2 Are there any performance indicators, or other flags, which measure how a DI is performing or which can alert the HTA when there are problems?

See comment above. Also, compliance with Directions, provision of compliance information in agreed timeframes, information shared with the HTA by whistleblowers, etc.

10.2.3 How is a DI assessed during an inspection of licensed premises?

Through a combination of 1:1 interviews, interactions during and prior to the inspection, through their response to inspection findings and their handling of CAPA plans, etc.

10.2.4 How is the HTA assured that DIs are appraised on their performance in relation to their DI responsibilities as part of their internal review?

The HTA licensing standards require establishments to have a system for staff appraisal. We do not review specific staff appraisal records; we consider this to be outside of our remit.

10.3 Training

10.3.1 What induction training is provided for new DIs?

We do not provide training for DIs (or practitioners more broadly) and do not currently consider it as part of our role as the regulator, although we note that this is something that is sometimes raised with us. Although historically we had training material on our website, this has now been replaced by information resources that DIs can access. A paper submitted to the recent Stakeholder and Fees Group meeting considered options around what activity we could do to raise awareness

and understanding of our legislation and standards amongst practitioners and was well-received.

10.3.2 What ongoing training is a DI required to do to ensure that they remain up to date?

We do not stipulate what ongoing training a DI is required to do. The HTA licensing standards (GQ3) require that staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills. Staff training is reviewed during inspection.

10.3.3 How does the HTA know if this has been done?

See above

10.3.4 How is any training evaluated by participants and how has this feedback been used?

As noted above, we do not provide training for DIs. However, we have developed a series of online tests on the core requirements of the HTA's governing legislation. The tests are non-compulsory and are taken anonymously, although we capture information on the licence role (ie, if a DI, PD or CLH). These tests have been promoted via the professional e-newsletter, on the HTA website, and through social media. The tests have been well received by licensed establishments and we have received over 1,500 responses since their launch. This number continues to grow.

We will continue to monitor and promote these, and encourage our key stakeholders to share them through their networks. The Licensed Establishments Engagement Programme (LEEP) will also continue to discuss the data accumulated from these tests to support and inform other engagement activities, such as the licensing requirements communications project.

10.3.5 What are the expectations on a DI to ensure that staff at the establishment are appropriately trained?

It is a statutory requirement that DIs must ensure that suitable practices are carried out by those undertaking the licensed activities. The HTA considers that staff training is an important part of this and so we look for evidence of suitable staff training on inspection and during the licence application process. For example, one of the questions asked in the DI variation form is:

“Please explain your involvement in ensuring that staff who will work under the licence are appropriately qualified and trained in techniques relevant to their work and that they are continuously updating their skills”.

The information provided by the DI in response to this question is reviewed as part of the application for a licence; if we are not satisfied that the DI has put appropriate arrangements in place for staff training, this may lead to a delay, or a rejection, of the licence application.

10.4 Underperforming DIs

10.4.1 What does the HTA do when it is aware of an underperforming DI? How much support is it able to put in place for such an individual?

This varies on a case-by-case basis. If the DI wants/needs support then we will usually provide this to help the DI raise standards. This can be achieved in a number of ways, including provision of specific information or documents, CAPA follow-up visits, putting them in touch with similar establishments with good practices, etc.

There is also the relationship we have with License Holders (LHs) and Corporate License Holder Contacts (CLHCs) to be considered in these circumstances: we involve LHs/CLHCs as they play key roles in ensuring their DIs are effective and replacing them if not.

10.4.2 What is the process for removing and replacing a DI where required? How often has this been done in practice?

The removal or replacement of a DI would be managed through the Regulatory Decision Making (RDM) process and recorded as an action arising from that meeting.

Audit and Risk Assurance Committee paper

Date	12 June 2019	Paper reference	AUD (10/19)
Agenda item	14	Author	Morounke Akingbola, Head of Finance and Governance
Protective Marking	OFFICIAL		

HTA Gifts and Hospitality

Purpose of paper

1. To present the Gifts and Hospitality Policy as part of the suite of policies that are presented annually to ARAC.

Decision-making to date

2. None

Action required

3. Members are requested to review and comment on the attached policy (Annex A).

Background

4. This policy was brought to ARAC in February 2018 alongside the Gifts and Hospitality Register. The register was presented at the February 2019 meeting. The attached policy has not changed however as part of our good governance process, the Committee are required to review it every two years.

Gifts and Hospitality Policy

Version number	1.0	Date last approved	January 2019
Reference	HTA-POL-051	Next review due	January 2021
Author(s)	Head of Finance	Owner	Director of Resources
Reviewed by	HTA SMT	Distribution	HTA Staff & Authority
Approved by	Audit and Risk Assurance Committee		

Revision history

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

Date	Version	Comments
05 May 2017	0.1	Drafted
18 May 2017	1.0	Approved by ARAC
20 Jan 2019	1.0	Reviewed by HoF – no fundamental changes made
March 2019	1.1	GDPR passage referring to the HTA's HR Privacy Policy and privacy notice inserted at paragraph 19.

Purpose

1. This policy sets out the procedure to be followed when giving or receiving gifts and hospitality.

Scope

2. This policy applies to full time and part time employees on a substantive or fixed-term contract, Authority members and to associated persons such as secondees, agency staff contractors and others employed under a contract of service.

Policy Statement

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

Receiving gifts

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

9. All other gifts should be passed to the Director of Resources who, in conjunction with the Chief Executive, will decide on the most appropriate action, which may include:
- returning the good to the supplier;
 - sharing the gift with all staff;
 - retaining the good within the HTA;
 - donating the gift to charity; or
 - allowing the member of staff to keep the gift.

Accepting offers of hospitality – genuine business reasons

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

Gifts and hospitality offered by the HTA

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

Declaration

16. You should make your declaration as soon as possible after the offer or receipt of gifts or hospitality. All declarations are to go to the Head of Finance and Governance in the required format as shown below. The Head of Finance and Governance will record the declarations in the register. The register is an annual document and will be broken down and filterable by financial year. It is recommended that you make your declaration by email, and retain a copy for your personal records.
17. Your declaration will need to include the following information:
- the date of any offers of gifts or hospitality, and the date of events where relevant;
 - the name, job title and the organisation of the recipient/provider;
 - the nature and purpose of the gift or hospitality received or declined;
 - the name of any other organisation involved;
 - the estimated value of the gift or hospitality.
18. **For example:**
- | | |
|---|--|
| Date received | 12 Dec. 2016 |
| Recipient (Name & Directorate) | Jane Brown (Resources) |
| Received from (Name, position & organisation) | Josh Sergeant (AAA Ltd) |
| Description of Gift/Hospitality received | Lunch |
| Value £ (Estimate if unknown) | Approx. £15.00 |
| Reason given for providing gift/hospitality | Working lunch provided during contract discussions |
19. Personal data of HTA employees processed by the implementation of this document will be done so in accordance with [HTA-POL-108 HTA HR Privacy Policy](#). Personal data of non-HTA employees processed by the implementation of this document will be done so in accordance with the HTA's [Privacy Notice](#).
20. You should consult the Director of Resources or Head of Human Resources for any guidance required on this Policy. If you have any doubt about whether an item should or should not be accepted, you are advised to decline and declare it.

Monitoring

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

Policy breach

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

Review

24. This document will be reviewed every two years