

Audit and Risk Assurance Committee (ARAC)

Date: 26 January 2023

Time: 09.45 – 10.00 Private ARAC Members session with Auditors
10.00 – 12.00 ARAC meeting
12.00 – 12.30 Private ARAC Members session

Venue: Virtual

Protective Marking: OFFICIAL

Agenda

1. Welcome and apologies **(10 mins)**
2. Declarations of interest
3. Minutes of Meeting 6 October 2022 meeting (AUD 01/23)
4. Matters arising from 6 October 2022 meeting (AUD 02/23)

Internal Audit (15 mins)

5. Item 5 is confidential and not included

Data Security and Protection Toolkit (15 mins)

6. DSPT HTA's status report regarding preparation for 2022/23 submission (AUD 04/23)

Annex A and B are confidential and not included

Cyber Security (5 mins)

7. Cyber Security report (AUD 05/23)

Audit Tracker (10 mins)

8. Item 8 is confidential and not included

External Audit (10 mins)

9. Item 9 is confidential and not included

Risk Update (25 mins)

10. Risk Update (AUD 08/23)

Annex A – Strategic Risk Register Summary (AUD 08a/23)

Annex B – Strategic Risk Register (AUD 08b/23)

11. Sector Risk Assessment (AUD 09/23)

Annex A - Data Annex (AUD 09a/23)

12. Consideration of Risk Appetite and Tolerance within the HTA (AUD 10/23)

Policies and Procedures (20 mins)

13. Summary of Policies (AUD 11/23)

14. Whistleblowing Cover Paper (AUD 12/23)

Whistleblowing Policy (AUD 12a/23)

15. ARAC Handbook Cover Paper (AUD 13/23)

ARAC Handbook (AUD 13a/23)

16. ARAC Terms of Reference Cover Paper (AUD 14/23)

ARAC ToR Document (AUD 14a/23)

17. Gifts and Hospitality Register – Cover Paper (AUD 15/23)

Annex A - Gifts and Hospitality Register (AUD 15a/23)

Regular Reporting (5 mins)

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

Any Other Business (5 mins)

19. DAO Letter regarding internal audit reports (AUD 16/23)

Copy of DA005-2022 (AUD 16a/23)

20. Committee's Effectiveness Review (Oral)

21. Any Other Business (Oral)

Minutes of the Audit and Risk Assurance (ARAC) meeting

Date: 6 October 2022

Time: 10.00 – 12.30

Venue: 2RP

Protective Marking: OFFICIAL

Attendees:

ARAC Members

Professor Gary Crowe (GC), Chair
Helen Dodds (HD)

Observers

Dylan Parrin (DP), Senior Policy
Manager, Department of Health and
Social Care
Dean Gibbs (DG), (KPMG)
Mohit Parmar (MP), National Audit
Office
Joanne Charlton (JC) Government
Internal Audit Agency

Apologies

Dave Lewis (DL)
Morounke Akingbola (MA), Head of
Finance and Governance

In Attendance

Dr Colin Sullivan (CS), CEO
Louise Dineley (LD), Director of Data
Technology and Development
Richard Sydee (RS), Director of
Resources
Nicolette Harrison (ANH), Director of
Regulation
John McDermott (JMcD), Deputy
Director for Performance & Corporate
Governance
Gisella Amabilion, Corporate Services
Manager
Alison Margrave (AM), Board Support
(*minute taker*)

Item 1 – Welcome and apologies

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

2. The Chair informed the Committee of his discussions with the Chief Executive and Director of Resources regarding several items. He reminded the Committee that HTA's Remuneration Committee has been established and the remit of this Committee, noting that an ARAC member sits on both Committees.

Item 2 – Declarations of interest

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

Item 3 – Minutes of 9 June 2022 meeting [AUD 27/22]

4. The Chair introduced the report and highlighted the proposed amendments to the minutes which are shown in red in the report.
5. The proposed amendments were accepted, and the revised minutes were agreed to be an accurate record of the meeting on 9 June 2022.

Item 4 – Matters arising from 9 June 2022 meeting [AUD 28/22]

6. The Chair introduced the report and the Committee discussed a number of outstanding actions and the work which had been undertaken to date; the Committee agreed that a number of actions could be closed.
7. The Chair informed the Committee of his proposal to amend the format of this report and he would work with the Executive to achieve this.
8. **ACTION:** The Chair to work with the Executive to revise the format of the matters arising report.
9. **ACTION:** The Executive to prepare a risk paper on each sector for a future ARAC meeting.

Item 5 – Internal Audit [AUD 29/22]

10. Jo Charlton (JC) introduced the report and spoke of the need to ensure better profiling of the proposed audits throughout the year to ensure that departments were not overloaded with multiple audits at the same time.
11. In response to a question, she confirmed that GIAA had provided a number of recommendations to the Executive with regard to the Data, Security and Protection toolkit and it's their responsibility to implement these.
12. JC informed the Committee that since the last meeting she had undertaken a mid-year review with the Senior Management Team to ensure that audit activity remains focused in the right areas. From this review two changes are proposed to the plan.
13. The Committee discussed the proposed changes to the plan, noting the explanation provided by the Executive for these changes.
14. **ACTION:** The Committee agreed the proposed changes to the HTA plan for 22/23 and noted the August 2022 GIAA supplementary report.

Item 6 – Data Security and Protection Toolkit [AUD 30/22]

15. Louise Dineley (LD) introduced the reports which included an update on HTA's 2021/22 assessment against the DSPT toolkit standards and the preparation for the 2022/23 assessment based on published standards. She spoke of the challenges which HTA has faced in preparing for the 21/22 assessment including loss of key staff and issues with the portal for submitting evidence.
16. LD highlighted the detailed action plan for the 2022/23 assessment and the lessons learnt from the previous assessment. She highlighted the plans to resource this with a dedicated member of staff and how this work cuts across all departments and is not just linked to one. She spoke of the difficulties for small organisations in achieving this assessment. In response to a question, she provided further information about the proposed shared services.
17. The Chair expressed his disappointment, that despite assurances being given at a previous Committee meeting, this audit had not been achieved at the

desired level. He asked that the Committee be kept better informed on this matter in future.

18. After further discussion the Committee noted the 21/22 assessment and improvement plan; the 2022/23 DSPT standards and action plan; an interim submission date of 28 February 2023 and a submission deadline of 30 June 2023.

Item 7 – Cyber Security Update [AUD 31/22]

19. Louise Dineley (LD) introduced the report and stated how this has been refined so that it is aligned to support the new NHS digital reporting and DSPT requirements. She stated that this report supports HTA's Cyber Security Policy and provides information on the main themes of identify, protect, detect, respond and recover.
20. She referred to slide 3 and informed the Committee that there had been no successful phishing attacks in this period, and all had been intercepted. The Committee discussed staff training in this regard and whether it is regularly tested.
21. The Committee noted the Cyber Security report.

Item 8 – Audit Tracker [AUD 32/22]

22. The Chair introduced this agenda item and stated that whilst some improvements have been made, he questioned how this could be enhanced so that the relevant staff take ownership of audit actions and evidence provided. He asked that future reports contain an executive summary.
23. **ACTION:** Future reports to include executive summary report.
24. Richard Sydee (RS) responded that since July the audit tracker is reviewed as part of the monthly business portfolio review, so this should ensure greater oversight of all the outstanding actions. The Executive will also consider whether GIAA could and should consult directly with the HTA staff rather than being channelled through one access point. He stated that several of the

outstanding recommendations need amending and the Executive will liaise with GIAA regarding these.

25. The Chief Executive commented that with the appointment of the Deputy Director for Performance & Corporate Governance this should strengthen HTA's position for management of governance matters. In addition, HTA should not step away from challenging any audit recommendations which they do not feel are suitable.
26. The Committee noted the report.
27. **ACTION:** The Deputy Director for Performance & Corporate Governance to meet with the ARAC Chair.

Item 9 – External Audit

28. Dean Gibbs (DG) informed the Committee that since the last meeting KMPG had signed and certified HTA's Annual Accounts for 2021/22.
29. He spoke of the audit plan for 2022/23 and informed the Committee that this would be brought forward to the next meeting. He informed the Committee of key changes to auditing standards, in particular the additional requirement to make more active risk-based assessments of areas for substantive testing and the need to include all IT systems that may provide information and data that support the financial statements.
30. The Chair thanked DG for the update and for having a good working relationship with the HTA.
31. The Committee noted the verbal report.

Item 10 – Risk Update [AUD 33/22]

32. Richard Sydee (RS) introduced the reports and informed the Committee that 6 of the 7 risks are above tolerance and spoke about the actions taken to mitigate these. He informed the Committee that monitoring of these reports had been moved into the monthly Business Portfolio meetings and this could account for greater movement between tolerance levels.

33. The Chair proposed the following questions to the Committee:

- Does the Committee recognise the risks and agree the ratings set by the Executive.
- Does the Committee recognise the actions which the Executive are taking to mitigate these risks and bring them back into tolerance level.
- For the risks which are ranked at the same tolerance level, should there be a further ranking to identify which is most pressing?
- What resource issues is the organisation facing?

34. The Chief Executive informed the Committee that the Executive may be calibrating the risks differently due to staff changes within the Executive. He spoke of resource issues which all public sector organisations face especially with regard to pay and recruitment.

35. The Committee discussed these documents in-depth, noting that they would be conducting a deep-dive discussion on risk 5. The Committee questioned whether the report could be enhanced by the Executive providing proposed trajectory and time frame for risks to be brought back to tolerance level.

36. The Committee noted the progress made and the update provided to the Committee.

37. **ACTION:** Executive to amend the report to add these trajectory elements to future reports.

Item 11 – HTA Counter Fraud, Bribery and Corruption Strategy [AUD34/22]

38. Richard Sydee (RS) introduced the reports and explained the guidance issued by the Cabinet Office and how these documents align with that guidance. In response to a question, he commented that Cyber Risk is managed by the operational risk register and is not governed by this policy.

39. After further discussion the Committee approved the HTA Counter Fraud, Bribery and Corruption Strategy and approved the Fraud Risk Assessment shown at Annex B of the document.

40. **ACTION:** Further information to be provided to the Committee regarding the proposed assessment at the end of October

Item 12 – HTA Reserves Policy [AUD 35/22]

41. Richard Sydee (RS) introduced the report and stated that the policy remains unchanged. He spoke of proposals to access the cash reserves to fund certain projects.
42. The Committee approved the HTA Reserves Policy and were supportive of seeking a solution to access reserves.

Item 13 – Gifts and Hospitality Register [AUD 36/22]

43. Richard Sydee (RS) introduced the register, which was noted by the Committee.
44. The Committee discussed whether all offers of hospitality which are refused by HTA staff are being reported.

Item 14 – Reports on grievances, disputes fraud and other information

45. No reports of grievances were discussed.
46. There was nothing to report to the Committee under fraud or dispute.

Item 15 – Governmental Functional Standards [AUD 37/22]

47. John McDermott (JMcD) introduced the report and informed the Committee that 3 of the proposed standards are not directly applicable for HTA and this approach had been confirmed by DHSC. He informed the Committee that HTA would conduct a self-assessment against these standards in Q3 and Q4.
48. The Committee noted the report.

Item 16 – Any other business (AOB)

49. There being no further business the Chair thanked all for their participation and drew the meeting to a close. He reminded all that the next meeting was scheduled for 26 January 2023

Human Tissue Authority

Audit and Risk Committee meeting

Date: 26 January 2023

Paper reference: ARAC 02/23

Agenda item: 4

Author: Alison Margrave, Board Support

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Matters Arising from previous Audit and Risk Committee meetings

Purpose of paper

1. To provide an update to ARAC on the actions arising from previous Meetings.
Colour coding used is blue = completed, green = on target and amber = at risk of not meeting target date.

Decision making to date

2. The Director of Resources agreed this paper on 12 January 2023 for submission to ARAC.

Action required

3. ARAC is to note the report.

Number	Date Added	Action	Assigned to	Target date	Revised date	Status
ARAC-2022_07	Jan 22	Executive to investigate training opportunities for the Autumn meeting.	Director of Resources and Head of Finance & Governance	Oct 22	Oct 23	Unfortunately, it was not possible for the planned training to take place in Oct 22. Training session to be arranged for June 23 meeting.
B_2022_12	July 22	The Board agreed in principle to the redefined strategic risks for the 2022/23 business year as shown at annex A of HTA 25/22 and asked the Audit & Risk Assurance Committee to consider the questions raised in relation to risks 2, 3 and 7.	Director of Resources	Oct 22	Jan 23	Completed , see agenda item 12.
ARAC_2022_17	Oct 22	The Chair to work with the Executive to revise the format of the matters arising report.	Chair and Board Support	Jan 2223		Completed , report amended, and new format used for both Board and ARAC.
ARAC_2022_18	Oct 22	The Executive to prepare a risk paper on each sector for a future ARAC meeting	SMT			Completed , see agenda item 11.
ARAC_2022_19	Oct 22	The Committee agreed the proposed changes to the HTA plan for 22/23 and noted the August 2022 GIAA supplementary report.	GIAA	Oct 22		Completed , changes made to the HTA plan 22/23.
ARAC_2022_20	Oct 22	Future audit tracker reports to include executive summary report	Head of Finance & Governance	Jan 23		Completed . Presentation of report amended as requested.
ARAC_2022_21	Oct-22	Executive to amend the SSR summary report to add these trajectory elements to future reports.	Head of Finance & Governance			Completed . Report revised and will continue to be reviewed throughout the year

HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the HTA Board meeting

Number	Date Added	Action	Assigned to	Target date	Revised date	Status
						by the Business Portfolio Review Meetings and Business Delivery Team Meetings
ARAC_2022_22	Oct 22	The Deputy Director for Performance & Corporate Governance to meet with the ARAC Chair.	Deputy Director for PCG and Chair	Jan 23		Completed , meeting held 12 December 2022.
ARAC_2022_23	Oct 22	Further information to be provided to the Committee regarding the proposed assessment at the end of October (Counter Fraud, Bribery and Corruption).	Head of Finance & Governance	Dec 22		Completed , email sent to ARAC members 1 December 2022.

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Draft policies may be subject to revision following the HTA Board meeting

Audit and Risk Assurance Committee (ARAC)

Internal Audit – Confidential

Audit and Risk Assurance Committee (ARAC)

Date: 26 January 2023

Paper reference: AUD 04/23

Agenda item: 6

Author: Uwaila Osawe, Information Governance Lead

Protective marking: OFFICIAL

DSPT HTA's status report regarding preparation for 2022/23 submission

Purpose of paper

1. This paper aims to provide ARAC with an update on the progress of the improvement actions against the 2021/22 assessment; the strengthened arrangements in place to co-ordinate the 2022/23 assessment and preparation for the 2022/23 DSPT assessment based on published standards.

Action required

2. ARAC Members are asked to:
 - Note progress against the DSPT improvement plan
 - Note the strengthened arrangements in place for the 2022/23 assessment
 - Note an interim submission date of 28 February 2023

Background

3. The HTA is required to submit an independently validated assessment on an annual basis against the DSPT standards. The standards are updated each year with different standards identified as mandatory.
4. In Q2 2022/23, an internal audit of the HTA's compliance with the DSPT standards generated a series of recommendations of improvement and achieving compliance with the toolkit.

5. In October a report was presented to ARAC which identified a number of key milestones for the assessment process these include:
 - Report to NHS Digital
 - Interim assessment – 28 February 2023
 - Final assessment – 30 June 2023
6. These milestones have previously been used to structure the action plan submitted to NHS Digital to address recommendations in the 2021/22 assessment in and preparation for the 2022/23 assessment.

Progress to date

7. In previous reports to ARAC we have discussed the need to strengthen the project and governance arrangements supporting the Data Security and Protection Toolkit. Progress in this area had been limited by internal resource constraints and the absence of a dedicated resource to co-ordinate this work.
8. Since the last update report to ARAC in October, work has been undertaken to introduce a formal project management structure to the collation of DSPT activities. This has been made possible by the appointment of an Information Governance Manager, a dedicated resource appointed in November 2022.
9. In their first 8 weeks the Information Governance Manager has:
 - Established a MS Teams channel to act as a central repository of all project documents, support the central collation of evidence and to act as a shared communications channel on requirements, actions and as a library for latest guidance.
 - Reviewed and updated the DSPT action plan in line with the evidence requirements identified in the autumn following the publication of the 2022/23 standards.
 - Established a DSPT working group with membership including function and standard leads.
 - Held 1 to 1 meetings with all DSPT leads to share standards, requirements and address any concerns or challenges that may prevent progress and compliance being achieved.
10. It is hoped that the combined impact of these activities will help in driving forward the required activities and support the tracking of actions.

Progress against the DSPT Improvement Plan and Action Plan

11. Following the 2021/22 assessment and in preparation for the 2022/23 assessment, the HTA has generated an improvement and action plan to identify actions and activities to achieve compliance against the DSPT standards. In generating these plans it has again highlighted the volume of additional activity that smaller organisations need to undertake to demonstrate and evidence compliance against these standards. The HTA's DSPT action plan and improvement plan identifies actions and activities up to the end of Q4 2022/23 to be completed. These actions include the generation of the required evidence.
12. Annex A contains a working document that provides a RAG rated summary of action due to be completed by the end of Q3 2022/23. The RAG rating is based on the following descriptions:

RED: These deadline and actions have either not been met or completed
AMBER: There is some level of assurance provided as progress being made but not all relevant evidence generated
GREEN: Target deadline met and actions completed satisfactorily. Evidence generated as per checklist identified
13. The RAG rating was completed on 22 December 2022 and as such represents the assessment on this date. At the end of Q3, out of the 16 actions identified for Q3:
8/16 actions assessed as completed (GREEN)
6/16 actions assessed as in progress (AMBER)
2/16 actions assessed as not completed (RED)

Activities have continued since this date and as such RAG ratings will have changed and will continue to be updated.
14. In addition to the actions identified under the improvement plan, there are additional actions required to meet requirements of the 2022/23 standards. Annex B is also a working document and contains a RAG rated summary of progress as of 22 December 2022.
15. At the end of Q3 the assessment identified:
34 standards as met (GREEN)
43 standards as in progress (AMBER)
38 standards as not met (RED)

16. Activities have continued since this date and as such RAG ratings will continue to change in preparation for the February submission and again for the final assessment.
17. At the time of writing this report it is important to note two specific active actions. Firstly the additional oversight activity has been put in place with the start of monthly “check and challenge” sessions with all standard leads to review progress, identify any barriers or challenges to compliance and to generate the required assurance and evidence of compliance. These sessions chaired by the Director Data, Technology & Development will be held monthly up to the point of the assessment in June and will monitor progress as well as check the supporting evidence of the reported progress. Secondly, at the time of RAG rating in December a number of actions were rated as RED. Since this time recovery plans have or are in the process of being developed for the standards and the action required to achieve compliance. In reviewing the RED rated standards a common factor in making and sustaining progress is resource availability and competing priorities in Q3.

Next Steps

18. Since December, SMT have received a monthly update report on progress against the standards. The next update will be provided to SMT at the end of January. This update will include an overview of the findings of the first “check and challenge” and details, by exception, of any standards that require or would benefit from further action or focus.
19. Over the next 6 weeks, the IG Lead will be actively progressing the following actions: Completing the updating and documentation of the Register of Processing Activities (ROPA) & Information Asset Register (IAR).
 - Reviewing and updating the Data Protection Impact Assessment (DPIA) Process
 - Progressing the DSPT workplan for the interim assessment in readiness for the submission in February
 - Updating and collating the evidence log with available evidence
 - Ensure the DSPT workplan is given the required priority by leads with discussions centred around assigned standards and any remedial action plans
 - Completing round 1 of the “check and challenge” sessions with DSPT standard leads.
20. ARAC is asked to note the updates provided on progress and the additional arrangements that have been put in place.

ARAC Cyber Security Dashboard

January 2023

Q3 Update

AUD 05/23



Introduction

The Cyber Security dashboard provides a summary of cyber security systems and protection. The high level summary builds on the detailed report provided to ARAC in January 2022.



The Cyber Security Dashboard has been developed using the 6 key outcomes of the HTA's Cyber Security Strategy (2020). This strategy seeks to implement measures to achieve the mandatory protective security outcomes of the Minimum Cyber Security Standard. The HTA's cyber security systems are focused on the following outcomes:

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

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

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

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

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

Cyber Security Performance Q3 2022/23 – at a glance

Microsoft secure score	Viruses intercepted Q3 2022/23	Device exploit availability (no known)	Device vulnerability
93.54%	100%	0/65	A total of 9 devices had 15 known vulnerabilities
Alerts received from NHS X	Number of alerts responded to in 48hrs	Staff mandatory training (Completed Q3 2022/23)	Internet use: Identified access to restricted categories
4 (1 relevant to HTA)	100%	100%	23807

ARAC Cyber Security Dashboard – Overview

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



Microsoft Secure Score	Antivirus Update Status	HTA Exposure Score	Phishing & Viruses Detected	Spam Detected	
93.54% similar NHS entities scored 57.03% Meaning we have well defined and managed processes in place	100% out of 80 devices MS Defender identifies devices as laptops and servers	22%	64 Viruses over 3 months Less than 0.074% of mail received 18 Phishing attempts sent to 17 recipients	Month	Count
				Oct	2355
				Nov	2942
				Dec	2609
				Total	7906

Secure score is a defined standard that shows how well we are protected. It also shows how we compare to similar NHS entities. This shows we are significantly better

Our Antivirus solution is monitored and updated in real time ensuring we have the latest known virus threat and unknown breaches kept to a minimum

Higher the score the more at risk our devices are 22% is in the low bracket

With the onset of remote working email viruses and phishing attempts have never been more prevalent. The HTA had 64 viruses included in email with all intercepted by our security systems, this has seen an improvement since previous quarters

SPAM accounts for 7.4% of all inbound email. This figure is what was intercepted by our security systems. User feedback is critical in the event that spam breaches these controls. Incidents are reported to IT for follow up.

ARAC Cyber Security Dashboard – IDENTIFICATION & PROTECTION Summary



The HTA have well defined Advanced Threat Protection systems in place as a result of taking advantage of the NHS arrangement. As a result, we are required to Respond to NHS Cyber Alerts (RTANCA). These are underpinned by a comprehensive set of policies and procedures that allows the monitoring and governance of all sensitive data and requests from GDPR to FOI and access to confidential/personal information internally. This dashboard is an indicator of the policies and controls we have in place to address and manage request and incidents that directly relate to information potentially being extracted for malicious purposes.

Device Exploit Availability & Device Vulnerability Severity

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

0 Exploits Verified	6 Critical
0 Exploits Available	8 High
58 No Known Exploit	0 Low

With 48 devices with no known exploit is good. This includes Servers, Routers and other Infrastructure devices

WWW Analysis

0% of Machines affected
0% Blocked due to gaming
Greater than 50% Social Media/Streaming/Web Mail

Web Monitoring & Filtering

340 requests to access to potentially dangerous sites

ARAC Cyber Security Dashboard – DETECTION Summary

Potentially Malicious Events

ATP identified the following security attacks and successfully remediated the issues

0 Detections

0 Unique Files

0 Affected Devices

Exposure Distribution

Of the malicious threats only

0 device was at high risk

3 devices medium

50 devices low

The same device can be in all 3 categories depending on the type of risk

Health State

ATP identified 65 Active devices in the HTA estate and automatically applies security policies and default usage policies such as not allowing the use of unauthorised external USB devices

15 Inactive devices are almost certainly equipment no longer in use. The detailed logs will tell IT what devices they are so they can be removed from ATP monitors

Attack Surface Reduction

ASR polices are critical in the protection of mitigating misuse of equipment and preventing cyber threats. Currently applied to all active devices

ARAC Cyber Security Dashboard – RESPONSE & RECOVERY Summary Breakdown



NHS Cyber Security Alerts

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

NHS Cyber Security Alerts

Q3 2022
 Total of 4 alerts
 4 High
 0 Medium
 0 Low

HTA Affected

4 request were made 3 were not applicable
 1 was addressed and dealt with

RTANCA

Responded to within 48 Hours
 100%

WWW Analysis

0% Machines affected
 0.54% Blocked due to gaming
 Greater than 50% Social Media/Streaming/Web Mail

Web Monitoring & Filtering

340 requests to access to potentially dangerous sites

Top Vulnerable Software

Zoom
 MS Office
 Google Chrome
 Windows 10
 IT are making recommendations to remedy.

ARAC Cyber Security Dashboard – Staff Awareness Training



Cyber Security Training Completed	Mandatory Cyber Security Training	Planned Realtime Simulated Security Training
<p>Introduction to GDPR Phishing Awareness Display Screen Equipment Q1 2021 Fraud Awareness Freedom of Information Q2 2021 Using email and the internet Information security diagnostic assessment Accountability & GDPR Information Security</p>	<p>2022 Personal Data Security Physical Risks – Information Security Toolbox (talk) Consequences of Cybercrime</p>	<p>These tests are part of the NHS ATP security toolkit to test all HTA staff in Malware Attack Phishing Attempts Credential Harvest (attempt to obtain personal information) Link to Malware Attack Consent Grant Attack (this is when you give access to data that do not have the right to see) The reports will identify those who pass or fail so more detailed training can be given</p>

Conclusion

- Over the last quarter the HTA's cyber security threat protection has been maintained via existing monitoring systems and responding to regular alerts via the RTANCA (Response to an NHS Cyber Alert) system.
- All issues identified either through detection, reports or alerts have been actioned without risk to the organisation.
- The information highlights the HTA is in a good position to monitor and protect its systems, devices and users from potential attacks.
- The continual threat and creativity of cyber attacks means that in addition to maintenance of existing systems we need to continue to seek opportunities to improve the security of IT systems and digital data stores.
- We also will be running an equipment refurbishment project which will see an increase of devices periodically recognised in ATP, this will drop down again to normal numbers but might impact the next ARAC report

Audit and Risk Assurance Committee (ARAC)

Audit Tracker Update – Confidential

Audit and Risk Assurance Committee (ARAC)

Audit Planning Report – Confidential

Audit and Risk Assurance (ARAC) meeting

Date: 26 January 2023
Paper reference: AUD 08/23
Agenda item: 10
Author: Richard Sydee, Director of Resources

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Risk Update

Purpose of paper

1. To provide ARAC with an update on HTA's strategic risks, and proposed mitigations as of January 2023.

Decision-making to date

2. This paper was approved by the Director of Resources on 16 January 2023.

Action required

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

Background

4. The strategic risks are reviewed annually by the SMT to ensure they align to the strategic objectives and deliverables agreed within the annual business plan. The risks are then reviewed monthly at SMT, and the register is updated and stored. The strategic risk register that was discussed and updated at the beginning of January 2023 is at Annex A.
5. The Executive Team undertook their most recent review of the strategic risk register on 20 December 2022; the assessment is summarised below:

Risk assessment

6. **Risk 1 – Failure to regulate appropriately (9 – Medium, below tolerance).** Activity across most regulatory sectors has returned to normal, with the HTA approach to on site and virtual assessments aiming to achieve 210 inspections in the 2022/23 business year.
7. **Risk 2 – Failure to manage the impact of an incident (9 – Medium, above tolerance).** The HTA believes that our incident management response plans have been effective and robust through the last business year.
8. SMT notes that our arrangements have stood up well and that current activity levels are still high, with some uncertainty on timing in some areas – we continue to score this risk above tolerance as 9 - Medium. Plans to test resilience through a critical incident test exercise will provide further evidence to potentially lower the current risk scoring.
9. **Risk 3 – Failure to manage expectations of regulation (8 – Medium, below tolerance).** SMT noted the number of matters currently impacting on the organisation, and that these matters are all being actively managed. The HTA continues to have clear dialogue with the FII and is preparing in line with known timelines .
10. This risk is unchanged since July 2022 and remains below tolerance.
11. **Risk 4 - Failure to deliver a diverse, capable workforce (12 - High, above tolerance).** This risk has been recast, with a narrower focus on the delivery of a diverse and capable workforce.

12. This risk has remained above tolerance since the beginning of this business year, we continue to see high staff turnover, and consider this to be an area for ongoing challenge. There has been progress with recruitment and a number of new starters over the past month, there are currently 6 vacancies in active recruitment, 4 of which are currently vacant posts.
13. This risk remains high, with the pending recruitment action likely to reduce the level back to tolerance with further successful appointments.
14. **Risk 5 – Insufficient, or ineffective, management of financial resources (4 – Low, above tolerance).** Although this risk remains above tolerance SMT are content to accept this risk at the assessed residual risk level.
15. The 2022/23 financial position sees an increasing underspend, as plans to recruit external contractor and professional service support for the Inspection review and other projects remain on hold pending Departmental approval processes for such activity. Although this does not pose a risk in terms of lack of funds it does represent both a missed opportunity to maximise investment this year and will add to the ongoing questions around utilising our surplus – an issue the Department are aware of.
16. This risk remains scored as 4.
17. **Risk 6 – Failure to achieve the benefits of the organisational transformation programme (12 - High, above tolerance).** This risk focusses on the HTA's programme work and revised delivery plans for the 2022/23 business year.
18. Plans have been developed although implementation will be partly dependent on successful approval for expenditure under the Departmental approval process highlighted above. Given the likely risk of slipped delivery this risk remains above tolerance with risk scoring unlikely to fall until approval for expenditure and appointments are made.
19. **Risk 7 – Failure to optimise the safe use of digital, data & technology (12 – High, above tolerance).** This risk relates to the IT elements of the previous risk 4 and has been separated and recast to provide more oversight of the increasing dependence on DDT for current and future operational success of the HTA.
20. Resource continues to constrain progress in this area with key appointments under active recruitment. Progress in reducing this risk is anticipated on successful completion into key roles.

Latest review date – 12/01/2023

Strategic risk register 2022/23

Risk summary: residual risks

Risk area	Strategy link*	Residual risk	Risk owner	Status	Tolerance	Trend**
R1: Failure to regulate appropriately	Delivery (a-d & f) and Development (a-d) objectives	9 – Medium	Director of Regulation	Below tolerance	10	↔↑↔↓
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	9 - Medium	Director of Regulation	Above tolerance	6	↔↓↔↔
R3: Failure to manage expectations of regulation	Delivery (e) and Development (c)	8 - Medium	Director of Regulation	Below tolerance	9	↔↓↔↔
R4: Failure to utilise our staff capabilities effectively	Delivery, Development and Deployment (a, c, and d)	12 - High	Director of Resources	Above tolerance	9	↔↔↑↔
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	4 - Low	Director of Resources	Above tolerance	3	↔↔↔↔
R6: Failure to achieve the benefits of organisational transformation	Development (a-d) objectives	12 - High	Director of Data, Technology and Development	Above tolerance	9	↔↔↔↔
R7: Failure to optimise the safe use of existing and available digital data and technology	Delivery (a-e), Development (a-d) Deployment (a, c and d)	12 - High	Director of Data, Technology and Development	Above tolerance	9	↔↔↑↔

* Strategic objectives 2021-2024:

** This column tracks the four most recent reviews by SMT (Senior Management Team) (e.g. ↔↔↔↔).

R1: There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	5	15 - High	3	3	9 - Medium
Tolerance threshold:					10 - Medium

Commentary
<p>Below tolerance.</p> <p>We have a good regulatory framework, having received moderate assurance on the most recently completed internal audit focusing on our regulatory role (on the Effectiveness of the Inspection Process, final report issued 11 April 2022) and previously substantial assurance on the internal audit on key regulatory processes (final report issued 16 April 2019).</p> <p>The HTA is on track to meet this year’s significantly increased inspection target of 210 (for existing licenses) through a combination of onsite and virtual regulatory assessments, in addition to assessing a significantly increased number of licence application assessments. We have in particular increased inspection coverage in the PM sector to about 40% (with a target of 77 PM inspections this year compared to 44 in 2021/22) in response to recognised risks in this sector. Our re-introduced KPIs and Portfolio Management Process includes reporting on delivery of our core business and provides visibility at SMT and board level.</p> <p>We continue to use all other regulatory tools and processes, such as managing and responding to incident reports (Serious Adverse Events and Reactions and HTA Reportable Incidents), whistleblowing / informant information and ongoing engagement with our regulated sectors, with investigations and active regulatory action having continued.</p> <p>Whilst we are involved in a number of more uncommon and unusual regulatory matters, including a small number of cases related to regulated activity on which criminal investigation and prosecution under other legislation is being pursued, we have no indication of any systemic issues that might jeopardise public safety or confidence.</p> <p>SMT believes this risk is now reduced to just below tolerance.</p>

R2: There is a risk that we will be unable to manage an incident, event or issue impacting on the delivery of HTA objectives.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	3	3	9 – Medium
Tolerance threshold:					6 – Medium

Commentary
<p>This risk concerns our ability to respond to incidents irrespective of their nature or cause, which could be from matters outside the HTA’s remit or control as well as matters for which we are directly responsible. The Executive has therefore set a lower tolerance level on this risk as our ability to respond appropriately is within the HTA’s control.</p> <p>The HTA believes that our incident management response plans have been tested and found effective through their deployment in several different circumstances over the past two years. These have included managing the impact of the pandemic and related restrictions, in their adaptation for use in managing the potential impacts of EU Exit following the end of the Transition Period and in our mobilisation planning in preparation for the Fuller trial.</p> <p>Having increased the risk scoring in July 2021, in anticipation of the prospective Fuller trial, we now believe that the likelihood of this risk materialising has reduced but given continuing uncertainties, we believe it is still above the tolerance level and has remained unchanged from the last review.</p> <p>We have accepted the recommendations of a specialist consultant who has reviewed our Critical Incident Response Plan and processes and are planning to do more work to implement those, including a test exercise in January. We anticipate concluding this work by the end of March 2023 and that this will feed through into a lower risk level by the year end.</p>

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	4	12 - High	2	4	8 – Medium
Tolerance threshold:					9 – Medium

Commentary
<p>Below tolerance.</p> <p>We have no indications of any current specific factors that would contribute to this risk. The HTA continues to communicate our remit and advise where appropriate.</p> <p>The HTA is in ongoing dialogue with DHSC (Department of Health and Social Care) and wider stakeholders regarding actions being undertaken following the conclusion of the Fuller trial, including Sir Jonathan Michael’s Independent Inquiry. We have provided evidence to the Inquiry and assisted former colleagues by providing them with suitable secure access to relevant information to enable them to give their evidence. We published updated guidance to Standards in the Post Mortem sector in October concerning security and dignity of the deceased and have undertaken an informal consultation on similar changes in the Anatomy sector guidance, which we hope to publish shortly.</p> <p>The HTA has an established Horizon Scanning process and is building its Policy function, including updating and engaging with DHSC on our legislative log.</p> <p>The HTA has worked with colleagues in the Northern Ireland Executive and NHSBT (NHS Blood and Transplant) to ensure there can be effective implementation of the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 which will introduce deemed consent for organ and tissue donation through changes to Code of Practice F, Part 2.</p> <p>We have also worked with stakeholders on the impacts for the HTA of the recent amendment to s32 Human Tissue Act 2004 by the Health and Social Care Act 2022 to introduce an offence for ‘organ tourism’. This may require an update to the HTA’s Police Referral and Warrants Policy. We continue to engage with NHSBT and other relevant stakeholders, including the police, to ensure that a suitable referral mechanism is in place.</p> <p>All these matters are being actively managed.</p> <p>SMT consider this risk to be below tolerance.</p>

R4: Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives

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

Commentary
<p>Above tolerance.</p> <p>Over the past quarter there has been a significant increase in the number of vacancies advertised and unfilled across the HTA. This is a combination of high organisational churn as well as the need to fill a number of short-term project and admin roles to support wider activity.</p> <p>The time from advert to new colleagues joining the HTA is around 2 - 3 months, leading to significant pressure in some teams who have been carrying vacancies in key roles for a number of months. Although we are filling the majority of vacancies this is not always at the first attempt and there have been some vacancies where with have repeatedly advertised before securing a viable candidate.</p> <p>There is some evidence that the continued controls on public sector pay are contributing to high churn levels and making it more difficult to recruit, the HTA will need to ensure it remains competitive amongst other public sector employers in similar sectors.</p> <p>We believe this risk remains above tolerance levels in December 2022, we will start the new calendar year with c 10 post to fill and will review our risk level in January when we expect a number of vacancies to have been filled (awaiting start dates).</p>

R5: There is a risk that the HTA has insufficient or ineffective management of its financial resources

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	2	2	4 – Low
Tolerance threshold:					3 – Low

Commentary**Above tolerance.**

Budgets for 2022/23 have been agreed and delegation letters to Directors issued. Our Grant in Aid (GIA) funding from the Department has been confirmed at previous levels and we have been provided with cover for asset purchases (Capital DEL - £80k) and depreciation and amortisation costs (Ring Fenced RDEL).

Our underspend continues to grow as we fail to fill a number of vacancies across the organisation and the controls on agency and consultancy spend placed upon us by DHSC have constrained our ability to commence a number of key activities in support of the 2022/23 business plan – this will have an impact on in year spend and could place additional pressures in to the next business year if programmes of work now need to straddle financial years. We have offered to return £150k of the additional GIA funding the Department provided for costs incurred in assisting the FII (for 2022/23 only), we believe this is affordable in year.

Our income budget and fees for 2023/24 have been set and agreed with the Authority, and these will be published at the end of December 2022. Expenditure risks for 2023/24 will be linked to public sector pay, both in terms of pay remit restrictions and external drivers to appoint at higher salary levels – pay represents c 70% of all expenditure and controls in this area will limit wider inflationary pressures on the organisation.

SMT have agreed that this risk is unchanged, although acknowledge that we are unlikely to deliver against our 3% variance target for spend against budget.

R6: Failure to identify opportunities and achieve the benefits of transformation and continual change to support modernisation and improvement of the HTA.

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

Commentary
<p>Above tolerance.</p> <p>Following the Q2 review of the projects identified across the business as development priorities in 2022/23, resources were agreed to support the individual projects. Since October each project has worked in different ways to secure the additional contracted, external resource. These actions have included business cases, attempts to recruit specialist roles on time limited contracts and specifications to support procurement of services and support.</p> <p>At the end of Q3 resource commissions have been posted for:</p> <ul style="list-style-type: none"> • IT Consultancy support to deliver a PID for the IT shared services project. This commission will also map out the approach to be taken to in exploring and evaluation potential options • Data collection and analysis to aid the next stage of development of the Regulatory Insight Model and Index • The review of inspections <p>In addition, there has been a further commission to support the evaluation of the HTA’s impact and contribution to the sectors, innovation and growth of life sciences and as a regulator working as a partner in the wider health system. It is anticipated that this commission will provide further insight and evidence to inform and prioritise future developments. Current capacity in the organisation has been a constraint and has been a significant factor in setting the risk level above tolerance. It is hoped that securing resource via these commissions will assist in making progress and reducing risk levels at the next review.</p> <p>SMT believe that some areas of activity are at risk of slipping and this would have impact on anticipated benefit realisation although the extension of timescales on some projects may reduce risk without impacting on the overall output. Oversight of the progress will be maintained by SMT.</p>

R7: Failure to optimise the safe use of existing and available digital data and technology

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	4	16 – High	4	3	12 – High
Tolerance threshold:					9 – Medium

Commentary
<p>Over the last 2 years the HTA has been progressing with the planned development of its digital data and technology (systems and architecture) as part of the Development Programme. The planned development had been incremental based on available resources and aimed to future proof business needs. Following the review of the Development Programme in Q1 2022/23 two projects have been identified to support the use of existing and available digital and technological capabilities. These are the adoption of an IT Shared Services model and the stage 2 development of the Regulatory Insight Model and Index. As identified under risk 6 action has been taken in Q3 to commission external and specialist resource to support progressing the planned developments.</p> <p>Utilising internal resource and integrating actions with BAU activities progress has been made to strengthen existing capabilities through the review and consolidation of licenses, establishing internal reporting on the use and performance of systems and in identifying a further action for Q4 to map current systems and interdependencies to inform and prioritise future upgrades and potential replacements.</p> <p>It is anticipated that the additional resource and focus on BAU activities will assist in reducing the likelihood of the residual risk level.</p>

Reviews and revisions

(23/02/22) SMT review March 2022

Risks 1, 2 and 4 were discussed in detail. SMT agreed that the impact score of risk 1 should be reduced as the tools in place continue to work; risk 2 likelihood score was also adjusted down; and risk 4 likelihood has been reduced from 3 to 2 reducing overall rating to 8 as key posts have been recruited to.

(19/05/22) SMT review April/May 2022

The SMT reviewed the current register in light of the finalised business plan and agreed the following:

- Risk 2 to be shortened in the summary leaving the detail to remain in the register itself;
- Risk 4 it was agreed to separate this risk into a people risk (risk 4) and a digital risk (risk 7) which is more reflective of the current situation;
- Risk 6 it was agreed to re-framed to reflect the fact that it is broader than just the Development programme.

(09/06/22) SMT review June 2022

Following the full review of risks for the new business year SMT reviewed the risk register following a detailed discussion at the HTA ARAC meeting:

- Risk 2 to be shortened in the summary leaving the detail to remain in the register itself;
- Risk 4 it was agreed to separate this risk into a people risk (risk 4) and a digital risk (risk 7) which is more reflective of the current situation;
- Risk 6 it was agreed to re-frame to reflect the fact that it is broader than just the Development programme.

(26/07/22) SMT review July 2022

(08/09/22) SMT review September 2022

SMT reviewed the register at its meeting on 8 September. The following changes were made to the risk scores:

- Risk 1 it was agreed that the likelihood should be increased based upon recent issues that may materialise, which together would increase its likelihood;
- Risk 4 was increased. In part the reason relates to the number of recruitments currently underway and the challenge it continues to be to recruit to certain roles. The SMT believed the likelihood is increasing;
- Risk 5 has not changed however, SMT recognise the impact that restrictions on recruitment may pose if there is a change in focus of the DHSC and Cabinet Office;
- Risk 6, SMT believe that there is a thread which impacts risks 4 – 6 from the potential savings we are being asked to make. The various pieces of work (IT Shared Services, Inspections Review) will be affected should we be required to make further savings.

(27/10/22) SMT review October 2022

SMT reviewed all seven risks and agreed that Risk 1 scoring should be reduced from 12 to 9 as it was felt that the work we have done around Living Organ Donation, latest position re Fuller has impacted this risk.

(29/11/22) SMT review November 2022

Overall, there has been no changes to the risk scores. SMT discussed risk 4 and the possibility of the Board agreeing to accept where we are due to issues that are outside of our control such as the challenges around recruiting to specific posts and its impact on the organisation as a whole. Risk 3 was discussed and the associated increase in obtaining legal advice.

(20/12/22) SMT review December 2022

SMT discussed each of the risks in detail and agreed that none of the risk scores required a change. However, risk 4 '*Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives*' had become an issue that will need to be flagged to the Board via ARAC. The challenges around recruitment for key posts is having an impact across the organisation despite all efforts to explore other avenues to go to market.

Strategic Aims

Delivery: Deliver a right touch programme of licensing, inspection, and incident reporting, targeting our resources where there is most risk to public confidence and patient safety.

- (a) Deliver effective regulation of living donation.
- (b) Provide high quality advice and guidance in a timely way to support professionals, Government, and the public in matters within our remit.
- (c) Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards.
- (d) Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.

Development: Use data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target resources effectively.

- (a) Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
- (b) Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements.
- (c) Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation.

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

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

Criteria for inclusion of risks

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

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

Rank

The risk summary is arranged in risk order.

Risk scoring system

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

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

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

Risk appetite and tolerance

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

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

Assessing inherent risk

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

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

Contingency actions

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

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

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L			1	2	3			
1	<p>There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.</p> <p>Risk Owner: Nicky Harrison</p>	<p>Cause</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 <p>Effect</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	3	Ongoing	<p>Regulatory model</p> <p>Regulatory model comprising a mixture of proactive and targeted regulatory assessments (e.g. through inspections and sector engagement) and reactive tools (such as responding to incidents reported to the HTA, investigations of concerns raised etc).</p> <p>Process for consideration of police referral maintained and used.</p> <p>Annual collection of activity data in HA sector; periodic collection of information from other sectors.</p>	3	3	<p>Remote assessment methodologies are embedded into business, alongside a decision-making framework to inform appropriate decisions about type and composition of inspections.</p> <p>A "Review of Inspections" project is on the business plan for 22/23.</p> <p>An ambitious target of 210 risk-based inspections has been implemented to give greater coverage across our sectors as we emerge from pandemic restrictions.</p>	10	X			Preventative	<p>Internal Audits on key regulatory processes and inspections.</p> <p>KPIs reintroduced from 2022/23 to enable oversight and monitoring of delivery of key regulatory processes.</p>	<p>Remote assessment methodologies incorporated into BAU in all sectors, as evidenced in Business Plan and inspection schedule.</p> <p>A Regulatory Assessment (Inspection) Decision Making Framework has been introduced, setting out the approach to inspection for each sector and is regularly (at least annually) reviewed by SMT.</p> <p>Internal Audit on the Effectiveness of the Inspection Process Quarter 4 2020/21 gave moderate assurance - management actions in progress.</p> <p>Management actions from previous Internal Audits (on the Inspection Process during Covid19 and on Key Regulatory Processes) all completed.</p> <p>Police referral for breach of HT Act (licensing requirements) is awaiting a decision from CPS.</p>
						<p>Regulatory decision-making framework</p>			<p>Heads of Regulation using dashboards to track open cases and ensure there is effective follow-up, in accordance with the HTA's decision-making framework.</p> <p>PowerBI used in Post Mortem sector to increase effectiveness of monitoring of core business e.g. inspections, HTARIS and enquiries.</p>		X			Preventative	<p>Details of Regulatory Decision Meetings recorded in CRM included in business monitoring/reporting.</p> <p>Case Review Meetings summarised in CRM.</p>	<p>Strong assurance Internal Audit report on key regulatory processes, which included inspections, QA and RDM processes, November 2020.</p> <p>HTA-SOP-026 (Regulatory Decision-Making SOP) previously last reviewed March 2020 but recently completed review (January 2023) with updated version now awaiting approval to move into published folder.</p> <p>Evidence of regulatory decision making framework being used in practice e.g. Case Review Meetings and Regulatory Decision Meetings recorded in CRM and numbers of RDMs reported monthly. RDM process adapted for use on a temporary basis since August 2021 to manage certain categories of living organ donation cases pending the outcome of an internal review, Internal Audit consideration of that review and the outcome of other related processes.</p>
						<p>Well established processes support our core regulatory business</p>			<p>Good progress made on completing management actions identified by Internal Audit on the Effectiveness of the inspection process due by 31/12/22 to review and rationalise inspection-related SOPs etc and improve inspection workbooks. (Submission of evidence to GIAA early Jan 2023.)</p> <p>Further actions due by 31 March 2023 relate to undertaking a delivery time study to improve resource planning for Regulation Directorate.</p>			X		Detective	<p>GIAA currently considering evidence provided in support of actions management have completed so far, with assured position to be reported to ARAC January 2023.</p>	<p>ARAC to consider GIAA / HTA audit tracker at its meeting in January 2023, to include whether evidence submitted re management actions from Internal Audit on the Effectiveness of the Inspection Process.</p> <p>All management actions from previous Regulation-focused internal audits have been noted as complete by ARAC previously.</p>
						<p>Quality management systems</p> <p>HTA quality management system coordinates activities to ensure policies are reviewed and updated.</p>			<p>The HTA's Corporate Service Manager coordinates activities to ensure policies are reviewed and updated.</p>		X			Preventative / Monitoring	<p>Management oversight, through business monitoring and reporting.</p>	<p>Limitations in QMS remain.</p> <p>QMS and performance reporting includes evidence of degree to which the documents are current.</p>
						<p>Training and development of professional competence</p>			<p>Structured induction programme for new Regulation Managers (or other new staff in Regulation Directorate e.g. Living Organ Donation Officers) with clear criteria for sign-off for probation.</p> <p>Buddy system for new recruits.</p> <p>Regulation Directorate Training Days (or mornings) held quarterly.</p> <p>Regulation Directorate budget for conference attendance.</p>		X			Preventative	<p>Formal induction and probation sign-off process.</p> <p>Annual PDPs (with quarterly reviews), which include Development Objectives, Corporate Training Programme (led by Head of HR), Career Investment Scheme proposals to SMT, induction programme for new entrants, with a bespoke programme for RMs.</p>	<p>Evidence of Regulation-focused induction and probation programmes for new recruits into technical regulatory roles.</p> <p>Evidence of corporate training programme, including quarterly mandatory training.</p> <p>Evidence of regular Regulation Training Days and other all-HTA training sessions (e.g. "lunch and learn" sessions) as well as All Staff Days.</p>
						<p>Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas</p>			<p>As vacancies arise, SMT take the opportunity to review business requirements and target building capability and filling skills gaps</p>		X	X		Preventative / Monitoring	<p>SMT assessment of business requirements as vacancies arise through the business case process.</p> <p>HTA Recruitment policy.</p>	<p>Staffing levels and risks reported quarterly to the Board.</p> <p>Recruitment policy - substantive review by SMT May 2021 with updates in 2022 to refine business case process.</p>
						<p>Regulatory model</p> <p>Development work being undertaken to become a more data-driven risk based regulator as part of the HTA Development Programme</p>					X			Preventative		
						<p>Other</p> <p>Strengthening horizon scanning arrangements</p>					X			Preventative		

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L			1	2	3			
2	<p>There is a risk that we will be unable to manage an incident, event or issue impacting on the delivery of HTA objectives.</p> <p>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 <p>Risk owner: Nicky Harrison</p>	<p>Cause</p> <ul style="list-style-type: none"> Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management) Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning) Failure to work effectively with partners/other organisations Breach of data security IT failure or attack incident affecting access to HTA office External factors such as terrorist incident, large scale infrastructure failure or pandemic <p>Effect</p> <ul style="list-style-type: none"> Loss of public confidence Reputational damage Legal action against the HTA Intervention by sponsor 	5	4	Ongoing	<p>Critical Incident Response Plan, SOPs and guidance in place and communicated to staff</p>	3	3	<p>An external specialist consultant has provided expert input to formally reviewing and updating our CIRP and is being issued to all staff in hard copy. The consultant has also assisted us in developing a CIRP test. We anticipate concluding this work by the end of March 2023</p>	6	X	X		Preventative	<p>Policies etc. reviewed annually, training specification and notes after incident reviews</p>	<p>Revised version of CIRP published and issued to staff January 2023. CIRP test scheduled for January 2023. CIRP previously deployed in March 2020 to manage coronavirus pandemic and used as framework for managing 'Operation Sandpiper' critical incident in Autumn 2022</p>
						<p>All specific roles identified in the Critical Incident Response Plan are filled.</p>			<p>1 2 3</p>		X		Preventative	<p>Evidence of regular review and updating of the CIRP and no specific CIRP roles left vacant or, if role is vacant, cover arrangements put in place</p>	<p>CIRP reviewed and updated January 2023</p>	
						<p>Media handling policy and guidance in place and Critical Incident Response Plan includes requirement to involve Comms Team. Comms Team have embedded media handling and development of lines to take into business as usual</p>			<p>X</p>			Preventative	<p>Policy reviewed as scheduled. Reports on any key media issues and activity in the Chief Executive's Report. Evidence of active Comms Team participation in issues with potential for media or public interest.</p>	<p>Media issues are included in the quarterly Board reporting as they arise and as relevant. Media enquiries successfully managed during critical incident phase of Fuller work.</p>		
						<p>Availability of legal advice</p>			<p>X</p>			Preventative	<p>Lawyers specified in Critical Incident Response Plan, SMT updates</p>	<p>Evidence that suitable arrangements are in place to enable the HTA to have access to legal advice during potential critical incidents, issues or events. Evidence of use of legal advisers through Operation Sandpiper mobilisation phase (when CIRP was used as a framework for our planned response) and through the period of our engagement with the Independent Inquiry. Evidence of use of legal advisers to support significant regulatory decision-making e.g. on complex living organ donation approval case, December 2022 / January 2023.</p>		
						<p>Fit for purpose Police Referrals Policy</p>			<p>X</p>			Preventative	<p>Annual review of policy (minimum), usage recorded in SMT minutes</p>	<p>HTA-POL-023 Police Referral and Warrants Policy reviewed and significantly updated and approved by the Board February 2022. Evidence of Police referral process used regularly by SMT and captured in SMT minutes when there is evidence of potential breaches of the Human Tissue Act and related regulations. Police referral of a potential offence relating to a licensing breach from 2019/20 currently with CPS for prosecution decision. Police referral for another licensing breach not taken up by police but related matters being prosecuted by NHS Fraud Authority (with HTA witness evidence)</p>		
						<p>Onward delegation scheme and decision making framework agreed by the Board</p>			<p>X X</p>			Preventative	<p>Standing Orders and Board minutes</p>	<p>Framework agreement between HTA and DHSC updated, approved and published June 2022. Onward delegation scheme reviewed and approved by the Board [INSERT MONTH] 2022.</p>		
						<p>Regulatory decision making framework</p>			<p>X</p>			Preventative	<p>Reports to Board of key decisions in Chief Executive's Report to the Board</p>	<p>Number of Regulatory Decision Meetings detailed in monthly management performance pack, for review by SMT. Regulatory Decision Making SOP reviewed late 2022 and awaiting publication (January 2023).</p>		
						<p>Critical incident response plan regularly reviewed and tested</p>			<p>X X</p>			Preventative	<p>Critical Incident Response Plan significantly reviewed Q2-Q3 2022/23 and test scheduled for Q4. Use of CIRP and report of CIRP Test to be reported to SMT.</p>	<p>CIRP used to manage response to coronavirus pandemic from March 2020. CIRP deployed for a short period in May / June 2021 to deal with confidential matter. CIRP used as basis for Fuller response planning in Autumn 2021. Specialist consultant to assist testing our Critical Incident Response Plan by the end of March 2023.</p>		
						<p>Evaluate test exercise of incident and feedback to all staff</p>			<p>X</p>			Preventative	<p>We have appointed a specialist consultant to assist with formally reviewing, updating and then testing our Critical Incident Response Plan and anticipate concluding this work by the end of March 2023</p>	<p>Noted in ARAC Audit Tracker</p>		
<p>Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA</p>	<p>X</p>		Preventative / Detective / Monitoring	<p>Inspections (and audits for ODT) include assessment of licensed establishments' knowledge and use of the relevant HTA incident reporting process. Annual SARE (Serious Adverse Reactions and Events) HA SAEARs data reported to European Directorate for the Quality of Medicines (EDQM). Monitoring establishments' reporting of incidents through the HTARI, HA SAEARs and ODT SAEARs groups and advice, guidance and CAPAs regarding those incidents.</p>	<p>Findings at inspections. Minutes of quarterly meeting with NHSBT to review SAEARs cases in ODT sector - latest meeting was December 2022 Most recent SARE report (for NI only following end of Transition Period) submitted June 2022. Publication of closed SAEAR and HTARI incident summaries included in the HTA publication scheme - published quarterly - and reporting in the Board's data annex. Publication of incident numbers in the regular (bimonthly) Professional Newsletter.</p>											

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3	<p>There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.</p> <p>Risk Owner: Nicky Harrison</p>	<p>Cause</p> <p>External factors</p> <ul style="list-style-type: none"> No scheduled review of Human Tissue Act 2004 and associated regulations, or Quality and Safety Regulations (other than for EU Exit) Rapid advancements in the life sciences Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in currency exchange rates Deemed consent for organ donation in England <p>Matters which certain stakeholder groups believe require review</p> <ul style="list-style-type: none"> Scope of relevant material e.g. waste products Licensing requirements e.g. transplantation research Regulation relating to child bone marrow donors Issues raised by emergence of social media e.g. non-related donors Strengthening of civil sanctions for non-compliance <p>Matters which stakeholders/public may expect to be inside regulatory scope</p> <ul style="list-style-type: none"> Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure Police holdings Products of conception and fetal remains Data generated from human tissue Funeral directors Forensic research facilities Cryonics Body stores / Taphonomy Imported material Clinical waste DNA Other Inadequate stakeholder management <p>Effect</p> <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 Reputational damage 	4	3	Ongoing	<p>Horizon scanning process in place that creates and maintains an up to date log of issues known to the HTA with respect to the legislation (updates, amendments or emerging issues) to inform DHSC and manage messages</p> <p>Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope</p> <p>Active management of issues raised by the media – including the development of the HTA position on issues</p> <p>Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence</p> <p>Action where we believe it will support public confidence</p> <p>Use of s.15 function of advising Ministers (in England, Wales and Northern Ireland) of developments relating to activities within the HTA's remit</p> <p>Communications and Engagement Strategy developed and being implemented to ensure HTA role and remit understood and well-communicated</p> <p>Stakeholder evaluation surveys undertaken in Q4 2019/20 and Q4 of 2021/22, reported to Board in May 2022 and used to inform further developments</p>	2	4	<p>Comms & Engagement strategy under development to strengthen the HTA's approach and impact of stakeholder engagement. Updated C&E Strategy planned for Q4.</p> <p>Lines currently under review and update</p> <p>Monthly informal meeting between Directors of Regulation and of Data, Technology and Development with DHSC Sponsorship Team Manager</p> <p>Regular engagement and scheduled meetings between HTA teams (HA, ODT, Policy) and specialist teams in DHSC (e.g. Substances of Human Origin, SoHO Team)</p> <p>Publication of HTA update on its advice to the SoS following the Fuller trial</p> <p>Reactive media lines prepared where relevant</p> <p>Publication of Regulatory Alerts and Regulatory Updates when and where relevant</p> <p>Ongoing engagement between HTA and DHSC (as noted above) and with Devolved Administrations in Wales and N Ireland.</p> <p>Standing stakeholder engagement forums and ad-hoc round tables being initiated for professional engagement.</p> <p>Greater emphasis on proactive publication of digital content to engage public and professionals and reinforce role and remit of HTA.</p> <p>Operationally focused engagement with sector stakeholders by Heads of Regulation.</p> <p>Work in Q1 to identify and pilot new approaches to stakeholder engagement</p>	9	1	2	3	<p>Monitoring</p> <p>Preventative/ Detective</p> <p>Preventative/ Detective</p> <p>Monitoring</p> <p>Preventative</p> <p>Preventative/ Detective</p>	<p>Ongoing log</p> <p>Stakeholder Group meeting minutes. Authority minutes (including Public Authority Meeting). TAG and HWG meetings. Evidence of engagement with other relevant stakeholder forums, not necessarily organised by HTA.</p> <p>Quarterly reports to Board on communication (including media) activities</p> <p>Quarterly Accountability meetings with DHSC plus DHSC attendance at Board meetings and evidence of HTA engagement with DHSC sponsor team and other relevant policy teams (eg SoHO, Investigations Team)</p> <p>Advice to Secretary of State (re mortuary offences) and update on HTA actions published Q1 2022/23.</p> <p>Clarification of use of Regulatory Alerts and Regulatory Updates by SMT Q3 2022/23 and publication of actions in line with this.</p> <p>Statutory functions of HTA under s15 Human Tissue Act 2004, including to monitor and provide advice to Ministers, understood by SMT and Chair</p> <p>Communication and Engagement Strategy approved by Board and SMT and being implemented. Initial Round Tables and sector-focused forums planned for Q4 2022/23.</p> <p>Reporting of Comms-team led public and professional engagement activity through provision of an increased variety and range of digital content to reinforce the HTA's role and remit.</p> <p>Evidence from surveys used as an evidence and information source to inform and drive improvements</p>	<p>Log in place and shared with Board in outline at the Strategic planning session in 2021.</p> <p>HS process under active review and discussion with the Board to ensure inputs are effective and can inform strategic decisions.</p> <p>Last Stakeholder and Fees Group meeting in October 2019; Histopathology Working Group February 2020; Transplant Advisory Group October 2019.</p> <p>Public Authority Meeting May 2022. Professional newsletters issued regularly - last one May 2022. Sector-specific engagement e.g. with the post-mortem sector through multi-agency forums (Death Investigation Group, Excess Deaths Working Group).</p> <p>Quarterly Accountability meetings - last one December 2022.</p> <p>Diary slots - evidence of other regular meetings with DHSC sponsorship team and other policy teams.</p> <p>Updates to the Board and DHSC re SoS advice and publication of HTA update on actions noted at Board meeting May 2022.</p> <p>SMT minutes approving criteria for publishing Regulatory Alerts and Regulatory Updates, Q3 2022/23.</p> <p>Publication of Regulatory Updates or Regulatory Alerts in line with defined criteria (e.g. re mortuary capacity and perfusion fluid issues, planned for January 2023).</p> <p>HTA has provided advice and guidance about the referral process required in relation to amendments to section 32 Human Tissue Act (2004) (re commercial dealings).</p> <p>HTA submitted advice to Secretary of State re the Fuller matter on 15 December 2021 (published on website in Q1 2022/23) and has also had engagement with Welsh Government and Northern Ireland officials on this matter.</p> <p>HTA has had ongoing engagement with NI Executive over NI Deemed Consent and has updated Code of Practice (F).</p> <p>Evidence of activities under the Comms and Engagement Strategy - Sector Engagement Forums and Round Tables planned for Q4 2022/23 and reports to Board and SMT on communication and engagement activity.</p> <p>Evidence from Heads of Regulation of wider sector engagement e.g. with other regulators and sector-focused forums e.g. in Board reports.</p> <p>Evidence from stakeholder survey presented to the Board in May 2022</p>

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			I	L			I	L			1	2	3			
4	<p>Failure to adequately deliver a diverse, capable workforce the HTA requires or needs to fulfill its functions and objectives</p> <p>Risk Owner: Richard Sydee August 2022</p>	<p>Cause</p> <ul style="list-style-type: none"> 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 Loss of productivity as a result of the effects of changes to ways of working 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 Inadequate balance between serving Delivery and Development objectives 	3	4		People capability	3	4	All major projects have project management rigour further enhanced through benefits realisation and plans to assess ROI at year end	9	X	X		Preventative/ Monitoring	Board approval of the Strategy	Board approved the Strategy at its meeting in February 2019 and is provided with regular updates on all facets of its progress in quarterly board reporting. Most recently in July 2021. Revised Strategy delayed due to shared service exploration
						People Strategy for the period 2019 to 2021 is in effect			Efforts to recruit		Recruitment to identified vacancies and skills gaps ongoing. Succession planning and future skills needs to be developed further as part of a workforce model. Work planned for Q2 & 3					
						Full suite of people policies and procedures (including performance management)					Review of processes and procedures required to ensure these are appropriately supporting and enabling adherence to the relevant policies. Development of new policies relating to e.g. Due Diligence and Contracting of Suppliers to be undertaken to ensure alignment with DHSC and UKGOV requirements (Q2). Overarching guidance document to assist Line Managers / Heads of Function in understanding corporate policies / relevance to their teams to be developed (for Q2)					
						External assessment of utilisation of capabilities					Further work may be identified as part of the Cultural Review in Q2 & Q3					
						Adherence to the HTA Workforce Capability Development Framework										
						Investment in the development of the HTA leadership team					Further work may be identified as part of the Cultural Review in Q2 Q3					
						Handover process is formalised via a checklist to ensure corporate knowledge is retained					Ensure the process identified and published is adhered to. Ensure that documentation is saved in the appropriate EDRMS folder for wider access as needed					
											More formal assessment of future capability needs and how these should be met including through better knowledge of internal skills. Work to adopt a portfolio management approach to support more effective resource deployment and identification of skills required					
		Establish a formal role within SMT terms of reference to look holistically at people and capability issues across the organisation focusing on short and long term impacts and deliverables		X			Preventative/ Monitoring	SMT terms of reference and SMT minutes	SMT ToRs revised and approved. BDT ToRs revised and approved.							

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5	<p><i>There is a risk that the HTA has insufficient or ineffective management of its financial resources</i></p> <p><i>Risk Owner:</i></p> <p><i>Richard Sydee</i></p>	<p>Cause</p> <ul style="list-style-type: none"> Fee payers unable to pay licence fees The number of licenced establishments changes, leading to reduced fee income Management fail to set licence fees at a level that recover sufficient income to meet resource requirements Failure to estimate resource required to meet our regulatory activity Poor budget and/or cash-flow management Unexpected increases in regulatory responsibilities Unforeseeable price increases / reductions in GIA Fraudulent activity detected too late <p>Effect</p> <ul style="list-style-type: none"> Payments to suppliers and/or staff delayed Compensatory reductions in staff and other expenditure budgets Increased licence fees Requests for further public funding Draw on reserves Failure to adhere to Cabinet Office Functional Standards <p>Leading to:</p> <ul style="list-style-type: none"> Inability to deliver operations and carry out statutory remit Reputational damage and non payment of fees 	5	4	Ongoing	Budget management framework to control and review spend and take early action	2	2		3	X	X		All	Budgetary control policy reviewed and agreed by SMT	Revised version reviewed by SMT in November 2020. AUD 16b/21. Next review January 2023.
						Financial projections, cash flow forecasting and monitoring			X				Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report to Board in November 2022.	
						Licence fee modelling							Preventative	Annual update to fees model	Fees agreed by the Board at the November 2022 meeting	
						Rigorous debt recovery procedure			X				Preventative	Monthly finance reports to SMT and quarterly to Authority	Debt position reviewed by Portfolio Team and reported at ARAC meetings 22/23	
						Reserves policy and levels reserves			X				Monitoring	Reserves policy reviewed annually and agreed by ARAC	Last agreed by ARAC October 2022	
						Delegation letters set out responsibilities			X		X		Preventative	Delegation letters issued annually	Issued in April 2022	
						Fees model provides cost/income information for planning			X				Preventative	Annual review of fees model, reported to SMT and Authority	Went to the Board November 2021, a review of the current data underpinning the fees model was undertaken in Q2 of 2022/23 financial year	
						Annual external audit						X	Detective	NAO report annually	Unqualified Accounts produced June 2022 for 2021 - 2022	
						Monitoring of income and expenditure (RS) Ongoing						X	Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Reviewed monthly	
						Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) Ongoing			X		X		Detective	Quarterly Finance Directors and Accountability meetings	Monthly DHSC Finance Director meeting provides oversight of future changes/issues. Quarterly meetings with DHSC finance covers specific HTA issues.	
Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards	X	X		Preventative	Counter fraud Strategy and Action Plan developed and presented to ARAC Oct-19. Annual training of staff completed in Q4	Cabinet Office - CDR submissions made quarterly last submission October 2022 (Q2 2022/23). Counter-fraud activities now part of BAU.										

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6	<p>Failure to identify opportunities and achieve the benefits of continual change and improvements to support the modernisation of the HTA</p> <p>(Development objectives a-d)</p> <p>Risk owner</p> <p>Louise Dineley</p>	<p>Causes</p> <ul style="list-style-type: none"> • Uncertainty of funding • Programme and project benefits poorly defined and understood • Inadequate programme and project governance arrangements • Poorly specified programme and projects • Insufficient programme, project and change management skills • Inadequate leadership of change • Inability to access the necessary skills required at a affordable cost • Lack of staff buy-in to change • Management and Head stretch of delivering transformation alongside business as usual and other development activity • Insufficient agility in (re)deploying people to change projects • Poorly specified procurement and inadequate contract management • Realisation of single points of failure for DDAT and People Strategy <p>Effects</p> <ul style="list-style-type: none"> • Wasted public money • Failure to achieve the central strategic intent of the Authority • Distracts senior management from operations at a time when demands have increased • Reputational damage • Unaffordable cost over run • Staff demotivation • Data remains under-utilised • Technology inadequate to meet future needs (cost, functionality) • Limited ability to achieve improvements in efficiency and effectiveness • Pace of change is inadequate and impacts negatively on other work 	3	4		SMT experience of organisational change, programme and project management	4	3		9	X			Preventative	Recruitment of an HTA Programme Director	The Director of Data, Technology and Development will act as Programme Director
						HTA approach to the management of change projects (underpinned by project management methodologies)					X			Preventative	Dedicated permanent project manager appointed	PM in place and operating effectively
						A number of trained project managers among HTA staff			Project Management skills further strengthened by introduction of a toolkit and induction session by PM		X			Preventative		
						Experience of procurement and contract management					X			Preventative		
						Existing mechanisms for engaging staff			Plans developing for strengthening internal communications function		X			Preventative		
						Well established corporate governance arrangements and financial controls						X		Monitoring	Internal audit of key controls	Assurance provided by Internal Audit of adequacy of key financial controls
						Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding			Further alignment of projects on the business plan to strengthen phasing of actions, resource deployment and consolidation of actions to encourage smarter working		X			Preventative	Programme plan in place	
						Project management rigour including benefits to be realised			Embed Benefits Realisation Management methodology within programme		X			Preventative		
						Monthly reporting to SRO in place			Adopt Programme Management principles		X			Preventative		
									Board approval to proceed at key Gateway decision points			X		Monitoring		
									Training plan to encompass project and change management and HTA approach		X			Preventative		
						Strengthened planning supports a single message and focus on an agreed set of priorities			Development of procurement plan to deliver and support the DDAT Strategy		X			Preventative		
									SROs identified for programme and individual projects		X			Preventative		
						Project management includes a monitoring of costs			Schedule a regular programme of staff engagement events		X			Preventative		
						Scope of projects aims to deliver benefits including on a phased and incremental design			Establish an external stakeholder communications and engagement plan		X			Preventative		
									Recruitment of new Board Member(s) with digital and organisational change experience			X		Monitoring		
									Agreed priorities in Business Plan and underpinning foundations for future strategy maintain required pace				X	Monitoring/ Detective		
									Identified success measures and benefits to be realised for the Development Programme and individual projects				X	Preventative		

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			I	L			I	L			1	2	3				
7	<p>Failure to optimise the safe use of existing and available digital data and technology</p> <p>Risk Owner: Louise Dineley</p>	<p>Cause</p> <ul style="list-style-type: none"> Historic under investment is a contributory factor to the required data and tech management Inadequate business technology or appetite to adopt and use technology Lack of ring-fenced resource to support developments and business requirements <p>Effect</p> <ul style="list-style-type: none"> Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed Poor use of technology resulting in inefficient ways of working Resources are constrained to BAU activities Inadequate balance between serving Delivery and Development objectives 	3	4		Data capability	3	4		9	1	2	3				
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)			Ongoing development of the electronic management of all information and records. Phase 1 complete. Phase 2 paused for 22/23		X			X	Preventative/Monitoring	Upgrades to CRM, are prioritised and carefully developed and managed into live environment. Internal audit of personal data security	Major CRM upgrade completed successfully. Ongoing review of security and version patches part of routine activity. Future of CRM to be determined and included in future tech development plans
						No common understanding of the breadth of data that we hold within systems or how it is actively managed			Creation and publication of a single common data model on intranet. Business System Owner roles, with IT collaboration to identify and work towards 23/24 Business Planning						Preventative	Internal audit of data and technology practices	
						Appropriate procedures to manage personal data including GDPR compliance					X			X	Preventative/Monitoring	Internal audit of data and technology practices	Part of ongoing Cyber and data security and SIRO reporting. Now absorbed in BAU Information Governance and Cyber Security work
						Business technology capability											
						Staff training in key business systems and mandatory training on policies and required controls			System development needed to enable devolution of responsibility to line managers for verifying and ensuring that all their staff are up to date on their mandatory training. Supportive guidance document to assist Line Managers / Heads of Function in understanding corporate policies / relevance to their teams and risks (to HTA) of non-adherence to training to be developed		X				Preventative	Systems training forms part of the induction process for new starters	Ongoing records of all new starters trained in key business systems. Induction programme to be reviewed by HR
						IT systems protected and assurances received from 3rd party suppliers that protection is up to date			Quarterly Reporting to ARAC on Cyber Security and system security in place		X	X	X		Preventative/Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Cyber Security update and Annual SIRO report reviewed and agreed at SMT and ARAC June 2022
									Business technology								
	Identify refresher training plus any targeted software specific training needs via the regular PDP process	X				Preventative	Evidence of targeted training in last quarter to support the roll out and adoption of ED RMS. Further strengthening of core training requirements included in updated induction programme										
	System performance analytics available and reported monthly						Analytics provide assurance on system performance and support targeted intervention with members of staff as necessary										

Audit and Risk Assurance Committee (ARAC)

Date: 26 January 2023

Paper reference: AUD 09/23

Agenda item: 11

Author: Nicky Harrison
Heads of Regulation

Protective marking: OFFICIAL

HTA's risk-based approach to regulatory operations

Purpose of paper

1. To respond to an action point from the previous ARAC meeting (October 2022) for "The Executive to prepare a risk paper on each sector."
2. To give ARAC the opportunity to consider the Regulation Directorate's approach to managing sector-based regulatory risks, including our risk tolerance, increasing use of data and evolving approach to inspection. It does this by:
 - setting out the HTA's approach to identifying, defining, evaluating and managing regulatory risks across and within our sectors; and
 - illustrating that, whilst some risks are sector-specific, our approach to risk assessment considers risk across sectors. We recognise that whilst specific risks may vary, different types of risks may have equivalence.

Decision making to date

3. The HTA does not have a formal relative risk assessment between sectors.

4. The HTA has undertaken different analyses of sector risks using data and insight from inspection reports, incidents and periodic data collection exercises. These have informed regulatory activity including inspection plans.
5. The HTA also produced a large-scale analysis of its data in the HTA Safety KPI Report (2019), which was presented to ARAC in October 2019.
6. With the reintroduction of inspections and site visits following the Covid-related suspension, the HTA developed an Inspection Assessment Decision Making Framework, which describes the approach to managing risk through inspection and regulatory assessment in each sector. This has been updated annually, to take account of significant changes in circumstances and our assessment of risk. It will be updated as part of our planning for the 2023/24 business year.

Recommendation

7. ARAC is invited to note and discuss the current methodologies adopted by the Regulation Directorate to assess and manage sector risks.
8. ARAC is invited to note and discuss the proposed developments in this area, in particular the segmentation model, based on the HTA having an effective and systematic risk engine, known as the Regulatory Insight Model and Index (RIMI) and feedback mechanism.

Background

9. HTA's overall approach to regulation, including inspection, has accounted for differences in risk profiles between sectors. As one of our most intensive regulatory tools, inspection has generally been deployed more frequently in our higher risk sectors; for example, in the Post Mortem sector more than in the Research sector.
10. The higher frequency of inspections in the HA sector is driven by the legal obligation to undertake a site visit inspection at least every two years, which is itself an indicator that the sector was considered high risk when the legislation was formulated.
11. The HTA has also recognised greater risk in the Post Mortem sector through its introduction of the mandatory (but non-statutory) HTA Reportable Incident (HTARI) process. This mirrors the statutory Serious Adverse Event and Adverse Reaction (SAEAR) reporting system in the HA and Organ Donation and Transplantation (ODT) sectors. The statutory nature of the incident reporting schemes in the HA and ODT sectors can be considered to represent

legislative recognition of the higher level of risk in those sectors, in particular the risk of physical harm to patients.

12. The HTA uses several regulatory tools to superintend and promote compliance with licensing requirements and manage regulatory risk. These range from giving advice to licence revocation.
13. The HTA considers both the risk inherent in any regulated activity and the risk of regulatory non-compliance. This involves consideration of the history of compliance of the establishment, including shortfalls, enquiries, incidents and complaints. This is currently a manual process, supported by policies, documented procedures and guidance.
14. Early work on the development of the RIMI - including a proof-of-concept model using existing data - confirmed the value of a central data and risk engine. The development of the RIMI is on the business plan for 2023-24, subject to resources being available.

Risk considerations across all sectors

15. The HTA's assessment of risk is influenced by numerous factors, including the likelihood and potential impact of a problem or event leading to:
 - loss of dignity of the deceased
 - distress or psychological harm to individuals and their families
 - physical harm to individuals
 - civil legal harm to individuals or their families e.g. failure to respect the appropriate consent requirements of the Human Tissue Act or Human Rights Act - breaches of the right to respect for privacy and family life in case of distress caused to family members by failure of a licensed establishment to properly manage the condition of deceased in their care (see *Brennan and others v (1) City of Bradford Metropolitan District Council (2) Leeds Teaching Hospitals NHS Trust [2021]*¹ WLUK 429)
 - Human Tissue Act (and related legislation) regulatory breaches undermining the integrity and effectiveness of the regulatory regime
 - criminal offences, either under human tissue or related legislation (e.g. exploitation for the purposes of organ donation under the Modern Slavery Act) or other criminal offences (as in the recent Fuller case) which have the potential to undermine public trust and confidence in the integrity and effectiveness of the legal framework relating to human tissue; and

- damage to the HTA's reputation, which could arise from any of the considerations noted above or from a misperception of the HTA's role and remit, leading to a loss of public confidence in the ability of the HTA to fulfil its core duty of superintending compliance with the Human Tissue Act (2004) and related legislation.

16. In taking a risk-based approach, the HTA makes judgements about the relative likelihood and impact of these risk factors in, and between, each sector. This approach determines the operational planning and prioritisation of inspections and other assessments in each sector, along with the inspection target and profile for each business year.
17. At an operational level, the HTA uses the data and tools currently available to assess the relative risk of an individual establishment, both in terms of its profile compared to other comparable establishments and by looking at its regulatory history.

Risk considerations within each sector

18. Although the profile of risks and distribution of regulatory issues arising from those risks varies between sectors, we adopt a consistent approach to assessing the likely harms. The criteria for assessing shortfalls as minor, major or critical is the same for all sectors and is set out in Appendix 2 to our inspection reports (see **Annex A**). These criteria include consideration not only of the specific issue that has been identified but also the likely impact, harms and impact on public confidence that may arise from that issue. This is moderated through quality assurance (QA). In practice, this means that all draft inspection reports undergo QA by a Head of Regulation. Two-person inspections (where applicable) are also subject to peer review and a final QA of inspection reports is done by the Director of Regulation where at least one major shortfall has been identified.
19. Not all risk considerations are relevant to the same extent across all sectors. For example, the risk of physical harm is significant in considering risks in the HA and ODT sectors but is likely to be less relevant to other sectors.
20. In making risk judgements, we also consider the whole risk formula, *impact x likelihood*. Even in our higher risk sectors, some establishments are better than others at managing their high impact activities.
21. It is important to recognise that the number of shortfalls can be influenced by the number of applicable standards, which varies considerably across sectors, and how many standards are assessed.

Data analysis, risk profiling and the development of a Regulatory Insight Model & Index (RIMI)

22. The PowerPoint slide deck [AUD 09a/23 Data Annex] is derived from the data analyses summarised in **Annex B**. These slides present a series of charts and tables produced from analysis of our existing data. These provide evidence of the differing risk profiles between sectors and the distribution of risks within sectors.
23. The chart of shortfalls at inspection shows the impact of the introduction of new licensing standards in 2017 and the extent to which this varied between sectors. The most marked impact appears to have been in the Post Mortem sector, with a significant rise in findings of higher severity (major) shortfalls. This may be a consequence of several risk factors, including there being an increased number of standards that also became more prescriptive and the sector struggling to meet the standards. Whilst the position is improving, there are continuing issues (particularly, at the moment, concerning body storage capacity) and so this sector remains a significant focus of attention for regulatory activity, including site-visit inspection. At the other extreme, the ODT sector has a strong (albeit with some variation) pattern of low levels of shortfalls and no shortfalls above minor. Between these two extremes is the Research sector, which despite its rapid and continued growth remains a relatively compliant sector, underpinning the emphasis on more remote-based assessments than site-based inspections.
24. Time delays in resolving agreed CAPAs following inspection is another risk indicator, on which we have presented analyses by sector. Here the HA sector has the greatest range and highest average closure time, although the PM sector has a somewhat similar pattern. Whilst the immediate causes may be different, this indicates the challenges faced in these sectors in successfully resolving issues found on inspection and is another indicator of relatively greater regulatory risk in these two sectors.
25. Similarly, analysis of enquiries from establishments shows that these are primarily from the HA and PM sectors. However, it is important to note that these are two of our three most numerous sectors, with high levels of activity and complexity.

Licence numbers by Sector (9 January 2023) are:

HA	154
PM	173
ODT	36
Research	193
Anatomy	44
PD	12

26. The analysis of incidents data (HA, ODT and PM sectors only) all show a broad upward trend in incidents reported to us. In the PM sector, much of that increase appears to relate to incidents not subsequently deemed to be HTARIs. Whilst over-reporting may be preferable to under-reporting, there is clearly a risk if this trend persists of HTA resource being diverted to managing unnecessary workload. The increase in HA SAEARs in 2018 reflects a shift in the HTA's approach to the reporting of contamination events linked to the procurement of bone marrow and peripheral blood stem cells. The increases, and numerical variations from the general upward trends in reportable incidents in the ODT sectors has been highlighted previously in Board Performance Reports and is a focus for regulatory response and more strategic engagement.
27. The data currently available has also been used to provide an early framework of sector-based dashboards and learning that could be applied to the development of a HTA risk engine and structured insight to risk. An early and experimental risk model is set out in slides 8 and 9 of the accompanying PowerPoint slide set [AUD 09a/23 Data Annex] and is reproduced below. **Figure 1** provides a visual representation of indicative sector risk scoring and **Figure 2** sets out the underpinning data, which fall broadly within the categories named, 'Change', 'Regulatory Action', 'Inspections' and 'Incidents'.
28. The simplicity of this model means there are limitations. This approach requires testing, refinement and validation but provides an illustrative profile of risk scoring across sectors. In this model, PM and HA are markedly the two highest risk sectors, with the other four sectors at a notably lower level. This approach helps to conceptualise a future more refined, data-rich model with relative weighting of factors.

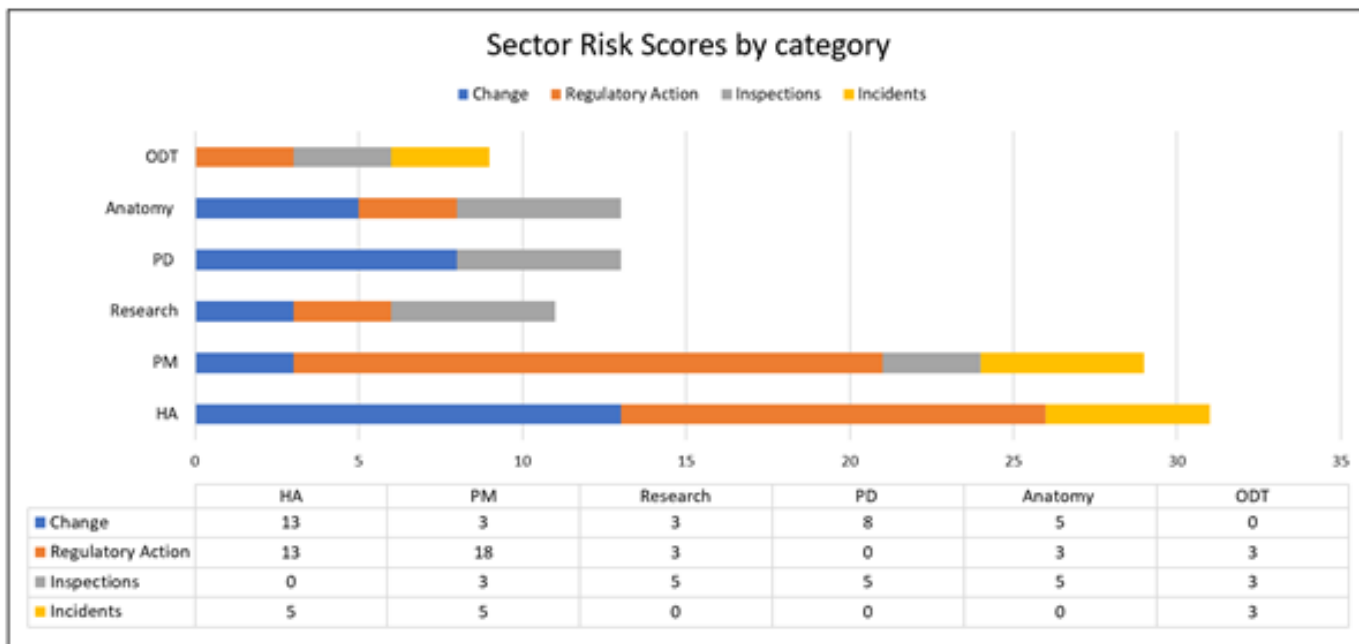


Figure 1. Risk model: indicative sector risk scoring

	HA	PM	Research	PD	Anatomy	ODT	Groupings	Scores
Change								
Number of new licences	6	0	11	0	1	0	0 : 1-3 : 4+	0:3:5
Score	5	0	5	0	3	0		
Number of change tickets per est. (Change of DI, change of licenced activities, satellite addition, import variation, tissue/organ types)	47%	22%	15%	25%	14%	8%	0-10% : 10%-25% : 25%+	0:3:5
Score	5	3	3	5	3	0		
Number of PPDs authorised/conditionally authorised	6	0	0	0	0	0	0 : 1-5 : 5+	0:3:5
Score	3	0	0	0	0	0		
Regulatory action								
Number of CAPAs open > 6 months	15	19	2	0	1	2	0 : 1-3 : 4+	0:3:5
Score	5	5	3	0	3	3		
Number of major / critical shortfalls per inspection	0.5	4.3	0	0	0	0	0 : 1-3 : 4+	0:3:5
Score	3	5	0	0	0	0		
Number of RDMs	19	9	0	0	0	0	0 : 1-3 : 4+	0:3:5
Score	5	5	0	0	0	0		
Number of complaints	0	1	0	0	0	0	0 : 1-3 : 4+	0:3:5
Score	0	3	0	0	0	0		
Inspections								
Average time since last inspection (months)	12.9	25.8	52.2	52.1	56.9	29.5	<2 years : 2-4 years : 4+ years	0:3:5
Score	0	3	5	5	5	3		
Incidents								
Number of incidents resolved	89	96	0	0	0	38	0 : 0-50 : 50+	0:3:5
Score	5	5	0	0	0	3		
Total Scores	31	29	16	10	14	9		

Figure 2. Contributory data for risk model illustrated in Figure 1

29. **Annex C** gives more detail of our current assessment of risk for each sector and how we are responding to those risks through our inspection and related regulatory processes.

Risk matrix and segmentation

30. Given the risk factors noted earlier and the differing ways these can manifest both within and between sectors, the HTA has increasingly adopted a segmented targeting model to represent our approach to managing risk.

31. This segmentation model is currently conceptual and can be envisaged in various ways. For example, concentric rings in a circle whereby each ring represents a different population segment for which the intensity of our regulatory approach varies according to our assessment of risk.

32. The outer ring of the circle would therefore represent those establishments with lower risk profiles which can be regulated in a more proportionate, less resource-intensive way. These form the bulk of our establishments, the proportion varying by sector and sub-sector.

33. Moving towards the centre are the segments comprising increasingly fewer numbers of establishments (or sectors / sub-sectors) which present greater regulatory risk and for which we have a lower tolerance. The regulatory response is therefore increasingly direct, active and resource intensive.

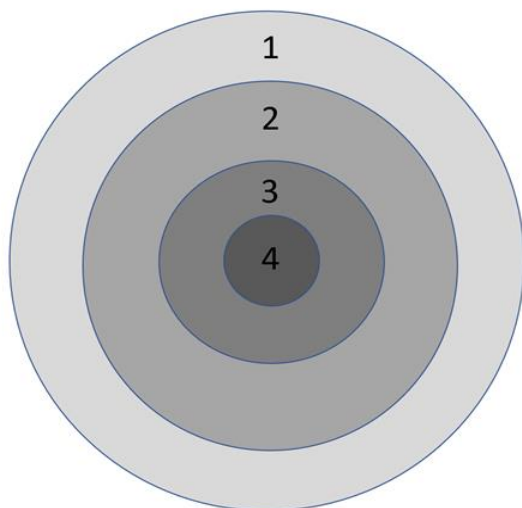


Figure 3. Risk segmentation model concept

34. The details and outcomes of this segmentation model are set out below in **Table 1**.

Risk segment	Description	Regulatory approach (level of intervention)
1	These establishments present the lowest risk, intrinsically or through mitigation	Remote monitoring and virtual post-licensing assessments are the mainstay for establishments in this segment
2	These establishments are not considered to present the lowest level of risk due to a combination of their activities and their ability to manage them effectively	Remote monitoring is likely to be suitable but there is a greater likelihood that solely virtual assessments will not be suitable to provide necessary assurances
3	These establishments do not present the highest risk but have the potential to do so.	Remote monitoring may be supporting elements of the regulatory oversight, but these establishments need proactive management and greater intervention.
4	These establishments present the highest risk	These establishments require more frequent monitoring and assessments have the highest level of intervention

Table 1. Risk segmentation model details and outcomes

35. We will define and refine our risk segmentation model as we evolve our compliance strategy through projects, including the Review of Inspections and the data collection and analysis exercises involved in the development of the RIMI. The intention is to **apply our early developments to a model of activity for our 23/24 regulatory regime and to bring this to the Board for discussion in March 2023**. This will build on the refinements already made by introducing a more tailored and proportionate approach to managing regulatory risk through the adoption of different types of inspection, as set out in **Annex D**.

36. While inspection is an important aspect of our work, it is also important to note that this is just one regulatory tool. We also consider and take risk-based actions and decisions in our management of enquiries, whistleblowing, incidents and other regulatory activities.

37. This management of regulatory risk includes sector or thematic engagement on specific topics; for example, our current engagement with a range of stakeholders in connection with significant body storage capacity challenges in the Post Mortem sector.
38. The focus in the coming year will be to develop the risk targeting and segmentation approach.
39. The development of the RIMI will assist us in informing the parameters for each segment across and within sectors.

Next Steps

40. Whilst our current approach enables us to assess and compare regulatory risk in a consistent way across diverse sectors, we are committed to further developing our use of data to refine and systematise a segmented model of regulation.
41. This will enable us to be more risk-based and proportionate in our interventions, which includes reducing regulatory burdens for those establishments that are more compliant.
42. Following this presentation to ARAC, we propose to take a paper to the Board meeting in March 2023. This paper will outline our approach to regulatory risk and, within that framework, set out our proposed inspection regime for the 23/24 business year.

Recommendations

43. ARAC is invited to note and discuss the current methodologies adopted by the Regulation Directorate to assess and manage sector risks.
44. ARAC is invited to note and discuss the proposed developments in this area, in particular the segmentation model, based on the HTA having an effective and systematic risk engine, known as RIMI, and feedback mechanism.

Annexes:

Annex A: Criteria for assessing shortfalls (as listed in inspection reports)

Annex B: Data analyses – basis of data analyses presented in the PowerPoint data Annex

Annex C: Sector risk descriptions

Annex D: Current approaches to inspection (2022/23)

Annex A: Criteria for assessing shortfalls at inspection: (Copy of Appendix 2 of HTA inspection reports)

Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'.

Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- A notice of proposal being issued to revoke the licence
- Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- A notice of suspension of licensable activities
- Additional conditions being proposed
- Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.

Annex B: Data analyses to inform risk matrix

1. Even without the development of the RIMI, we have increasingly made use of regulatory data to inform our understanding of sector-based risk. Recent analyses are summarised in the **PowerPoint Data Annex** [AUD 09a/23 Data Annex]. These have included data on inspection shortfalls, incidents, CAPA plans, Enquiries and Preparation Process Dossiers (PPDs).
2. Other data sources available to Heads of Regulation in assessing sector risk include:
 - Compliance Updates data, which was last collected in 2019;
 - the annual HA sector Annual Activity data collection exercise;
 - occasional *ad hoc* data collection exercises (such as a survey of all ODT establishments in 2021 and a Covid-risk survey of all HA establishments in 2020);
 - the previously mentioned Safety KPI Report; and
 - External data sources, such as data on mortuary capacity in the NHS in England that is shared with us by DHSC.
3. We recognise that data on risk needs to include various types of risk factor, some of which relate to the sector / sub-sector or nature of activity undertaken and some are establishment or organisation specific.
4. Work previously undertaken has identified that a very limited proportion of our routine data collection is considered to be “opinion-forming”. This means that further and new data collection is required to support and inform the development of the RIMI. Development of the RIMI and a suitable feedback loop to test its effectiveness in identifying risk will enable an increasingly data driven and automated approach to be taken to assessing regulatory risk in the future.

Annex C: Sector risk descriptions

Human Application sector

1. The human application sector is currently considered our highest risk sector, due in part to the potential impact that regulatory non-compliance could have on patient safety and clinical outcomes. However, it also reflects the complexity and diversity of the work undertaken in this sector and the heterogeneity of the organisations licensed, which includes many commercial organisations.
2. In addition to inherent risk, the HTA's assessment of risk in this sector is based on several factors including non-routine regulatory action (e.g. Regulatory Decision Meetings, issuing of Directions / Conditions), the frequency of changes to a licence (e.g. change of DI, addition of new sites/activities, authorisation of new preparation processes, addition of new tissue types to a licence), reports of serious adverse events and reactions (SAEARs) and complaints / investigations.
3. Other risk factors include the relative complexity of the wider regulatory landscape (e.g. the fact that some activity in this sector interfaces with other regulatory frameworks such as the ones that exist for medicines, medical devices, blood / blood components and medically assisted reproduction) and the fact that many tissues/cells intended for human application are imported from, or exported to, third countries with different regulatory requirements).
4. Our data shows some establishments in this sector have a recurring pattern of non-compliance and issues linked to the robust resolution of shortfalls found at inspection.
5. Our data also shows a relatively high frequency of major shortfalls in the HA sector (although it is rare to have critical shortfalls), another indicator of regulatory riskiness of the sector.

Post Mortem sector

6. In the Post Mortem sector, the primary document that informs the framework for regulatory risk is the HT Act. The Act is augmented by other documents that are developed by the HTA with input, where appropriate, from those we regulate and include Codes of Practice and licensing Standards.
7. Of the sectors the HTA regulates, the Post Mortem sector is considered to have high inherent risk because of the special sensitivities around dealing with the deceased, and the potential for media interest and public concern

when things go wrong. The sector generally is also considered to have high regulatory risk due to the number and level of shortfalls found on inspection, which are strongly linked to physical infrastructure.

8. Shortfall data analysis shows that the absence of major shortfalls, implemented following inspections, is a rarity. Major shortfalls predominantly feature and there have been numerous instances of critical findings.
9. Escalation of cases within the sector is also a frequent occurrence following HTARI reporting, enquiries and complaints received. These have, on occasion, resulted in unannounced inspections due to the gravity of concerns concerning the dignity of the deceased.
10. Risks within the Post Mortem sector are often linked to seasonal factors. For example, the HTA received an influx of HTA reportable incidents last summer under the category of “major equipment failure” due to the severe heatwave.
11. Winter pressures also result in significant service pressures and increased inability to comply with HTA mandatory standards. In turn, this poses heightened risk to the dignity of the deceased due to mortuary capacity issues. Current winter pressures for 2022/2023, due to reported excess death rates, has resulted in a notable surge in HTA reportable incidents, enquiries and applications for extension to license. Media enquiries and social media references to the HTA have also increased as a consequence.
12. The above has resulted in an increase in caseload; increased complexity of inspections (which require a lead and support Regulation Manager as a minimum default); an increase in case escalation mechanisms; and a need for re-prioritisation of resource to proactively engage with the sector, as well as external stakeholders, to provide advice and guidance i.e. through local resilience forums, drafting of guidance and regulatory updates.

Organ Donation and Transplantation sector

13. The relevant legal frameworks are the HT Act and the Quality and Safety of Organs Intended for Transplantation Regulations 2012.
14. There are two roles to consider in ODT; our responsibilities under the HT Act, primarily the consideration and decision making on all living organ donation cases, and our role under the Q&S Regulations to licence and audit hospital undertaking organ transplants.
15. Major risk considerations:

- physical harm to the living (living organ donors and all recipients of organ transplants) e.g. from contamination and transmission of infections and diseases
- exploitation in living organ donation, and complexity with overseas cases for example.

16. Major risk factors:

- complexity of processes - transplantation is, by its very nature, very high risk with very high impact when things go wrong. However, this is a very controlled and highly regulated clinical environment especially within NHS.
- Less control and governance within the private sector eg often no Living Donor Coordinators.

17. The HTA carries out audits, not inspections, of transplant centres under the Quality and Safety regulations. Our regulation shows it to be a highly compliant sector; there have been no major or critical shortfalls.

18. However, we continue to see high numbers of SAEARs arising in the organ donation and transplantation sector, which can have very serious impact on living patients.

19. The HTA does not carry so much of that risk but the risks are higher in relation to Living Organ Donation approvals – recent circumstances have heightened our awareness of the potential for exploitation, where existing systems have not necessarily picked those up.

20. Our regulatory effort in ODT therefore tends to focus as much, if not more, on building sector expertise, sector engagement, managing the LOD approvals process and the investigation and management of incidents as it is on audit of transplant centres. We have also carried out an extensive data collection survey across all transplant centres in May 2021.

Research sector

21. The Research sector is considered to have a low inherent risk because of the nature of the licensable activities and our observation and findings that the principles of consent are generally well understood. Also, there are other assurance factors in the regulatory environment, such as research ethics committees. Inspection and compliance update data have confirmed that research establishments are highly compliant with our regulation.

22. There have been no critical shortfalls in the Research sector. Shortfall analysis has shown that, where shortfalls are identified, they are almost always minor. There is a very low incidence of major shortfalls.
23. Data collected from biennial compliance updates has been used to undertake risk-profiling and prioritise establishments for assessment. In terms of escalating arising risks, new issues are dealt with through our usual regulatory processes, meaning we can reprioritise an assessment.
24. The Research sector is large and grows year-on-year. There is an increasing public awareness of importance of Life Sciences, and the research 'industry' (commercial and academic research) has been promoted and supported by successive UK governments. The HTA has always had a small role in the wider research regulatory ecosystem and – like all regulators in this potentially complex area – there is an expectation that our approach is right touch and risk-tolerant to enable innovation and support growth. In the context of a continuously growing sector, set against fixed resources at HTA, we need to ensure that regulatory oversight remains proportionate to risk and maintains appropriate coverage. Alongside engagement activities and working with other organisations within the research regulatory environment (notably the Health Research Authority), it is likely that less interventional assessment activities are likely to remain important in our regulatory oversight of the research sector.
25. In previous years, we were able to undertake inspections on 10% of the research establishments each business year. In terms of numbers, our transition to the default inspection model of a single-person VRA, unless otherwise indicated, has enabled us to make a relative one-third increase on typical pre-COVID planning figures and increase the proportion of the sector that is inspected.
26. The expanding nature of this sector means that there are rising numbers of new licence applications, each of which require a detailed assessment and typically entail a pre-licensing inspection of premises. This approach ensures that we have a good coverage of newly regulated establishments, setting them off on a sound regulatory footing and reducing future non-compliance risks.

Anatomy sector

27. The Anatomy sector is considered low risk as there is a long history of regulation and a well-established culture of dignity and respect. There are also well-established and secure consent mechanisms for body donation.

28. The Anatomy sector is relatively small, with fewer than 50 main licences. Mostly, these licensed organisations are focussed on providing human anatomy training to undergraduate healthcare professionals but several also train established professionals, such as surgeons, in undertaking invasive procedures.
29. Within such a small sector, there are professional networks and good channels of communication, including with the HTA. This proved useful during the pandemic restrictions, enabling the HTA to keep up with evolving issues across the sector through regular teleconferences with numerous sector representatives.
30. As for the Research sector, inspection and compliance update data have confirmed that our anatomy establishments are highly compliant with our regulation.
31. There have been no critical shortfalls in our Anatomy sector. Shortfall analysis has shown that, where shortfalls are identified, they are almost always minor. There is a very low incidence of major shortfalls.
32. Data collected from biennial compliance updates has been used to undertake risk-profiling and prioritise establishments for assessment. In terms of escalating arising risks, new issues are dealt with through our usual regulatory processes, meaning we can reprioritise an assessment.
33. Although there has been some growth in the number of licensed anatomy sector establishments, our Anatomy sector is generally static. It is considered low risk; however, due to the nature of the activities within our remit, we also recognise that poor practices or adverse events have the potential to become high-profile incidents. The management of bodies of deceased donors means that there can be similar risks to those identified for our Post Mortem sector although they are much less likely to occur

Public Display sector

34. The Public Display sector is considered to have a low inherent risk primarily due to the size of the sector as well as the activities undertaken. However, this sector has been the subject of political attention with overall risk to the sector increasing in line with advancing technology and innovation in the way in which human tissue is displayed.
35. The HTA currently licenses 13 establishments in the Public Display sector. There have been no critical shortfalls identified in this sector.

36. Whilst no regulatory action has been taken to date, there has been engagement between the HTA and licensed establishments concerning the less traditional forms of Public Display ie non-static exhibitions.
37. In addition, the HTA has had cause to intervene in a proposed public dissection due to concerns regarding consent.
38. Recent media enquiries to the HTA have queried the display of human tissue through imagery and online mechanisms. The HTA position is that this area is outwith the scope of the HTA. However, it is noted that there is a growing risk in this area in line with increased online presence by users due to advances in technology and new ways of working post pandemic.
39. As such, there is an increased risk of reputational harm to the HTA if it is unable to keep up with the aforementioned technological advances as well as innovation within the sector eg proposals for public dissection.

Annex D: Approaches to inspection 2022/23

1. The Inspection Assessment Decision-Making Framework sets out our current approach to choosing an appropriate blend of assessment methodologies to satisfy any statutory obligations placed on us .¹
2. To increase assessment coverage and stimulate operational innovation in our approach to inspection and regulatory assessment, the target number of inspections was increased to 210 for 2022/23. This number does not include new licence application assessments, which take considerable time to assess.
3. The following paragraphs set out risk-based assessment methodologies we have adopted during 2022/23.

Virtual Regulation Assessments (VRAs)

4. We have continued to use VRAs to improve efficiency and help focus inspections and minimise time on site. These have been used alone or as an element of a hybrid inspection which includes a site visit.
5. Given our existing assessment of the Research and Anatomy sectors as low risk, VRAs have been default form of inspection in those sectors.
6. This approach has continued to receive positive feedback from both staff and stakeholders.
7. Adoption of VRAs has significantly reduced the RM resource on many of our inspections and regulatory assessments as well as reducing the time taken on individual regulatory assessments by up to 50%. This has been a significant enabler for the increased number of inspections.

Thematic / targeted inspections

8. Thematic / targeted inspections have been adopted, notably in HA and PM, sectors with inspections focusing on specific areas of risk. In HA, all planned inspections have been evaluated for their suitability for a focused inspection, in which only a subset of relevant licensing standards are assessed. To date this year, approximately 37% of HA inspections have been carried out in this way. The remaining inspections have all been abridged; none have involved an assessment of all 120 licensing standards.

¹ Current Inspection Assessment Decision Making Framework is available at this link <[Inspection Assessment Decision-Making Framework.docx](#)> [accessed 9 January 2023]

Back-to-back geographically-linked inspections

9. Where possible, we have scheduled site visit inspections within a geographic area on consecutive days, with RMs alternating the role of lead and support. This has been a key enabler of the significant increase in inspections. Where one or other of the linked inspections has required only one RM, travel has been adjusted accordingly.

Unannounced inspections

10. The HTA has always had unannounced inspections as a tool but we have used this option more frequently this year than previously, so far in the PM sector. Unannounced inspections are generally highly targeted and focused in response to a specific concern(s). They have often focused on premises, facilities and equipment (PFE) standards.

Solo inspections

11. There are now more solo inspections taking place. 18 solo site visit inspections were carried out in the HA sector in the first two quarters of this business year, compared to 7 in total in 2021/22 (note, a further 16 solo VRAs were conducted in 2021/22). However, comparisons with previous years are difficult because of the impact of the Covid restrictions and the introduction of VRAs.
12. For those inspections where a support RM is assigned, the decision is taken based on the risk profile of the establishment, and in some cases, the need to train RMs. However, the reliance upon the support RM has been scaled back thus freeing up resource. This has worked well particularly in conjunction with the geographically linked inspections. This combined approach is therefore being explored further with the licensing team as a methodology for future scheduling.

Data Annex

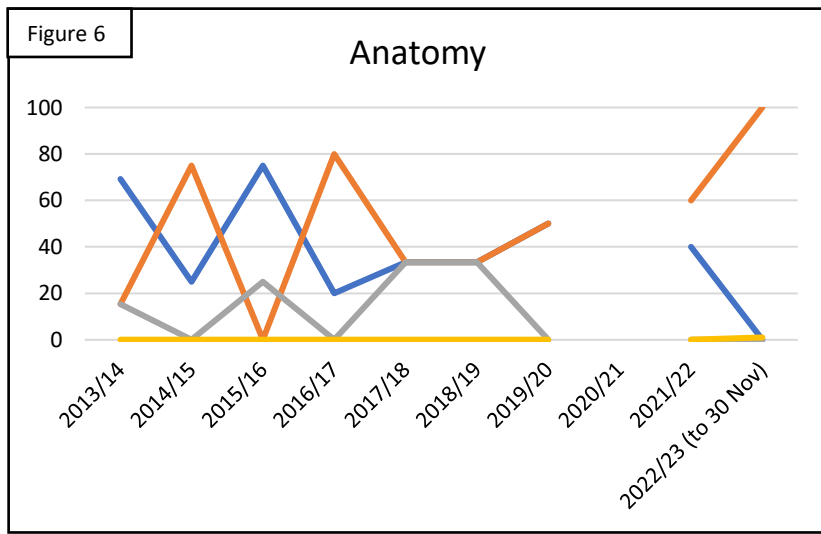
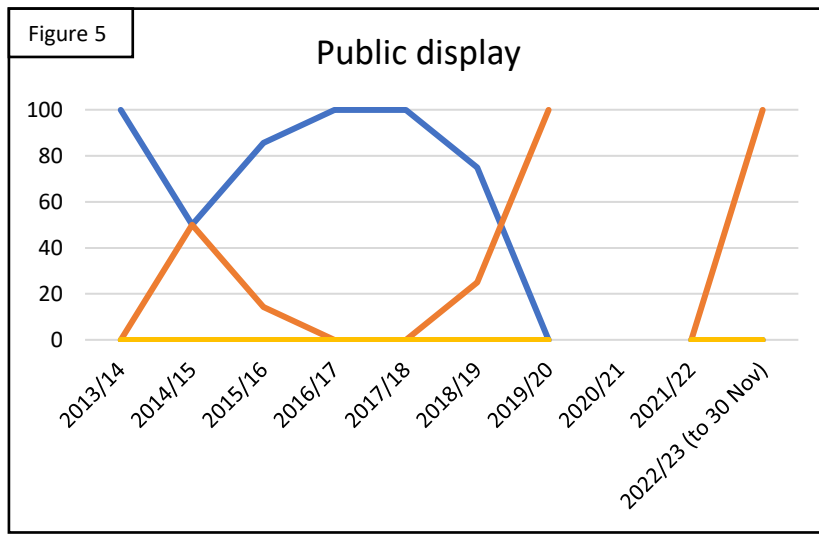
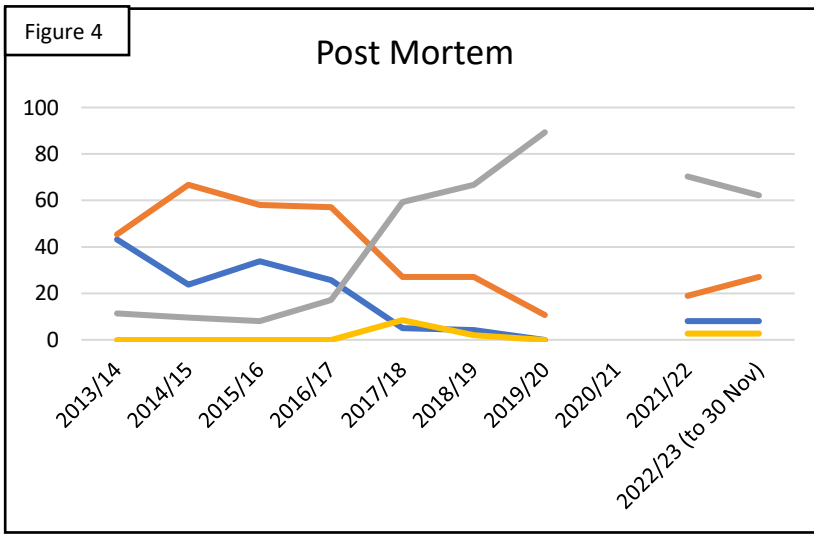
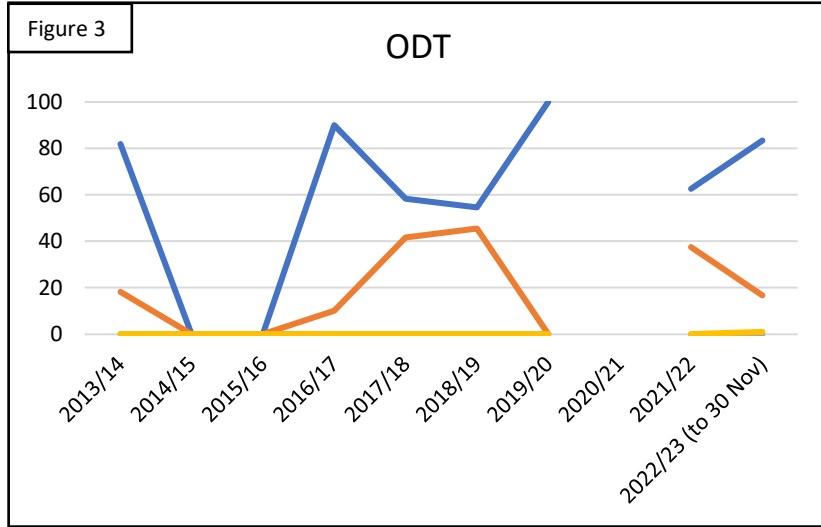
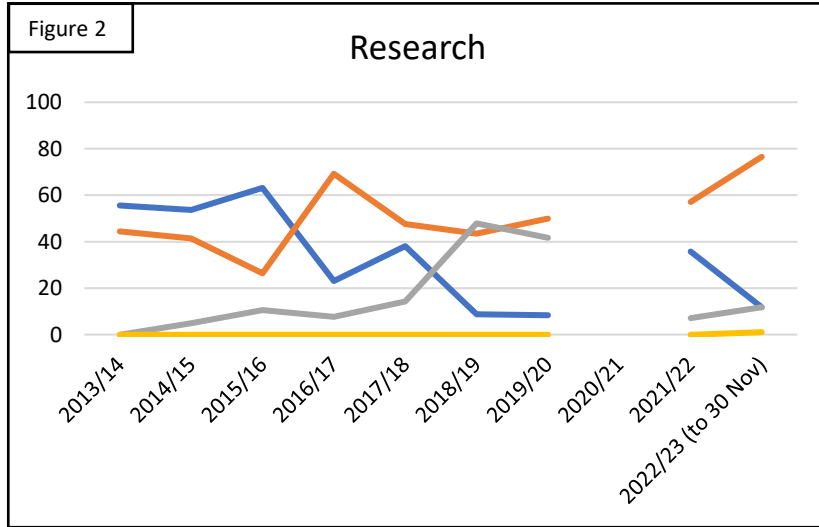
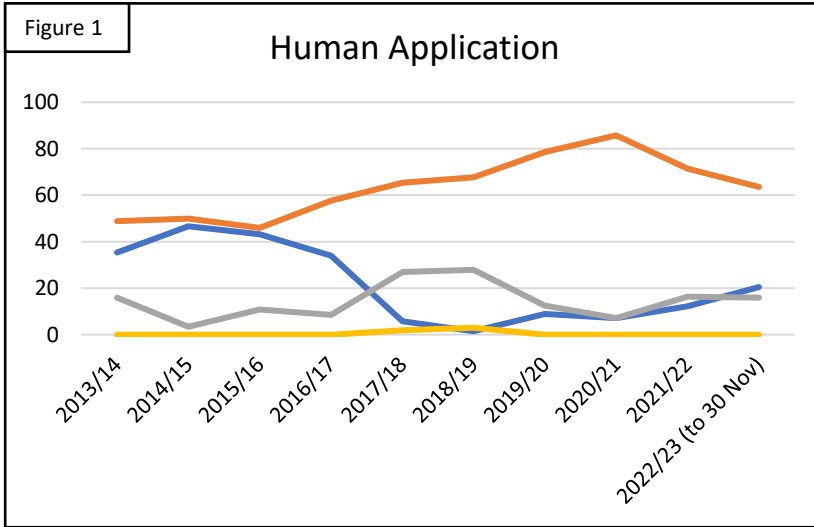
Regulatory risk for assessments, Jan 2023
AUD 09a/23



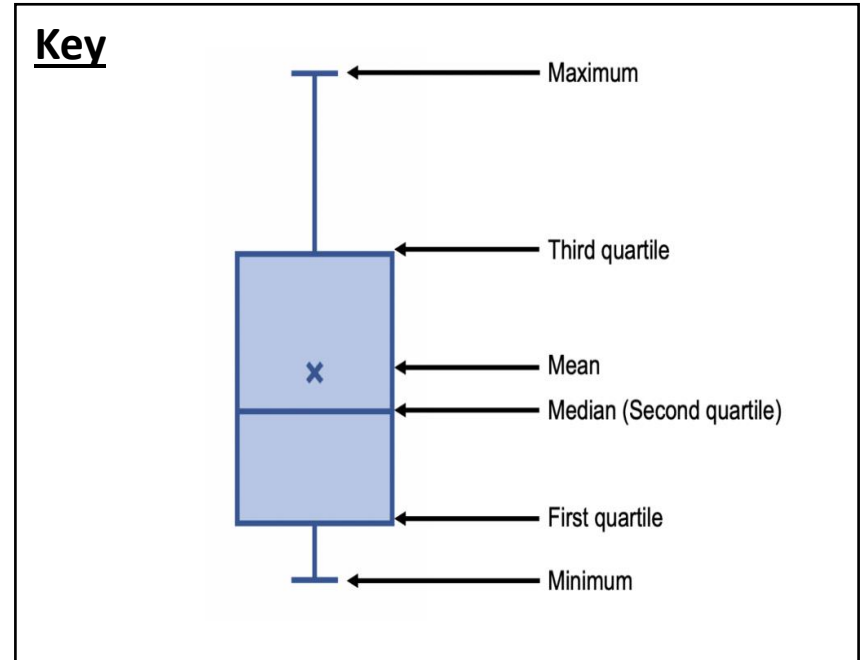
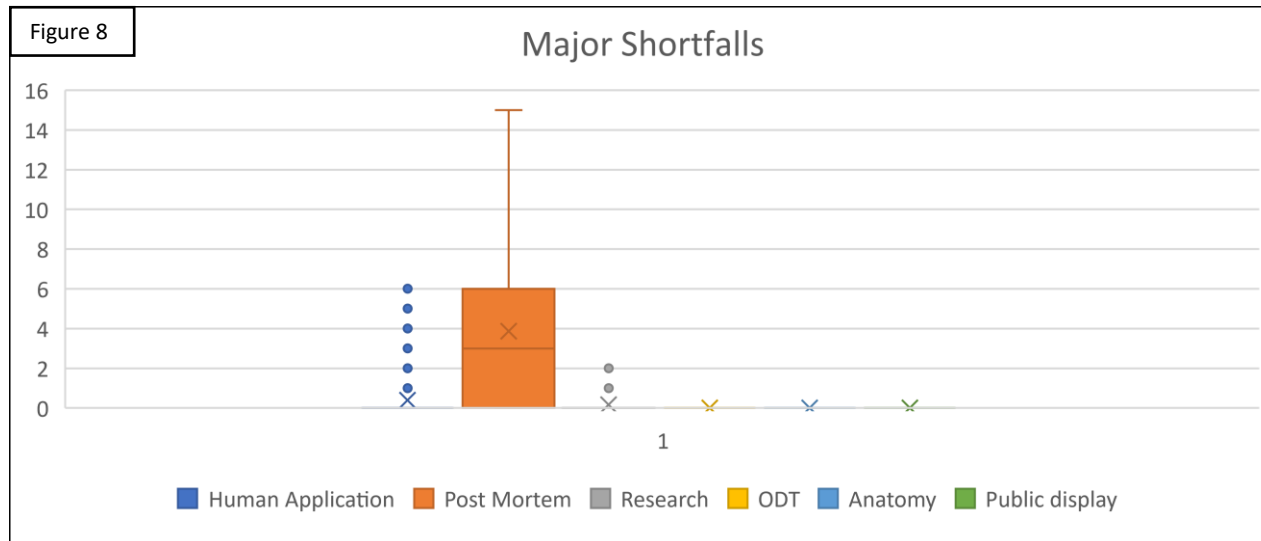
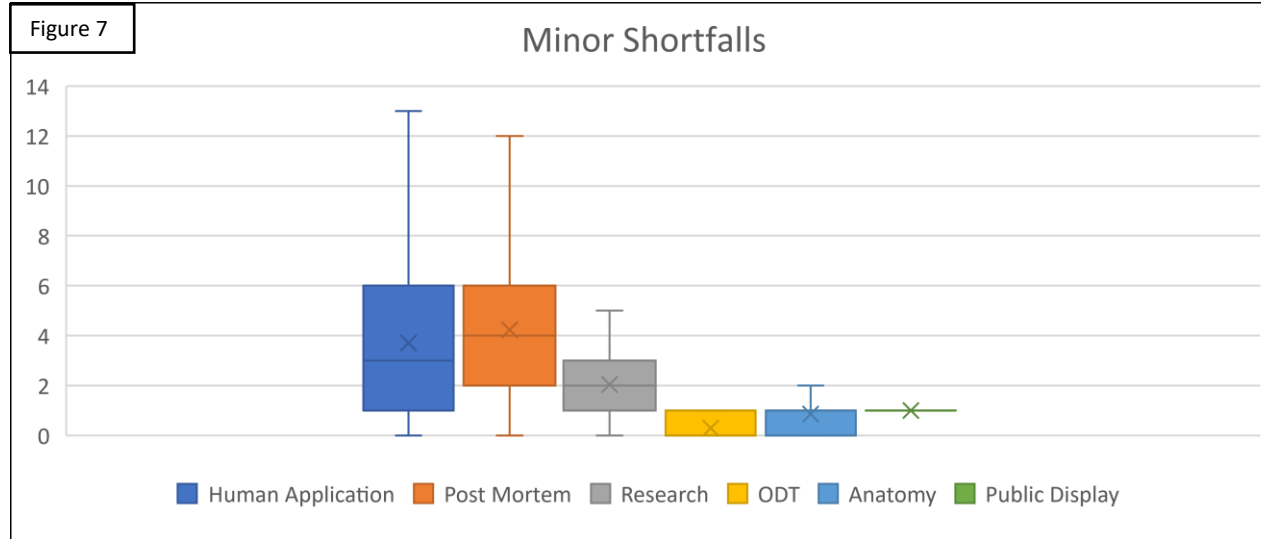
% of inspections with shortfalls



— % inspections with no shortfalls
— % inspections with Minor shortfalls only
— % inspections up to Major shortfalls
— % inspections up to Critical shortfalls



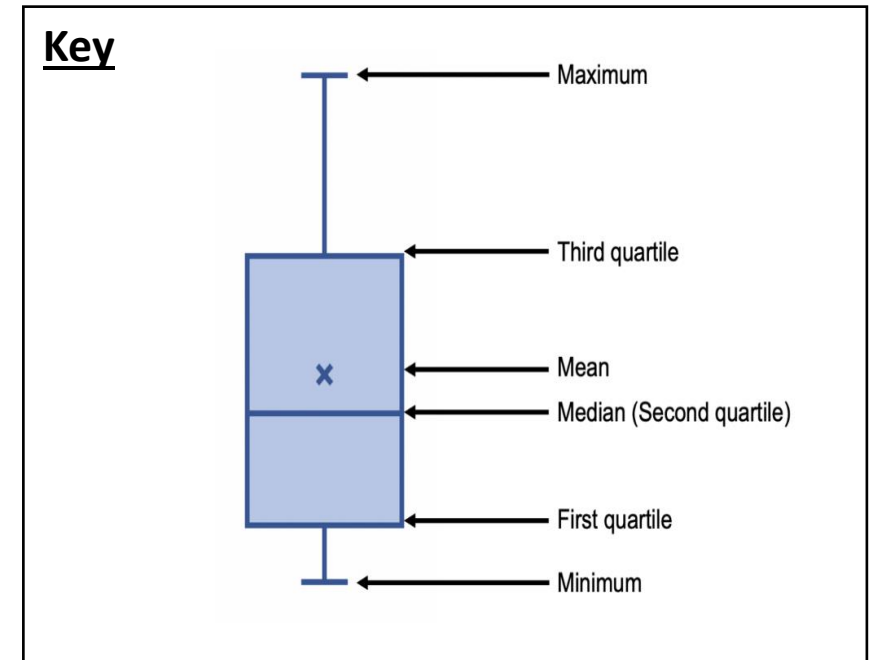
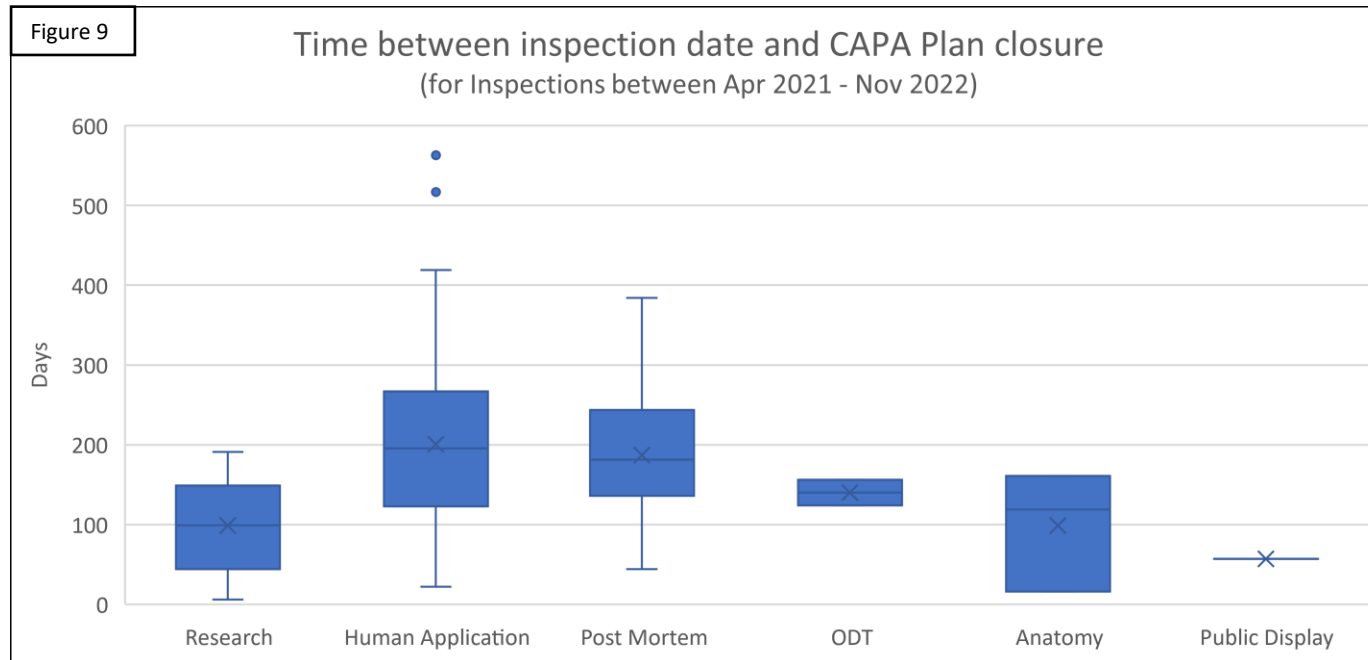
Distribution of shortfalls per inspection (Routine inspections between Apr 2021 – Nov 2022*)



*Note: the shortfalls are in relation to routine inspections that took place between Apr 2021 - Nov 2022, where the capa plan has been finalised. Inspections which have not had the CAPA plan finalised have not been included

Time between inspection date and CAPA Plan closure

(Inspections between Apr 2021 – Nov 2022*)



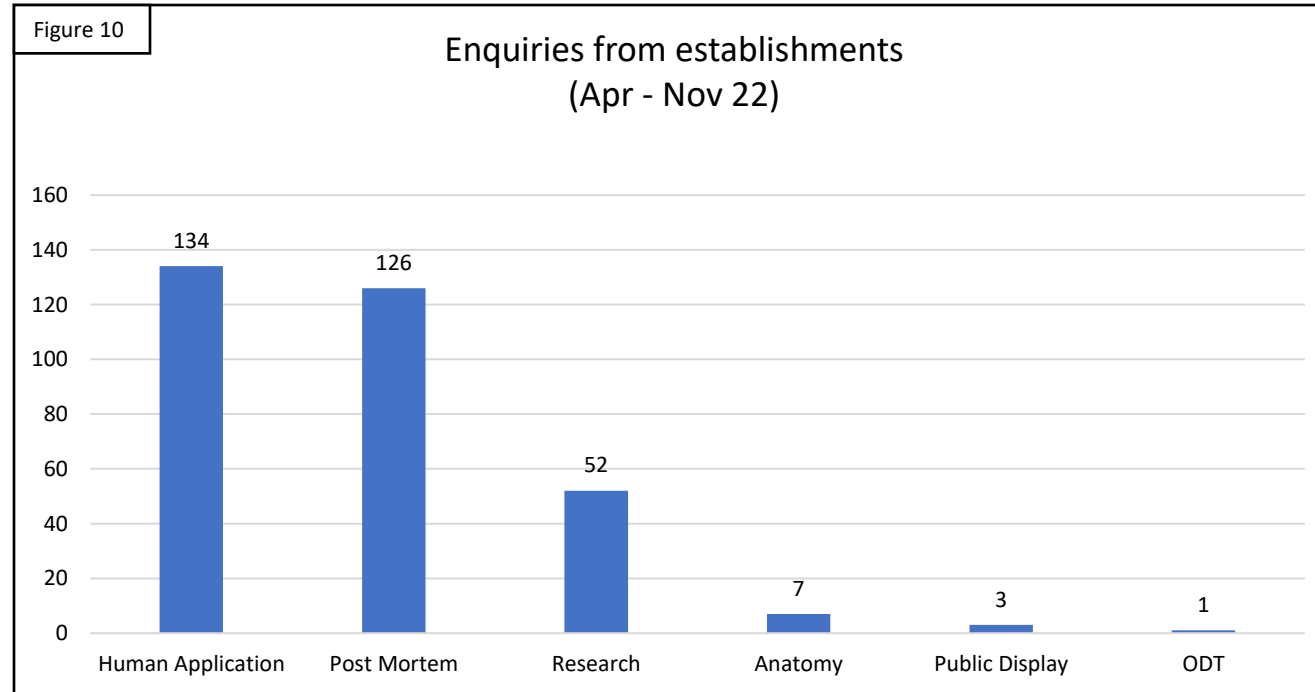
*Note: Data includes routine inspections that took place between Apr 2021 - Nov 2022, where the capa plan has been resolved. Inspections which have not had the CAPA plan finalised/resolved have not been included

Open CAPA Plans

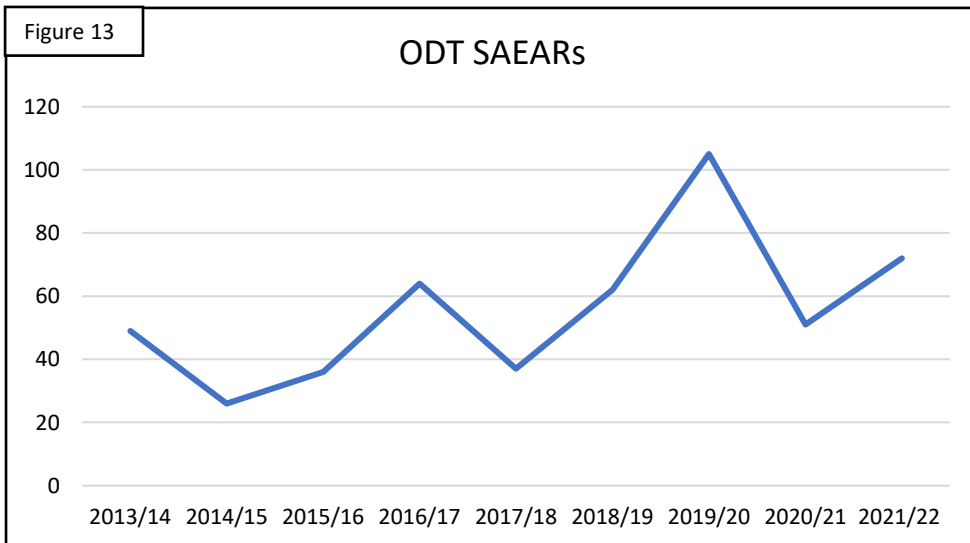
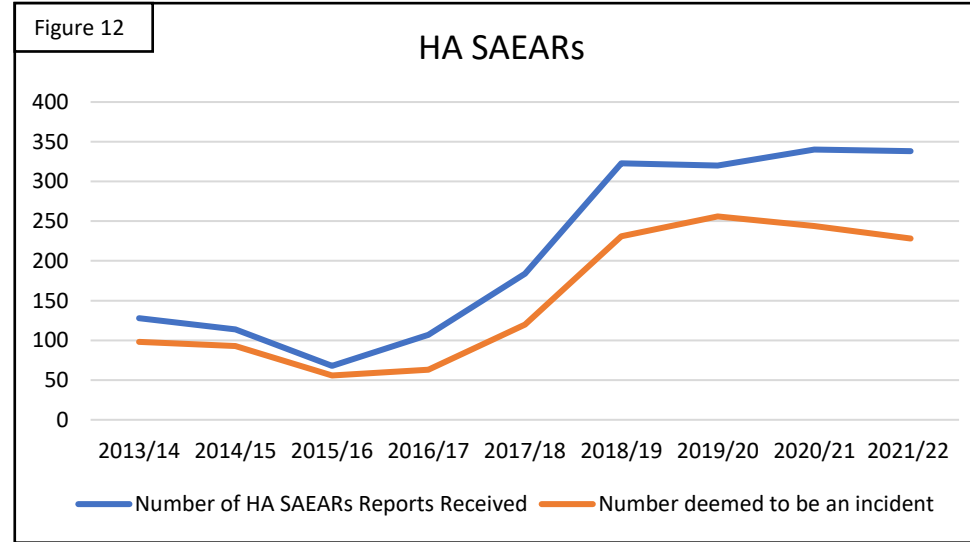
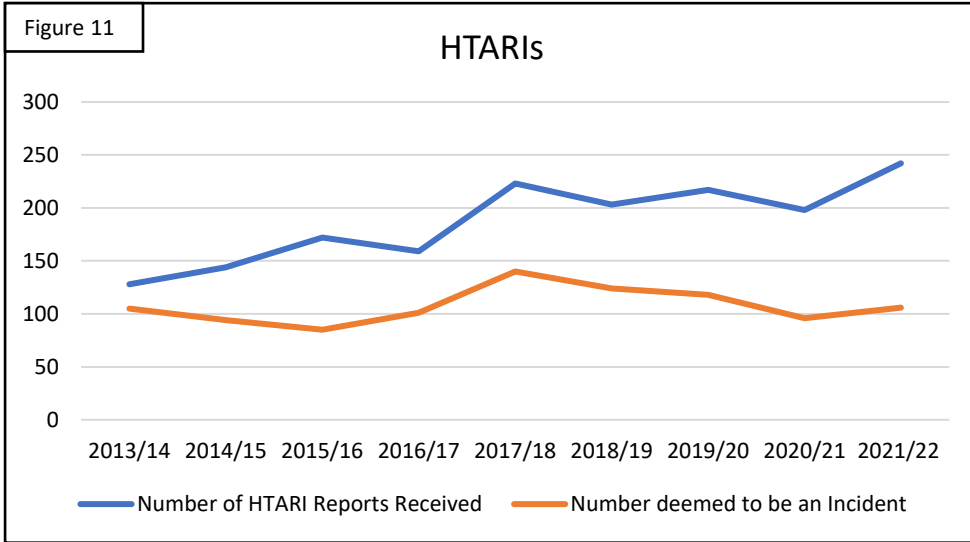
Open CAPA plans					
	HA	PM	Research	ODT	Anatomy
Age of 5 oldest open CAPA Plans (Months)	36	32	10	11	11
	17	11	8	7	
	12	10	3		
	12	9	2		
	12	9	1		
MEDIAN	4	4	1	9	11
RANGE	0-36	0-32	0-10	7-11	11-11

Table 1

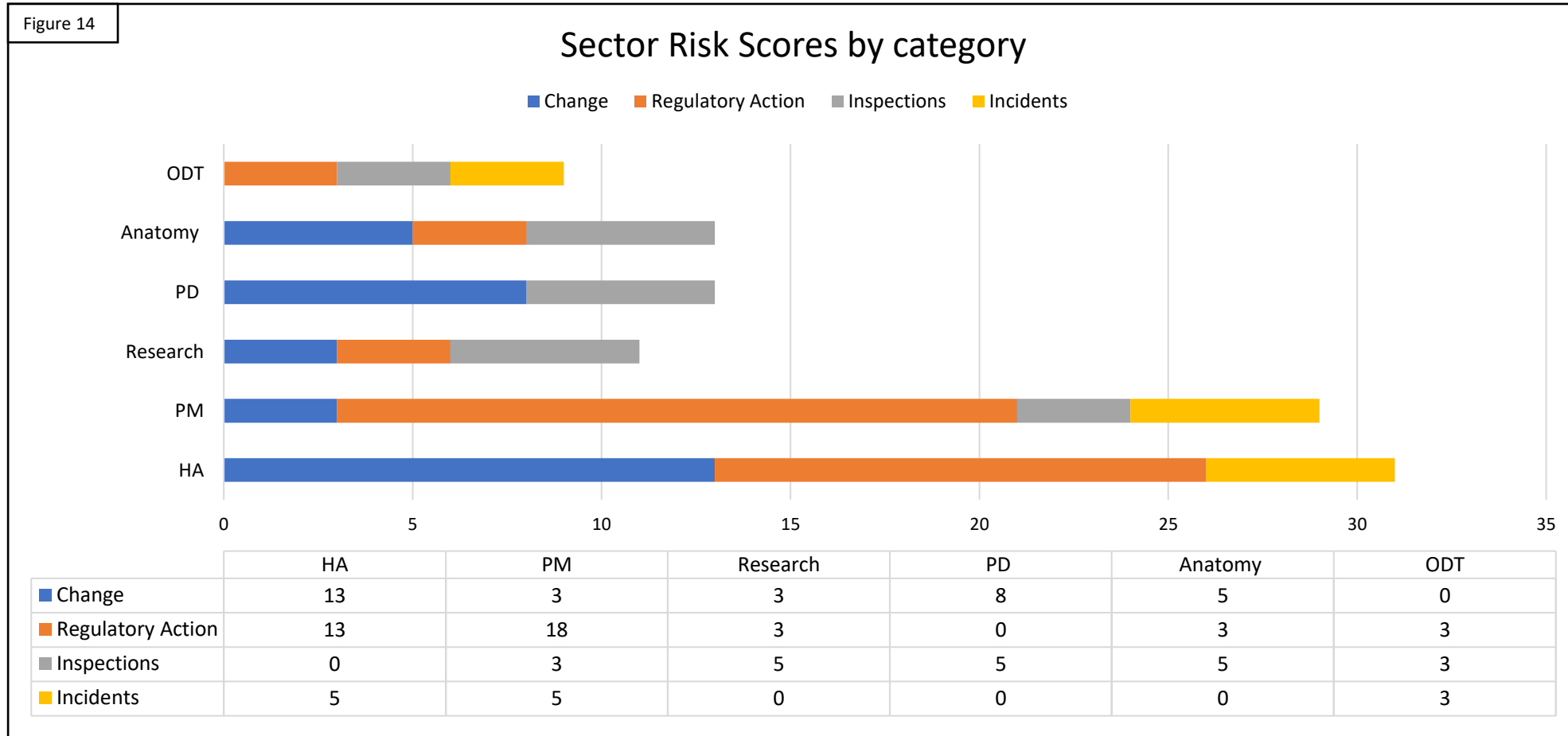
Enquiries from Establishments



Incidents



Risk model: indicative sector risk scoring



Risk model: indicative risk scoring

	HA	PM	Research PD	Anatomy	ODT	
Change						
Number of new licences	6	0	11	0	1	
Score	5	0	5	0	3	
Number of change tickets per est. (Change of DI, change of licenced activities, satellite addition, import variation, tissue/organ types)						
	47%	22%	15%	25%	14%	8%
Score	5	3	3	5	3	0
Regulatory action						
Number of PPDs authorised/conditionally authorised	6	0	0	0	0	0
Score	3	0	0	0	0	0
Inspections						
Number of CAPAs open > 6 months	15	19	2	0	1	2
Score	5	5	3	0	3	3
Number of major / critical shortfalls per inspection	0.5	4.3	0	0	0	0
Score	3	5	0	0	0	0
Number of RDMs	19	9	0	0	0	0
Score	5	5	0	0	0	0
Number of complaints	0	1	0	0	0	0
Score	0	3	0	0	0	0
Incidents						
Average time since last inspection (months)	12.9	25.8	52.2	52.1	56.9	29.5
Score	0	3	5	5	5	3
Incidents						
Number of incidents resolved	89	96	0	0	0	38
Score	5	5	0	0	0	3
Total Scores	31	29	16	10	14	9

Groupings	Scores
0 : 1-3 : 4+	0:3:5
0-10% : 10%-25% : 25%+	0:3:5
0 : 1-5: 5+	0:3:5
0 : 1-3 : 4+	0:3:5
0 : 1-3 : 4+	0:3:5
0 : 1-3 : 4+	0:3:5
<2 years : 2-4 years : 4+ years	0:3:5
0 : 0-50 : 50+	0:3:5

Table 2

Audit and Risk Assurance Committee (ARAC)

Date: 26 January 2023

Paper reference: AUD 10/23

Agenda item: 12

Author: Richard Sydee, Director of Resources

Protective marking: OFFICIAL

Consideration of risk appetite and tolerance within the HTA

Purpose of paper

1. For ARAC to consider the current risk appetite and tolerance levels for HTA's 7 strategic risks

Decision making to date

2. This paper was agreed by the SMT on 12 January 2023 for presentation to ARAC.

Action required

3. ARAC are to consider the current risk appetite and tolerance levels, in particular those of risks 2, 3 & 7, and propose any revisions or changes for approval by the Board at their next meeting.

Background

4. In June 2022 the HTA Board reviewed and agreed a revised risk appetite and tolerance statement. In doing so the Board requested that during the 2022/23 business year ARAC should further review the statements with a particular focus on risks 2, 3 and 7, where the Board felt that the statements as drafted may be too restrictive given the pressures facing the organisation and the plans for organisational change.
5. The agreed statement is attached at Annex A.
6. ARAC will wish to consider the companion papers, relating to the current strategic risk register and the regulation sector risk assessment, that have also been submitted to this meeting.

Next steps

7. Following ARAC's discussion, and any recommendations to alter the risk appetite and tolerances as currently stated, the Executive will submit a revised statement for the Board to approve at its March 2023 meeting.

Annex A – Extract from the HTA Risk Management Strategy & Policy

Risk Appetite Statement

- Risk appetite is the amount of risk an organisation is willing to accept in pursuit of its strategic goals.
- Following our review of the existing approach to risk we propose that the risk appetite statement considers separately five key areas of risk to which the HTA is exposed and provides an outline of the HTA's appetite for managing these types of risks. The HTA does not have a single risk appetite, but rather appetites across the range of its activities. We recognise that in pursuit of our strategic priorities and outcomes we may choose to accept different degrees of risk in different areas of the business.
- Where we choose to accept an increased level of risk, we will do so, subject always to ensuring that the potential benefits and threats are fully understood before actions are authorised, that there is sufficient capacity, and that sensible and proportionate measures to mitigate risks are established.
- The Executive will manage strategic risks in a manner that is consistent with this statement. The strategic plan and the business plans within the HTA should also be consistent with this statement.
- Below are the risk appetite descriptions established for each key activity identified.

Regulation

Risk 1 – There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.

Risk 2 – There is a risk that we will be unable to manage an incident, event or issue impacting on the delivery of HTA objectives.

- The HTA has **NO** appetite for any activity that disregards the need to obtain consent and any incidents that lead to serious public harm or breach of Data Protection Act.
- There is **LOW** appetite for risks that may result in the HTA providing misleading advice, especially when this advice could lead to an adverse impact on patient safety.

Corporate Governance

- There is a **LOW** appetite for activity that may result in non-compliance with legislation, statutory obligations, and government policies. The HTA has a **ZERO** tolerance for deliberate non-compliance with legal, statutory and policy requirements, except in exceptional circumstances.

Reputational

Risk 3 – There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.

- Although the HTA will not tolerate (**ZERO**) any action that could cause reputational damage it will explore innovative ways of regulating in line with better regulation principles and will have a clear view on its regulatory risk and areas of oversight.

Capabilities

Risk 4 - Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives.

Risk 6 - Failure to identify opportunities and achieve the benefits of transformation and continual change to support modernisation and improvement of the HTA.

- The HTA has a **MODERATE** appetite for change to ensure it has the right resources, capabilities, and organisational structure to optimise performance in the future whilst delivering value for money.

Information Security and Management

Risk 7 - Failure to optimise the safe use of existing and available digital data and technology.

- The HTA has a **LOW** appetite for risk that could lead to information or data security breaches and a **LOW** appetite for system failures that could disrupt normal business. We have **NO** appetite for activities that may increase our exposure to threats on our assets arising from external malicious threats.
- The HTA has **LOW** appetite for activities that may compromise processes governing the use of information, its management and publication. The HTA has **ZERO** tolerance for the deliberate misuse of its information.

Risk 5 – There is a risk that the HTA has insufficient or ineffective management of its financial resources.

- The HTA has a **LOW** risk appetite in relation to management of its finance. It will not tolerate annual expenditure in excess of income or any form of spend that contravenes HMT guidance. In addition, The HTA has **ZERO** appetite for any incidence of fraud and fraudulent behaviour.

Audit and Risk Assurance (ARAC) meeting

Date: 26 January 2023
Paper reference: AUD 11/23
Agenda item: 13
Author: Morounke Akingbola
Head of Governance and Finance

OFFICIAL

Summary of Policies

Purpose of paper

1. The purpose of this paper is to present to the Audit, Risk and Assurance Committee a summary of key policies that either require Committee approval or ensuring the Committee are aware of them.

Decision making to date

2. This paper was agreed by the SMT on 12 January 2023 for presentation to ARAC.

Action required

3. The Committee are requested to review and note the summary of policies annexed to this document.

Background

4. All policies and procedures in the HTA should be reviewed periodically, at least annually and sometimes more frequently. There are also policies that may be reviewed annually but brought to Committee bi-annually or every 3 years.

5. The annexed document sets out the full range of finance policy and procedure documents approved by ARAC and SMT, together with their present status.

Policy/Procedure & document reference	Purpose of policy/procedure	Frequency of Review	SMT	ARAC (approval/information)
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Documents that are brought to ARAC for approval				
Reserves Policy HTA/POL/049	Policy states the minimum level of cash reserves that the HTA should ideally keep as a contingency	Annually – next review Oct 23	Reviewed and approved Oct-22.	Approved – Oct-22 meeting
Antifraud Policy HTA/POL/050	Policy covers definitions of fraud, responsibilities of HTA employees	Every 3 years – next review Jan 25	Reviewed and approved Dec 22.	Approved – Jan-22 meeting
HTA Counter Fraud, Bribery and Corruption Strategy HTA/STR/001	Policy covers the framework within which the HTA tackles fraud and theft and makes reference to the Bribery Act 2010	Annually – next review Oct 23	Review and approved Oct 22.	Approved – Oct 22 meeting
Whistle-blowing Policy HTA/POL/017	Policy covers procedure to be followed if they have concerns about improper behaviour	Annually – next review Jan 23	Reviewed and approved Nov/Dec 21.	Approved – Jan-22 meeting <i>Brought to Jan 23 meeting for consideration</i>
Gifts and Hospitality Policy	Policy covers the procedure for receiving/declining gifts	Every 2 years – next review June 2024	Reviewed by SMT May-22 (including the register).	Approved – June-22 meeting

Policy/Procedure & document reference	Purpose of policy/procedure	Frequency of Review	SMT	ARAC (approval/information)
Risk Management Policy and Procedure HTA/POL/025	Policy for managing risk and setting risk tolerance level	Every 3 years – next review June 2025	Reviewed by SMT May 22.	Approved – June 22 meeting
ARAC Terms of Reference	Per HMT guidance – good practice	Annually – next review Jan 23	Reviewed by SMT Dec 21.	Approved – Jan 22 meeting <i>Brought to Jan 23 meeting for consideration</i>
ARAC Handbook	As above	Annually – next review Jan 23	Reviewed by SMT Jan 22.	Approved – Jan 22 meeting <i>Brought to Jan 23 meeting for consideration</i>
Documents that can be brought to ARAC for information, but are owned and approved by the Senior Management Team				
Business Continuity Policy	Policy covers the process for restoration of operations after an incident	Annually	Reviewed and approved by SMT June-22.	Brought to ARAC for information in June 22
Critical Incident Response Plan	Policy covers key roles for dealing with what the HTA has agreed is a critical incident	Annually	Reviewed and approved by SMT June-22.	Brought to ARAC for information in June 22
Procurement Policy HTA/POL/027	Policy covers the authorisation process for purchases of different values	Annually	Reviewed and approved in Nov-20 Procurement Thresholds updated and NICE added into section on contracts and frameworks.	For information

Policy/Procedure & document reference	Purpose of policy/procedure	Frequency of Review	SMT	ARAC (approval/information)
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Financial Policies and Procedures Manual HTA/POL/028	This is a compendium of key finance policies in one document. There are links and cross-references to individual policies are made within this document	Annually	Reviewed May 22	For information
Budgetary Control Policy HTA/POL/031	Policy deals with the budget-setting process of the HTA and includes a draft timetable	Annually	Under review post internal audit review in Q4 2021/22.	N/a
Expenses Policy HTA/POL/032	Policy covers reimbursement of Travel, Subsistence and other expenses	Annually	Reviewed April 22.	For information

Audit and Risk Assurance (ARAC) meeting

Date: 26 January 2023
Paper reference: AUD 12/23
Agenda item: 14
Author: Morounke Akingbola
Head of Governance and Finance

OFFICIAL

Whistleblowing Policy

Purpose of paper

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

Decision making to date

2. This paper was agreed by the SMT on 12 January 2023 for presentation to ARAC,

Action required

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

Background

4. The Whistleblowing policy was last presented to the Committee in January 2022. Since then the policy has been reviewed and minor updates have been made as follows:
 - a. Section on do's and don'ts has been added;
5. The Committee are requested to approve the above addition.

HTA Policy

Protective Marking: OFFICIAL

Whistleblowing Policy and Procedure

Purpose

1. The Public Interest Disclosure Act 1998 (PIDA) protects employees against detrimental treatment or dismissal as a result of any disclosure by them of normally confidential information in the interests of the public. The HTA's whistleblowing policy and procedure explains how concerns should be raised by staff and is in line with the Act.
2. This policy aims to mitigate the risk of inappropriate treatment of whistle-blowers.
3. In accordance with PIDA, this policy sets out a clear and fair procedure:
 - a. That staff may use if they wish to make disclosures about the HTA that they feel are in the public interest; and
 - b. which the HTA will use to investigate such disclosures.
4. This policy applies to all employees, permanent, fixed-term and any temporary/agency staff.
5. The policy does not form part of any employee's contract of employment. It may be revised or withdrawn at the HTA's absolute discretion and at any time.
6. Concerns that are raised about issues at other establishments should be handled under the relevant policy or SOP.

Introduction

7. The HTA is committed to high ethical standards and fosters an open culture.
8. Whistleblowing is when an individual reports suspected wrongdoing at work. This is also known as 'making a disclosure in the public interest'. Simply, it is raising concerns, usually acting from a feeling of fairness or ethics, rather than out of personal interest.
9. Whistleblowing is different to making a complaint or raising a grievance. Usually these actions are taken when the individual is personally affected. The HTA has separate procedures for these.

10. Whistleblowing is important to safeguard the effective delivery of public services, and to ensure value for money. It serves to protect and reassure individuals, and to maintain a healthy working culture and an efficient organisation.
11. The sections below provide guidance to staff on the procedures to follow if they have concerns about improper behaviour that might indicate fraud or have serious implications for the HTA.

Data Protection

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

Raising concerns

13. A member of staff who has concerns should initially raise the matter with his or her line manager or Director. A concern should always be raised as soon as the whistle-blower becomes aware of it and they should gather no further information at this point.
14. Types of improper behaviours include actions that:
 - a. are illegal;
 - b. are in breach of a professional code or are otherwise unethical;
 - c. make improper use of HTA funds;
 - d. make improper use of HTA assets or sensitive data;
 - e. involve maladministration;
 - f. cause harm to another member of staff, HTA users or the general public;
 - g. undermine the HTA's functions or reputation;
 - h. attempt to cover up such malpractice.
15. If a member of staff feels unable to raise the matter through their line manager they may do so through HR or their Director. If the Director is implicated the concerns should be raised with the CEO. This also applies if the member of staff is dissatisfied with the line manager's response to his or her concerns. The member of staff may seek the support of their trade union and choose to be accompanied by a trade union representative or work colleague at any stage of the procedure. Advice is also available from the charity Protect (formerly Public Concern at Work).
16. When a member of staff continues to feel that there has not been a satisfactory response by HTA management or that there are compelling reasons that the matter cannot be raised with HTA management, he or she may contact one of the following people detailed at Annex A

- a. If staff feel that they cannot raise the matter with anyone associated with the HTA, then they may contact the sponsorship team at the **Department of Health and Social Care** (also at Annex A).
 - b. HTA staff may also use the **Whistleblowing Helpline**, which offers free, confidential and anonymous advice: Protect whistle@protect-advice.org.uk formerly known as Public Concern at Work.
17. The National Audit Office (NAO) are a prescribed person to whom disclosures can be made in cases of concerns about the proper conduct of public business, value for money, fraud and corruption in relation to the provision of centrally-funded public services. Their whistleblowing helpline is 020 7798 7999. Further advice is on the NAO website at <https://www.nao.org.uk/about-us/contact-us/whistleblowing/>.
18. Staff should not raise their concerns publicly unless in consideration of all the circumstances it is reasonable to do so (such as they receive an inadequate response through the proper channels). To do so may breach other legislation and leave an employee unprotected by PIDA.

Protected disclosures

19. Certain conditions must be met for a whistleblower to qualify for protection under the Public Interest Disclosure Act 1998 (PIDA), depending on to whom the disclosure is being made and whether it is being made internally or externally.
20. Workers are encouraged to raise their concerns with the employer (an internal disclosure) with a view that the employer will then have an opportunity to address the issues raised. If a worker makes a qualifying disclosure internally to an employer (or another reasonable person) they will be protected.
21. No worker should submit another worker to a detriment on the grounds of them having made a protected disclosure.
22. Any colleague or manager (provided that they and the whistleblower have the legal status of employee / worker) can personally be liable for subjecting the whistleblower to detriment for having made a protected disclosure.
23. If a disclosure is made externally, there are certain conditions which must be met before a disclosure will be protected. One of these conditions must be met if a worker is considering making an external disclosure (this does not apply to disclosures made to legal advisors).
24. If the disclosure is made to a prescribed person, the worker must reasonably believe that the concern being raised is one which is relevant to the prescribed person.

25. A worker can also be protected if they reasonably believe that the disclosure is substantially true, the disclosure is not made for personal gain i.e. is in the public interest, it is reasonable to make the disclosure and one of the following conditions apply:
 - a. At the time the disclosure is made, the worker reasonably believes that s/he will be subjected to a detriment by their employer if the disclosure is made to the employer; or
 - b. The worker reasonably believes that it is likely that evidence relating to the failure/wrongdoing will be concealed or destroyed if the disclosure is made to the employer; or
 - c. The worker has previously made a disclosure to his/her employer.
26. Additional conditions apply to other wider disclosures to the police, an MP or the media. These disclosures can be protected if the worker reasonably believes that the disclosure is substantially true, the disclosure is of an exceptionally serious nature, and it is reasonable to make the disclosure.

Prescribed persons/organisations

27. Special provision is made for disclosures to organisations prescribed under PIDA. Such disclosures will be protected where the whistle-blower meets the tests for internal disclosures and additionally, honestly and reasonably believes that the information and any allegation contained in it are substantially true. Contact details can be found [here](#).
28. The HTA is not a prescribed organisation under PIDA and as such can only take limited action in relation to whistleblowing concerns in respect of other external organisations.

Action on concerns

29. It is fundamentally important to the success of the “whistleblowing” arrangements that staff can have confidence that their concerns will be taken seriously and that their position at the HTA will not be prejudiced unfairly by their raising issues of improper conduct. Whistle blowers who have acted in good faith have guaranteed protection under the provisions of PIDA.
30. All staff are protected from victimisation, harassment or disciplinary action as a result of any disclosure, where the disclosure is made in good faith and is not made maliciously or for personal gain.
31. There will be no adverse repercussions for an employee or other individual who raises a genuine concern in good faith, whether or not such a concern is subsequently found to be justified. If any harassment, bullying or victimisation of such a whistle-blower arises, this will be regarded as a disciplinary matter.
32. Whistle blowers may wish their identity and or the information they provide to be treated confidentially. In some cases, this may be possible, although the nature of the matter may be such that the investigation cannot be made or will

be restricted if this is the case. If concerns are raised anonymously, they will still be investigated, but this may restrict or prevent proper action.

33. As soon as a manager is made aware of a concern and he or she has checked that it is a matter where the interest of others or the organisation may be at risk, it must be reported upwards to the appropriate Head and the Director, as long as the Head and the Director is not the subject of the allegation. If so, the contacts in paragraph 15 should be used. The allegation must be reported upwards even if the matter is satisfactorily resolved by the manager who received the complaint. If necessary, the Head and Director will confirm the action to be taken and the likely timescales.
34. The member of staff who raised the issue must be given a report in writing of the outcome of the investigation. This report should be sufficiently detailed such that the member of staff has confidence that the investigation and any consequential actions were appropriate. If the investigations are lengthy, an interim oral report should be given to the member of staff to reassure him or her that appropriate action is being taken and appropriately documented that this has occurred.
35. Consideration should be given to referring an allegation to internal audit, either to conduct the investigation or to endorse the outcome. This should be discussed with the Director responsible for that area and the Director of Resources who is the HTA's principle point of contact with the internal auditors.
36. Raising a false allegation maliciously may lead to disciplinary action under the HTA's Disciplinary Procedure.
37. The nature of any whistleblowing allegation and the results of any investigation should be reported to the Audit and Risk Assurance Committee in order for the Committee to consider the impact on the HTA.

Do's and don'ts of Whistleblowing (from the whistleblowing charity Protect (formerly Public Concern at Work))

38. Do:
 - a. Keep calm;
 - b. Think about the risks and outcomes before you act;
 - c. Remember you are a witness, not a complainant; **and**
 - d. Phone Protect for advice on +44 (0)20 3177 252
39. Don't:
 - a. Forget there may be an innocent or good explanation;
 - b. Become a private detective;
 - c. Use a whistleblowing procedure to pursue a personal grievance; **or**
 - d. Expect thanks

Malicious Whistleblowing

40. Where it is found that a whistle-blower makes an allegation maliciously, and:
 - a. Does not act in the public interest;
 - b. Makes an allegation without having reasonable grounds for believing it to be substantially true;
 - c. Collects the information to support the allegations improperly, or;
 - d. Makes an allegation for personal or 3rd party gain.
41. They will be subject to formal disciplinary action, up to and including dismissal and in some cases may be subject to criminal investigation where illegality has occurred in order to achieve those aims.
42. Additionally where this criterion is met or the employee engages in improper conduct in relation to whistleblowing, they are unlikely to be protected as a whistle-blower under the PIDA Act.

Link to anti-bribery

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

Review

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

ANNEX A

- a) **Chief Executive**
Dr Colin Sullivan
020 7269 1946
colin.sullivan@hta.gov.uk

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

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

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

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

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

Revision history

Reference: HTA-POL-17

Author(s): Morounke Akingbola

Reviewed by: **Head of Finance**

Approved by: SMT/ARAC

Owner: Director of Resources

Distribution: All Staff

Protective Marking: OFFICIAL

- Jan 2015/15.0: Reviewed by Head of Finance
- Jan 2016/15.1 Reviewed by Head of Finance
- Nov 2017/15.2 Reviewed by Head of Finance
- Jan 2018/15.3 Updated by Head of Finance
- Jan 2019/15.4 Reviewed by Head of Finance
- Mar 2019/15.5 GDPR passage added referring to HTA's HR Privacy policy – inserted under Data Protection
- Nov 2020/15.6 Reviewed by Head of Finance
- Dec 2021/15.7 Reviewed by Head of Finance – section on malicious whistleblowing (para 38-40) and Link to bribery (para 41) added.
- Dec 2022/15.8 Para on do's and don'ts added/ Next review date Dec 23

Audit and Risk Assurance (ARAC) meeting

Date: 26 January 2023
Paper reference: AUD 13/23
Agenda item: 15
Author: Morounke Akingbola
Head of Governance and Finance

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ARAC Handbook

Purpose of paper

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

Decision making to date

2. This paper was agreed by the SMT on 12 January 2023 for presentation to ARAC.

Action required

3. The Committee are requested to review and comment on the handbook.

Background

4. The ARAC Handbook details the business of the Committee and is to be used as part of the induction of new members.
5. Since the last review, the following amendments/additions have been made:
 - a. Section 1 – para d referring to whistleblowing

- b. Section 1 – para e referring to cyber security which is an update made by HM Treasury to the handbook guidance.
6. The Committee are requested to approve the additions/amendments as detailed above.

[Request front cover from the Comms Team]

Audit, Risk and Assurance Committee Handbook

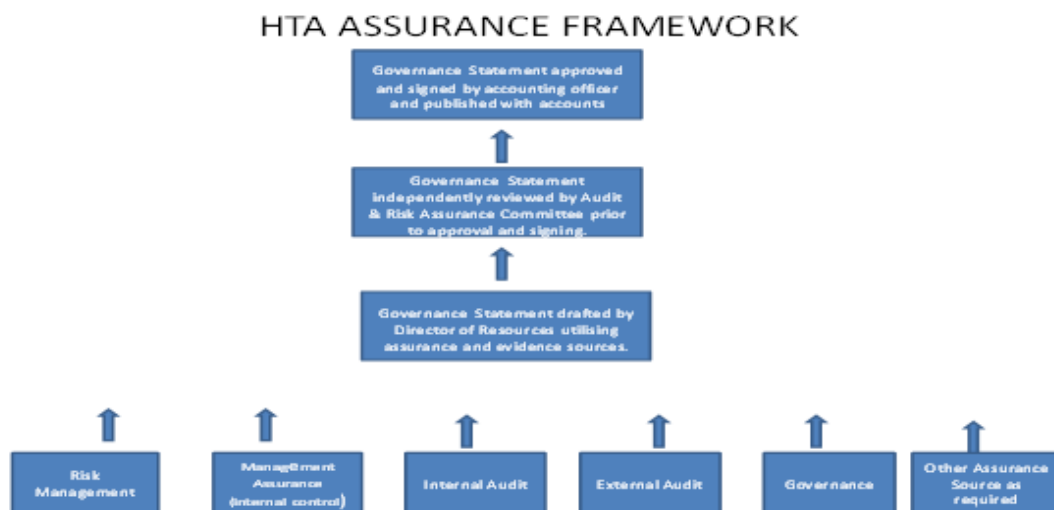
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Section 1

Introduction

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



4. In discharging its duties, the Audit & Risk Assurance Committee will:
 - a. Review the comprehensiveness of assurances in meeting the Board's / Accounting Officer's assurance needs
 - b. Review the reliability and integrity of these assurances

- c. Review the adequacy of the Board and Accounting Officer in discharging their responsibilities (particularly in respect to Financial Reporting)
 - d. Ensure their organisation is operating appropriate and effective whistleblowing practices and whistleblowing is considered regularly
 - e. Provide assurance to the Board that the organisation is properly managing its cyber risk including appropriate risk mitigation strategies
5. HM Treasury's Audit Committee Handbook provides further guidance on the role of audit committees, the role of the chair of the audit committee and good practice.

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

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

Section 2**Audit & Risk Assurance Committee yearly work programme****Introduction**

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

1. Winter meeting	
Regular items <ul style="list-style-type: none"> Assurance reports from Internal Audit Audit recommendations tracker report Strategic risk register review Polices/procedures updates Anti-Fraud Policy (bi-annually) Whistleblowing Policy 	Meeting specific <ul style="list-style-type: none"> Review and approval of the Internal Audit proposed Audit plan for the financial year Review of the Audit & Risk Assurance Committee's performance including Members' skills and training Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting)
2. Spring meeting	
Regular items <ul style="list-style-type: none"> Assurance reports from Internal Audit Audit recommendations tracker report Strategic risk register review Policies/procedures updates 	Meeting specific <ul style="list-style-type: none"> Receive Internal Audit Annual Report Approval of the Annual Report and Accounts SIRO Report Review of the External Auditors ISA 260 report (management letter) Consider key messages for the Audit & Risk Assurance Committee's report on its activity and performance (to the Board)
3. Autumn meeting	
Regular items <ul style="list-style-type: none"> Assurance reports from Internal Audit Audit recommendations tracker report Strategic risk register review Policies/procedures updates 	Meeting specific <ul style="list-style-type: none"> Approval of External audit's planning report Review of the Audit & Risk Assurance Committee's Governance including Handbook and Terms of Reference

Section 3

Role of internal audit

The role of internal audit at the Human Tissue Authority

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

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

Approach to internal audit

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

Statement of assurance

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

Reporting lines

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

Rights of internal auditors

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

Section 4

Role of external audit

Introduction

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

Financial audit

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

NAO timetable

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

Section 5

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

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

Internal audit

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

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

External audit

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

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

Risk register

51. Produce risk strategy for review by Audit & Risk Assurance Committee
52. Produce strategic risk register for review of Audit & Risk Assurance Committee

Governance

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

Version history

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

Latest version	Date	Comments	Reviewed by	Approved by
15.0	24 February 2015	Updated to ensure factual accuracy, update membership information and add version control.	Sue Gallone / Amy Gelsthorpe-Hill	Board Members
15.1	18 October 2016	Amendment to secretariat and updated forward plan as per May 2016 minutes	Sue Gallone / Morounke Akingbola	??
15.2	2 November	Updated per November 2016 minutes	Morounke Akingbola	ARAC Members 09-11-2017
15.3	18 September 2018	Amend role to Board Secretary	Morounke Akingbola	ARAC Members 23-10-2018
15.4	4 December 2020	Removed ToR; amend Authority to Board. Review period changed to bi-annually (TBA) by ARAC	Morounke Akingbola	ARAC Members 28-01-2021
15.5	13 December 2021	Reviewed, changed Authority to Board where appropriate	Morounke Akingbola	ARAC Members 27-01-2022
15.6	8 January 2023	Reviewed	Morounke Akingbola	ARAC Members 26-01-2023

Audit and Risk Assurance (ARAC) meeting

Date: 26 January 2023
Paper reference: AUD 14/23
Agenda item: 16
Author: Richard Sydee, Director of Resources

OFFICIAL

ARAC Terms of Reference

Purpose of paper

1. To inform the Committee that its Terms of Reference are due for a review and will be brought to the Board for approval in March 2023.

Decision making to date

2. The Terms of Reference have been reviewed by HTA staff who are proposing no changes to this document.

Action required

3. To note that the Executive are not proposing any amendments.

Background

4. The ARAC's Terms of Reference are due for review in January 2023. The HTA staff has reviewed the terms of reference and will be proposing the following amendments to the Board:

- None

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

Terms of reference

Reference number HTA-TOR-001

Next review date January 2024

Version 15.5

Reviewed by Head of Finance and Governance/ARAC

Owner Director of Resources

Distribution Internal

Date approved February 2023

Approved by HTA Board

Author(s) Head of Finance & Governance

Audit Risk and Assurance Committee (ARAC)

Constitution

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

Duties and functions

3. The ARAC will advise the Accounting Officer and Board on:
 - a. the strategic processes for risk, control and governance and the Annual Governance Statement;
 - b. the accounting policies, the accounts, and the annual reports of the HTA. This includes the process for review of the accounts prior to submission for audit, levels of error identified, and management's letter of representation to External Audit;
 - c. the planned activity and results of both Internal and External Audit;

- d. adequacy of management response to issues identified by audit activity, including External Audit's audit completion report;
- a. assurance relating to corporate governance requirements for the HTA;
- b. ensure that the remuneration report for staff and Members in the annual report and accounts reflects the strategy (permanently delegated to ARAC by the Remuneration Committee);
- c. (where appropriate) proposals for tendering for either Internal or External Audit services or for purchase of non-audit services from contractors who provide audit services; and
- d. where necessary, anti-fraud policies, whistle-blowing processes, organisational culture and arrangements for special investigations.

Rights

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

Access

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

Information requirements

- 6. As appropriate to the meeting the ARAC will be provided with:
 - a. a report summarising any significant changes to the organisation's Risk Register;
 - b. a progress report from Internal Audit summarising: work performed (and a comparison with work planned); key issues emerging from Internal Audit work;
 - c. management response to audit recommendations;
 - d. changes to the Internal Audit Plan;

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

Reporting to the Authority

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

Reviewing effectiveness

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

Recruitment and membership

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

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

Attendance

18. A minimum of two members of the ARAC (excluding the ARAC Chair) will be present for the meeting to be deemed quorate.
19. Committee members will be expected to attend every meeting. If a member is not able to attend a meeting they must provide apologies to the Secretary in advance of the meeting if possible. If a member does not attend more than two consecutive meetings the Committee Chair will arrange a meeting with the member to discuss their attendance and whether they wish to continue their membership of the Committee.
20. Board Members who are not members of the ARAC have the right of attendance at Committee meetings. Authority Members attending meetings shall be entitled to speak with the permission of the Chair of the meeting, but in no case shall they be entitled to vote.
21. If the ARAC Chair is not present at a meeting, an alternative Board member will be co-opted to chair that meeting.
22. The Chair of the Board may attend Committee meetings, say once per year and not so frequently as to compromise the independence of the Committee.

A Board Member who is not a member of the ARAC may be co-opted as a member of the ARAC for a specific meeting if necessary to ensure a meeting is quorate.

23. The Chief Executive in his or her role as Accounting Officer (as defined in the Framework Agreement), the Director of Resources, and any other officer (at the discretion of the Chair) and Internal and External Audit (or equivalents) will also attend meetings of the Committee.
24. Up to two observers from the Department of Health and Social Care will normally be invited to attend meetings of the Committee.
25. The ARAC may ask any other officials of the Board to attend to assist it with its discussions on any particular matter.
26. The ARAC may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters by the Committee.

Frequency of meetings

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

Secretariat responsibilities

31. The Executive Assistant will have secretariat responsibility for the Committee.
32. The Secretary must ensure Committee meeting dates are scheduled, meeting venues are booked and that Committee members are invited to attend all meetings.
33. The Secretary will liaise with the Committee Chair to create the agenda and will be responsible for collating and distributing the papers relating to the meeting. The agenda, minutes from the last meeting and the meeting papers for consideration will be distributed to the Committee one week before each meeting.

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

Review

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

Version history

- (Feb-15 / Version 15.0 : Updagted to ensure factual accuracy, update membership information and version control added)
- (Oct-16 / Version 15.1 : Amendment to secretariat and forward plan as per May 2016 minutes)
- (Nov-16 / Version 15.2 : Updated per Nov 2016 minutes)
- (Sept-18 / Version 15.3 : Amend role to Board Secretary)
- (Jan-22 / Version 15.4 : Updated to align with other governance documents)
- (Dec-22 / Version 15.5 : Transferred to new template)

Audit and Risk Assurance (ARAC) meeting

Date: 26 January 2023

Paper reference: AUD 15/23

Agenda item: 17

Author: Morounke Akingbola
Head of Governance and Finance

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Declaration of Interests, Gifts and Hospitality Register

Purpose of paper

1. To present the Committee with the Declaration of Interests, Gifts and Hospitality Register for noting.

Decision making to date

2. The register is presented for the Committee to note. The register is only tabled when there are items added.
3. There have been 7 declarations since the register was last shared with the Committee at its October 2022 meeting, 3 of which were accepted between August-October but not declared till December.

Action required

4. ARAC Members are required to note the register.

DIVISION / DEPARTMENT: HTA
FINANCIAL YEAR(s): 2021/22 - onwards

Details of the Gift or Hospitality							Provider Details			Recipient Details	
Type	Brief Description of Item	Reason for Gift or Hospitality	Date(s) of provision	Value of Item(s)	Location where Provided	Action on Gifts Received	Name of Person or Body	Contact Name	Relationship to Department	Name of Person(s) or Body	Contact Name
Provision	Artwork from 151 Buckingham Palace Road	Hanging in the HTA offices	01/07/2021	Unknown	151 BPR - HTA Office	Given	Human Tissue Authority	Richard Sydee	Director	Government Art Collection	Sarah McFadden
Receipt	Lunch	Lunch provided on inspection	19/10/2021	Unknown	On site	Declined	London Bridge Hospital [L/N 11069]		Licensed establishment	Helen Tang/A Shackell	
Receipt	Lunch	Lunch provided on inspection	07/12/2021	Unknown	On site	Accepted	CRF GMP Unit [I/n 22643]		Licensed establishment	Helen Tang	
Receipt	Box of chocolates	Interview given	??	£8	Sent to office	Accepted	Board Intelligence		None	Lynne Berry	
Receipt	Lunch and stationary items (x2 pens)	Lunch provided on inspection	18/03/2022	Unknown	On site	Accepted	NHSBT Colindale [22600]		Licensed establishment	Helen Tang/Louise Knight	
Receipt	Lunch	Lunch provided on inspection	17/05/2022	Unknown	On site	Accepted	Oxford DRWF [22496]		Licensed establishment	Helen Tang/Helena Tate	
Receipt	Lunch	Lunch provided on inspection	06/09/2022	£10 e.a	On site	Accepted	Queen Elizabeth Hosp B'Ham [11100]		Licensed establishment	Adam Whittaker/Philip Bergin	
Receipt	Lunch	Lunch provided on inspection	09/11/2022	Unknown	On site	Accepted	NHSBT Barnsley [22681]		Licensed establishment	Louise Knight/Adam Whittaker/Jonathan Spencer	
Receipt	Lunch	Lunch provided on inspection	22/11/2022	Unknown	On site	Accepted	Hospital Innovations		Licensed establishment	Ellen Donovan/Amy Shackell/Louise Knight	
Receipt	Lunch	Lunch provided on inspection	10/08/2022	Unknown	On site	Accepted	Golden Jubilee [40028]		Licensed establishment	Clare Wend-Hanson/Anna Briggs/Rita Barallon	
Receipt	Lunch	Lunch provided on inspection	29/09/2022	Unknown	On site	Accepted	Instil Bio (UK) [22657]		Licensed establishment	Rita Barallon	
Receipt	Lunch	Lunch provided on inspection	24/11/2022	Unknown	On site	Accepted	BioGrad Biobank [22707]		Licensed establishment	Rita Barallon	
Receipt	Lunch	Lunch provided on inspection	01/12/2022	Unknown	On site	Accepted	Leeds Teaching Hospital [40040]		Licensed establishment	Rita Barallon/Jennifer Scherr	
Receipt	Lunch	Lunch provided on inspection	18/10/2022	Unknown	On site	Accepted	University of Birmingham [22672]		Licensed establishment	Dr Christopher Birkett/Dr Colin Sullivan	
Receipt	Lunch	Lunch provided on inspection	11/01/2023	Unknown	On site	Accepted	Anthony Nolan Cord Blood Bank [11012]		Licensed establishment	Louise Knight/Christopher Perrett/Bethany Lloyd	

Audit and Risk Assurance Committee (ARAC)

Date: 26 January 2023
Paper reference: ARAC 16/23
Agenda item: 19
Author: Richard Sydee, Director of Resources
Protective marking: OFFICIAL

DAO Letter regarding internal audit report

Purpose of paper

1. To inform ARAC of recent advice regarding the protocol for sharing internal audit reports within government.

Decision making to date

2. This paper was agreed by the SMT on 12 January 2023 for presentation to ARAC.

Action required

3. ARAC to note the DAO letter which is brought to them for information only.

Background

4. In October 2022 HM Treasury issued advice for Principal Accounting Officers regarding the requirements of the Protocol for Sharing Internal Audit Reports within government, including the list of those who have standing to request a report and in what exceptional circumstances, the mechanism for making and responding to a request for sharing a report, and the Principal Accounting Officer's right of veto.
5. The Director of Resources has discussed this letter with both the Chief Executive and ARAC Chair and anticipates limited impact for the HTA.



HM Treasury
1 Horse Guards Road London
SW1A 2HQ

6 October 2022

For enquiries about distribution of this and other
DAO letters please contact Treasury Officer of Accounts at
TOAEnquiries@hmtreasury.gov.uk

DAO 05/22

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Protocol for Sharing Internal Audit Reports

Dear Principal Accounting Officer,

Contact

Please address enquiries to: GIAA.IAProfession@giaa.gov.uk

Action

Each Principal Accounting Officer and those who support them should be aware of the requirements of the Protocol for Sharing Internal Audit Reports within government, including the list of those who have standing to request a report and in what exceptional circumstances, the mechanism for making and responding to a request for sharing a report, and the Principal Accounting Officer's right of veto.

Protocol for Sharing Internal Audit Reports within Government: Context and Summary of Requirements

1. On 29 September, the Government Internal Audit Agency (GIAA) published the *Protocol for Sharing Internal Audit Reports*.¹ It has been prepared by the Government Internal Audit Agency in response to the recommendation (number 58) made by Lord Maude in his 2020 review of the Government functions, to the effect that “*The custom whereby internal audit reports are confidential to [departments] should be discontinued. A sharing protocol should be developed and agreed, setting out how and under what circumstances internal audit reports should be shared...*”. This recommendation was welcomed by the Government.
2. The Protocol, which fully reflects feedback received from the Civil Service Board, has also been included as a new annex to GovS 09 – *Internal Audit*, by which all those who have standing to request the sharing of an Internal Audit report within government ‘should’ only do so under the terms of the Protocol. The process will be managed by the Audit Profession team in GIAA through use of the dedicated mailbox referenced above. The Protocol will initially operate on a “test and learn” basis for the first year, during which GIAA will gather data on the number of occasions the Protocol has been used and the type of reports that are requested. GIAA will return to the Civil Service Board with this data in June 2023 for final endorsement.
3. After a short description of the purpose of internal audit in the government context, the Protocol focuses on the exceptional circumstances under which an internal audit report could be shared within government (the “when”); precise details of “who” can share or raise a request for a report to be shared; and “what” can be shared (including principles of information governance and data handling). The document concludes by describing the Principal Accounting Officer’s right to veto a request for a report to be shared, with list of those who can make a request under the Protocol (Annex A) and a comprehensive process guide (Annex B).
4. The Protocol acknowledges that a recommendation to share reports internally within government needs to be finely balanced to deliver the collective benefits to the public of identifying and understanding common areas of risk across departments but without undermining the quality of a fully independent internal audit service or the trust-based relationship that exists between internal audit and an Accounting Officer. The document is firmly grounded in the *Managing Public Money* standards of openness, accountability, transparency and objectivity and is presented from a context of continuous improvement and a desire to share relevant information for the common good. It is not intended for the purposes of censure or keeping score.
5. The Protocol provides an illustrative list of the occasions when it might be appropriate for an internal audit report to be shared with the limited group of government officials listed in Annex A, starting in the territory of the financial criteria applicable to the Major Project Review Group and then ranging to the broader context of when a policy or issue is to be delivered by multiple departments and the findings of a report in one department could helpfully indicate issues of concern elsewhere, or to provide insight about a significant or material decision made in a single department which highlights good practice or lessons

¹ [Protocol for sharing Internal Audit Reports - GIAA](#)

to be applied in other organisations.

6. The individuals with standing to request that a report is shared are limited only to those set out in Annex A. Essentially, potential requestors fall into three groups:
 - a. The Principal Accounting Officer of a department when they realise (or are prompted to take notice) that a report includes information of such import to the rest of government, that sharing is not only necessary, but is in fact objectively beneficial. It is envisaged that most requests will come from this group.
 - b. Those listed in Annex A of the Protocol, including Ministers and/or the most senior officials in HM Treasury and the Cabinet Office and/or the Principal Accounting Officer of a different department. It might be necessary to establish that a report exists by first asking GIAA via the mailbox.
 - c. In exceptional circumstances, the Head of the Government Internal Audit function (GIAA CEO) may decide there is a compelling reason for an Internal Audit report to be shared and would approach the relevant Principal Accounting Officer.
7. Finally, the Protocol recognises that there will be circumstances in which a Principal Accounting Officer does not agree to share an internal audit report under the terms of the Protocol. In line with the principles of *Managing Public Money*, the final decision on whether or not to share a report remains solely with that Principal Accounting Officer.
8. I hope you find the new *Protocol for Sharing Internal Audit Reports* useful. Sharing reports in the way described is new for government and GIAA stands ready to help Accounting Officers with any questions they might have about the scope or operation of the Protocol.



David Fairbrother
Treasury Officer of Account